

STRATEGIC PLAN FOR HEALTH LABORATORY SYSTEM IN ETHIOPIA



Ethiopian Public Health Institute
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FOREWORD



***H.E. Dr. Lia Tadesse
Minister of Health,
Federal Democratic Republic of
Ethiopia***

The pivotal role of the health laboratory system in determining the quality of clinical care services, effectiveness of preparedness, and responses to public health emergencies, and underpinning the validity and scientific merits of health researches is well established and cannot be overemphasized. A robust and functional health laboratory network is a vital component and backbone of a strong and resilient health system. The importance of a responsive laboratory system is now well recognized than ever before in the face of the ever-increasing need for reliable evidence to promptly and effectively address a complex array of old and new public health problems caused by familiar, emerging, and re-emerging infectious diseases as well as to avert imminent threats posed by the rapid rise in the incidence of non-communicable diseases around the world including our country.

Improving availability and increasing access to quality laboratory diagnostic services constitute key strategies for ensuring equitable provision of comprehensive healthcare services of acceptable quality at all levels of the health system and facilitating the country's strive towards achieving Universal Health Coverage (UHC), meeting the requirements of the International Health Regulations, and attaining the Sustainable Development Goals (SDGs) within the internationally agreed upon timeframe.

Without appropriate, high quality laboratory support to patients, disease surveillance undertakings and outbreak investigations, optimal provision of efficient and cost-effective clinical care and treatment services cannot be ensured and public health programs for disease prevention and control efforts cannot be maximally successful.

The need for the development of a resilient and sustainable national health laboratory system with adequate capacity and reliable capabilities for the provision of comprehensive, quality testing services in support of improved healthcare service delivery, public health interventions and management systems has been long recognized. Over the past three decades, utmost efforts have been made and huge resources have been invested to build and elevate the organizational and technical capacity of the national health laboratory system. As a result, a functional and responsive tiered laboratory network could be established and strengthened; advanced tests and technologies introduced and scaled up; supply chain management system improved; existing laboratory facilities upgraded and new ones constructed in accordance with international biosafety and biosecurity requirements; functional system for specimen referral linkage, integrated transportation and testing services developed and implemented; and in-service capacity building of laboratory workforce for the implementation of all-inclusive laboratory quality management system and accreditation to international quality standards has been strongly promoted. The capacity and capabilities of the national health laboratory system so built have been crucial in greatly contributing to the reduction in morbidity and mortality from major communicable diseases such as HIV, tuberculosis and malaria and better management of other priority

communicable and non-communicable diseases. The health laboratory system has served as the bedrock and the first line of defense against the most recent COVID-19 pandemic although the devastating event has also clearly revealed the many weak links in the organization, preparedness and resilience of the system underscoring the need for designing and implementing new strategies for filling the observed gaps for the system to effectively play its critical roles in supporting informed responses to future public health threats of epidemic or pandemic proportions.

In spite of the commendable progress made so far, there still remain several gaps and unmet needs underscoring the importance of redoubling our efforts towards building a responsive, resilient and sustainable health laboratory system that is capable of contributing its share to achieving the national goal of improving equitable access to quality and affordable healthcare services to all Ethiopian citizens as clearly stipulated in the Health Sector Transformation Plan II (HSTP-II). In this regard, the development of this National Health Laboratory Strategic Plan building on the achievements registered so far and aiming at strategically addressing all outstanding challenges presents a valuable tool for all stakeholders and partners to clearly understand the priority gaps of the health laboratory system, establish shared responsibilities and undertake harmonized concerted actions towards achieving all the anticipated strategic results of the plan.

On its part, the Ministry of Health is committed and looking forward to closely working with all stakeholders and partners for the successful implementation of this Strategic Plan and the achievement of the desired results over the next five years and seeing a strong, responsive and efficient health laboratory system with demonstrated capacity for providing quality and equitable diagnostic and other testing services to all in need. And finally, I wish to thank all organizations and individuals who were involved in and contributed to the development of this Strategic Plan.

H.E.Dr. Lia Tadesse
Minister of Health,
Federal Democratic Republic of Ethiopia

**Forward Message from
the Director General of
EPHI**



***Dr. Mesay Hailu, Director General,
Ethiopian Public Health Institute.***

The Ethiopian Public Health Institute (EPHI) is mandated to lead, and coordinate the prevention and control of public health emergency activities; build the capacity of health laboratories, provide referral laboratory testing services for public health emergency management, healthcare services, and undertake reference testing; undertake researches on priority public health and nutritional problems, programs and strategies; and establish and manage national health data management and analytics center by gathering health and health-related data from various sources.

As part of this mandate and its roles and responsibilities as a national public health authority, the institute has developed and implemented the first and the second Laboratory Strategic Master Plans from 2005 to 2009 and 2009 to 2013, respectively. In this regard, the institute has been focusing on strengthening the capacity of the national laboratory system and networks so as to enable it provide quality-assured testing services in support of clinical care service delivery, disease surveillance and effective response to public health emergency situations. Significant progress has been made in improving the capacity, functionality and responsiveness of the laboratory system through organizing and strengthening the leadership, management and coordination with a clear mission of promoting the implementation of laboratory programs at all levels of the national healthcare service delivery system.

Despite all efforts made so far, the Ethiopian laboratory systems is still being confronted with many compounded challenges and is very far from ensuring availability of quality-assured diagnostic services and their reliable accessibility to public health emergency management and healthcare delivery systems at all times. This limitation of the national laboratory system and the urgent quest for improved quality and accessibility of laboratory services have now gained recognition than never before in the face of the ever heightening need for reliable evidence to effectively address a complex array of old and new public health problems caused by familiar, emerging and re-emerging infectious diseases as well as to avert imminent threats posed by the rise in the incidence of non-communicable diseases in the continent at an alarmingly rapid rate. To address the current needs of the lab systems, it has been found crucial to develop this Third Strategic Plan for the health laboratory system in Ethiopia to serve as a national guiding document for the implementation of focused strategic initiatives and activities towards building a resilient, sustainable and accessible quality laboratory system. Therefore, the comprehensive and successful implementation of this Strategic Plan is believed to promote the development of reliable capacity and capability at all tiers of the

national health laboratory system to provide quality laboratory services in support of health care delivery services, surveillance & surveys, timely preparedness and effective responses to public health threats and disease outbreaks.

As it should, this edition of the health laboratory Strategic Plan perfectly aligns with the missions and goals of the institutional SPM and the Health Sector Transformation Plan (HSTP) and its development has followed standard international recommendations and procedural steps in that it was crafted and validated through a participatory, inclusive, and consultative process involving all key stakeholders and partners. It is my sincere belief that all committed to the advancement of the national health laboratory system will align their activities and resources with the strategic objectives of this plan and closely work with the Ministry of Health and our institute to successfully achieve its stated strategic results.

Finally, I would like to take this opportunity to express my heartfelt thanks and profound appreciation to all experts and organizations that have made invaluable contributions to the development of this Strategic Plan.

Dr. Mesay Hailu,
Director General, Ethiopian Public Health Institute.

ACKNOWLEDGMENTS

The Ministry of Health and the Ethiopian Public Health Institute greatly appreciate and acknowledge the contributions of professionals from the Regional Health Bureaus, Regional Public Health Institutes, Regional Reference Laboratories, the Africa Centers for Disease Control and Prevention, the US Centers for Disease Control and Prevention Ethiopia Office, African Society for Laboratory Medicine and other partner organizations, professional associations, the private sector and academia to the successful development of this third edition of Strategic Plan for Health Laboratory System in Ethiopia.

LIST OF ABBREVIATIONS AND ACRONYMS

CPD	Continual Professional Development
DHIS-2.	District Health Information Software-2
DNO	Diagnostic Network Optimization
EAS	Ethiopian Accreditation Service
EDL	Essential Diagnostic List
EID	Early Infant Diagnosis
eLIS	electronic Laboratory Information System
EMR	Electronic Medical Records
EPSS	Ethiopian Pharmaceutical Supply Service
EQA	External Quality Assessment
ESHPT	Ethiopian’s Selected Hazardous Pathogens and Toxin
ESIA	Environmental and Social Impact Assessment
ESMF	Environmental and Social Management Framework
ETORRS	Electronic Test Ordering and Result Reporting System
HSTP	Health Sector Transformation Plan
ICT	Information Communication Technology
ICWMP	Infection Control and Waste Management Plan
IEQAS	International External Quality Assessment Scheme
LIS	Laboratory Information System
LQMS	Laboratory Quality Management System
MDR-TB	Multi Drug Resistance Tuberculosis
NEQAS	National External Quality Assessment Scheme
NLSP	National Laboratory Strategic Plan
NMI	National Metrology Institute
POC	Point of Care
PPP	Public Private Partnership
QMS	Quality Management System
REQAS	Regional External Quality Assessment Scheme
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SWOT	Strengthen Weakness opportunity Treat

PREFACE TO THE THIRD EDITION

This Strategic Plan is developed to serve as a roadmap for developing Ethiopia's health laboratory services over the next five years. The first edition of the Strategic Plan was created in 2005 following the entrustment of a formal mandate to the Ethiopian Public Health Institute (EPHI) by the Ministry of Health to lead and build the capacity of the National Health Laboratory System. This first Strategic Plan was developed with a special focus on building the capacity of the laboratory system to effectively support the prevention, diagnosis, care & treatment of HIV/AIDS. This disproportionate development and capacity disparities between different laboratory disciplines constituting the national laboratory system and the shift in national laboratory programmatic focus from an isolated emphasis on HIV/AIDS laboratory system to an integrated approach for all laboratory services has led to the publication of the second edition of the Strategic Plan (2009-2013) to provide renewed national guidance and strategies for the integrated and balanced development of clinical and public health laboratory services.

Ethiopian Public Health Institute has followed standard international recommendations and procedural steps as well as used its previous experiences in developing a laboratory Strategic Plan to produce this third edition. This Third Edition of Ethiopia's Laboratory Strategic Plan defines the vision and mission of the national health laboratory system. It articulates the goals, strategic objectives, major initiatives, activities, and targets for developing a robust national laboratory system over the next five years. The document is also believed to assist all stakeholders, partners, and donor agencies in aligning their current and future activities, financial investments, and technical support to build the capacity of the national laboratory system following the strategic directions laid out in this Strategic Plan.

Utmost efforts have also been made to ensure that the anticipated strategic goals and objectives laid out in this NLSP are accounting for new developments to the best possible extent to address the evolving needs and priorities of the country as related to health laboratory services. As long-term strategies generally provide overarching guidance that spans over several years, EPHI considers it prudent to keep abreast of changes in the constantly evolving field of laboratory science, technologies, and practices to make sure that strategic objectives are regularly updated; initiatives and activities are reviewed and adjusted at all annual operational plan development processes to timely accommodate unanticipated changes in disease burden and health system priorities, testing methods and technology advancements, government, and donor support levels, human resource requirements and HR capacity development, among others.

CHAPTER ONE

1.1 Introduction

Ethiopian Public Health Institute is guided by a vision to exemplify a center of excellence in public health in Africa by developing an efficient and effective system for public health emergency management, strengthening the national laboratory system, conducting research on priority health and nutrition issues for the generation of strategic public health information, and promoting data management and utilization for public health decision-making and actions. As a mechanism towards successfully achieving its stated vision and mission, the institute is currently being guided by its third five-year Strategic Planning and Management (SPM III, 2020/21-2024/25), which was developed in line with Ethiopia's Health Sector Transformation Plan II (HSTP II) and the Growth and Transformation Plan II (GTP-II) in consideration of other relevant international commitments and initiatives for building resilient and sustainable systems for health and attaining the Sustainable Development Goal for good health and well-being by 2030. The SPM provides details on strategic themes, major initiatives, and associated activities which the institute envisions implementing over the plan period to advance public health in Ethiopia in line with its core mission.

The quality laboratory system theme seeks to build the capacity of the national health laboratory system to effectively contribute to the delivery of quality health care services through the provision of accurate, reliable, and timely results that are critical for the proper diagnosis of diseases, treatment monitoring, and prognosis of outcomes. It also details strategies and activities that need to be implemented to elevate the capacity, capability, and responsiveness of the laboratory system to reliably and effectively support the Public Health Emergency Management System (PHEM) through the precise and prompt detection of epidemic-prone diseases and hazardous environmental substances of public health importance as well as generate accurate and reliable data for laboratory-based surveillance/surveys, clinical and other public health researches.

Although the quality laboratory theme of the SPM presents well-articulated strategic objectives, initiatives and detailed activities for the development of the national laboratory system, experience gained during implementation indicated that producing a stand-alone blueprint for the development of the laboratory system would have marked positive impact by offering the opportunity for more visibility and focus on laboratory strategic directions as usually preferred by laboratory-dependent health programs, partners and donor agencies with vested interest in health laboratory agendas and looking to fill resource gaps. Thus, this

desire has led the EPHI to establish a Technical Working Group which has managed to produce the first draft of this third edition of the National Health Laboratories' Strategic Plan. The Plan was then further enriched and validated at a consensus building workshop with broader representations from all stakeholders and partners.

This Third Edition defines the roadmap and strategies by which EPHI strives to fulfill its mission and elevate the standard of Ethiopia's public health and clinical laboratories over the next 5 years. The Strategic Plan pertains to the National Health Laboratory System, which includes all laboratories whose work promotes the health and well-being of the public. The strategic objectives and initiatives have been defined by assessing the gaps between current services and the country's goals for the future. Through proper implementation of these strategies, EPHI aims to develop a functional and sustainable network of health laboratory system, whereby quality laboratory services are affordable and accessible to all Ethiopians in an equitable manner. Achieving the anticipated strategic result is also believed to greatly contribute to Ethiopia's efforts towards ensuring the health security of its people and fulfilling its commitments to addressing regional and global health security agendas.

The Strategic Plan is believed to enhance the concerted efforts of all stakeholders and partners towards building a strong and resilient National Health Laboratory System by providing a shared vision, key goals and targets to be achieved for the period 2023-2027. The document will serve as an important tool and basis for resource mobilization, annual activity planning and advocacy. EPHI will be closely working with the Ministry of Health (MOH) and its agencies, Regional Health Bureaus, Regional Public Health Institutes, Regional Reference Laboratories, partner organizations, professional associations, the private sector, academia, and experts from different fields for the realization of the strategic objectives, major initiatives and activities detailed in this document to materialize its vision of ensuring the provision of high-quality health laboratory services to all Ethiopian citizens.

1.2 Background: Structure and governance of the Ethiopian Health Laboratory System

The Ethiopian Laboratory System is comprised of four-tiered decentralized networks of laboratories arranged in a tier level with national reference laboratories assuming the apex position (Level IV) and those associated with health centers occupying the broader base (Level I). Despite their relatively different roles and functions, the regional reference laboratories are on a par organizational hierarchy with those of tertiary hospitals (Level III). Tertiary hospital laboratories are primarily engaged in clinical laboratory diagnosis whereas regional reference laboratories additionally shoulder the responsibilities of executing other public health functions such as disease surveillance and other public health research including testing of environmental samples for safety and quality. All other hospital laboratories belonging to primary and general hospitals are grouped into Level II of the laboratory system. Laboratory tiers are mainly defined and structured based on the minimum scopes of essential health service packages expected to be provided at the different levels of the country's health care service delivery system (Annex 3). As such, diagnostic laboratories are among the basic components of health care departments of all facilities from the health center level upwards, although health posts are also involved in screening of patients using simple Rapid Diagnostics (RDTs) such as for the diagnosis of malaria parasites, a testing service that has been given little attention in terms of closer technical support and overall quality assurance until now but which deserves the most in the coming years considering Ethiopia's efforts towards eliminating malaria from its selected territories. Laboratories operating in a given tier are technically supported by all higher levels following national guidance provided by EPHI.

According to a 2022 report from the MOH, there are a total of 517, 3921 and 17,500 functional hospitals, health centers and health posts, respectively, all of which provide laboratory diagnostic services as described above. In addition, there are 15 stand-alone regional reference laboratories, many from Uniformed Forces' (Army, Police and Prison Administration) Health Departments, University hospital laboratories, those linked to blood bank centers, private hospitals, and non-governmental organizations (NGO), as well as stand-alone private laboratories. Thus, the Ethiopian laboratory system is huge and complex requiring the development and implementation of suitable strategies, initiatives and activities that seek to promote and strengthen systems for efficient and effective communications and collaborations among laboratories along and across all tiers for improved specimen referral linkage and testing services, cascaded implementation of laboratory programs and provision of continued technical support from top to the lowest level of the tiers. Establishing, strengthening, and maintaining such robust and functional laboratory networks require

conducive administrative and technical support systems that are led and coordinated by competent laboratory managers and leaders at facility, regional and national levels.

National Health Laboratory Tier System and technical support structures of the Ethiopian health laboratory system are diagrammatically depicted on Annex 2 and 3.

2. Situation Analysis

2.1. The EPHI SPM-II Performance Analysis

The National laboratory System had implemented the Ethiopian Public health Institute second five-year Strategic Management Plan (2015/2016 – 2019/2020) which was developed in line with Ethiopia’s Health Sector Transformation Plan (HSTP) and Growth and Transformation Plan II (GTP-II) in consideration of other relevant international commitments and initiatives for building resilient and sustainable system for health towards achieving Sustainable Development Goal for good health and well-being (Goal 3) by 2030. Currently also implemented for two years’ form EPHI third Strategic Planning and Management (SPM-III) 2020/21-2029/30).

In the SPM III the National laboratory program had been addressed in the strategic plan by one strategic objectives and six strategic directions to building Sustainable and Resilient Laboratory System and-Quality Laboratory Services in Ethiopia, Strengthen the Implementation of Laboratory Quality Management System and Accreditation, Enhance the Standardization and Expansion of Laboratory Services, Strengthen Laboratory Equipment Management System, Strengthen Biosafety, Biosecurity and Hazardous Waste Management System, Enhance the Implementation of External Quality Assessment (EQA) Schemes, Strengthen the Implementation of Laboratory Information Management System (LIMS) . In this section, the major achievements presented based on the following six sections.

2.2. Laboratory Quality Management System and Accreditation

In the last five years, various programs have been developed and implemented to improve the quality of laboratory services provided in Ethiopia. In SPM III the institute has fully engaged in improving the status of laboratories through the Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA) program for hospitals and basic laboratory quality management for health centers and ISO standard accreditation for laboratories at all tiers.

The progress toward SLIPTA for hospitals and regional laboratories is from 5.5 % to 46%. And also, health centers implementing basic laboratory quality management system were increased from 50% to 85 %. However, the enrolments of regional laboratories /hospitals and Health centers were increased to 46% and 75% respectively from the total national-wide functional laboratories. Despite numerous challenges that

were encountered during the implementation process, noticeable changes and advancements were noted for laboratory services on a national level.

The accreditation program is the milestone to measure the quality management implementation and ensure the quality of services provided in the laboratory. EPHI design programs for ISO accreditation in limited and full scope accreditation schemes. Over the last five years, laboratories achieved limited and full scope accreditation was 41 and 3, respectively. During the implementation of this SLPTA and accreditation program, the institute faces challenges in continuous quality improvement such as weak follow-up, limitation in ownership to handle quality assurance initiatives at facility level, and unsuitable laboratory infrastructure were the most common challenges faced.

2.3. Laboratory Service Expansion

In the last five-year strategic plan, advanced laboratory tests have been deployed and expanded at different health facilities of the country to improve the laboratory services. About 27 Molecular laboratories have been established, capacitated technically, and equipped with high-tech instruments that can be used for laboratory diagnosis of multiple public health importance pathogens like HIV VL, HIV EID testing, Hepatitis B and C Viral load, Human Papilloma Virus (HPV), SARS CoV-2, Monkeypox, and other emerging diseases. More than 454 health facilities have been capacitated to improve TB detection rate by equipping with around 506 GenXpert machines and providing technical support. Moreover, the Point of care early infant diagnosis (POC EID) services have been initiated in 180 health facilities by integrating with TB GenXpert testing, which dramatically improve HIV EID testing TAT. There are also around 50 POC VL testing laboratories integrated with TB and EID services. Additionally, 11 AMR surveillance system (Advanced Microbiology) laboratories and four influenza laboratories have been established. However, there are still limitations to expanding different tests in most health facilities due to commodities, financial, and trained personnel constraints. One of the strategies to manage these problems is implementing a laboratory referral network system in the country. Currently, 90 % of the laboratories have been networked to specimen referral linkage and testing services. The other strategy (alternative specimen referral system) has been implemented to address the rest 10 % of health facilities that are not covered by the routine referral networking system due to hard reach for the sample carrier.

2.4. Laboratory Equipment Management System

One of the main activities in the third strategy plan was supporting the laboratory equipment maintenance and management system in the country. In line with this, to mention some of major activities accomplished

for the last three years, medical/laboratory equipment maintenance workshops were constructed for 11 regions, in 2015 EFY budget year additional 3 NSF certified engineers which makes a total of 6 certified engineers at National level and basic maintenance tools and cold chain consumable spare parts were distributed to maintenance workshops. For the last three years the proportion of major laboratory equipment with less than 5% downtime per year reached 85 % of health facilities who have major laboratory equipment. Another major activity under laboratory equipment maintenance and management system in the third SPM was supporting laboratories by calibrating and certifying biosafety cabinets (BSC) and Negative pressures systems. Ninety percent of the total BSC calibrated and certified the rest not certified due to Shortage of PPE for BSCs fumigation, HEPA filters and hydrogen Peroxide for fumigation and humidifier devices. Additional to these, personal protection devices which are used to fumigate the BSC, limited BSC testing tools and long process for annual calibration of testing tools as it is calibrated out of the country (it takes more 3 three month) are among the identified challenges in BSC calibration. Moreover 10 regional TB culture laboratories which have a Negative Pressure System providing semi- annual preventive maintenance services.

2.5. Biosafety, Biosecurity and Hazardous Waste Management System

Biosafety and biosecurity programs had been implemented for the last three years. As part of the activities, technical assistance on biosafety and biosecurity programs has been provided by EPHI for more than 11% of health facility laboratories which are National reference laboratories and Regional Public Health Institute/Regional Reference Laboratories, Federal hospitals, University specialized hospitals, Antimicrobial Resistance (AMR) laboratories, Uniformed Armed force hospitals laboratories and COVID 19 testing sites.

In addition, as part of the biosafety and biosecurity program, an assessment was conducted to monitor the status of biosafety and biosecurity system implementation using a checklist in these laboratories. Following the assessment, laboratories prepared an action plan to address identified gaps and improve biosafety and biosecurity in their respective laboratories. Moreover, a draft proclamation for the administration and control of Ethiopia's select hazardous pathogens and toxins has been developed based on the gaps identified by the joint external evaluation (JEE). In addition, a list of Ethiopia's selects hazardous pathogens and toxins (ESHPT) is identified and published. Moreover, as part of the BSL 3 laboratory construction project to enhance biosafety and biosecurity, Safeguard documents such as the Environmental and Social Impact Assessment (ESIA) for the BSL 3 National Reference Laboratory, the Environmental and Social

Management Framework (ESMF) for BSL2 laboratories, and the Infection Control and Waste Management Plan (ICWMP) for the BSL 3 National Reference Laboratory were prepared.

Furthermore, during the pandemic of the COVID-19 virus, technical assistance on biosafety and biosecurity programs was provided to COVID-19 testing sites, including how to ensure safe specimen handling, and testing, including safe waste disposal. An interim biosafety guideline for specimen collection, handling, and testing was developed and distributed to health facilities, and training on COVID-19 virus biosafety and biosecurity was provided for laboratory personnel and other health professionals working on specimen collection, transportation, and testing. In addition to this, the existing biosafety and biosecurity guidelines and biosafety and biosecurity training manual were revised and updated in order to improve the implementation of the biosafety and biosecurity program.

2.6. External Quality Assessment (EQA) Schemes

EQA is a system for assessing laboratory performance in a third-party system that is free of bias in order to provide objective evidence for the participation performance of enrolled facilities against predefined evaluation criteria. It has been implemented over a number of years through a variety of programs, including international, national, and regional EQA schemes, as well as various EQA methods such as proficiency testing panels, random blind rechecking, and onsite evaluation.

In the previous three years (2013, 2014 and 2015 EFY), it was planned to make EQA available to all diagnostic laboratories and to enroll 60%, 70%, and 80% of eligible diagnostic laboratories in the EQA system in either PT, RBR, or Onsite evaluations across the country. The overall EQA participation figures in the year of 2020 and 2021 become 35% and in 2022 it become 78% enrollment.

The participation rate was very low, as it had been in previous years, and this is due to several EQA activities were managed and coordinated separately within different programs, the roles and responsibilities for EQA program implementation were not clearly defined, the EQA implementation structure was not properly stated, the EQA implementation budget was insufficient; to make EQA accessible at lower level facilities across the country and to manage EQA in an integrated manner, National integrated EQA implementation guideline was developed to employ different EQA programs such as Proficiency panels testing, rechecking, and on-site evaluation techniques. This implementation guideline is expected to be implemented through an integrated way by the involvement of regional laboratories, EQA centers, woreda level focal persons, health facilities and postal courier services. To make it more convenient and effective for the implementer, an innovative and integrated EQA samples and slides collection and feedback delivery

was established, and currently more 2257 laboratories have been enrolled, accounting for 78% of the current functional laboratories of those facilities scoring >80% performance were 70% and 85% in 2014 and 2015 EFY respectively, which is acceptable when compared to the plan 65% and 80% in the same year. However, difficulties in setting up functional EQA rechecking laboratories with a full-fledged EQA database system, inability to create a standardized national proficiency panel's production center, limited financial and technical support to include all functional laboratories nationwide, and limited national capacity in strengthening EQA programs in the country were major constraints during the last three-years strategy implementation.

2.7. Laboratory Information Management System (LIMS)

Laboratory Information Management and Data management is one part of the SPM III implemented in the last three years. A total of twenty-five laboratories installed electronic Polytech LIS. In line with this during the COVID 19 pandemic five laboratories using electronic LMIS that is interoperable were networked with District Health Information System-2 (DHIS-2). Ethiopian Public Health Institute's efforts to interface electronic LIS implementation with suitable open source or proprietary LIS could not be materialized until now due to a lack of adequate budget required for the procurement, installation, and user training of new such software package or expansion of the existing Polytech commercial software.

2.8. Stakeholder Analysis

Stakeholders are key players in the health laboratory program, and understanding their needs is crucial to the success of National Laboratory Strategic plan 3rd edition.

The table below shows the key stakeholders whose needs and interests should be taken into consideration during the previous strategic plans.

Table 1: Stakeholder Analysis

Stakeholders	Behaviors We desire	Their needs and interests	Resistance issues	Institutional Response	Power	Influence
Community /Citizens	Participation, ownership, full information	Equal, Equity, access, Transparency Efficient service Accountability and effective use of public property public health risk communication	Poor image, dissatisfaction	Ensure participation, equitable services, quality service	High	High
The house of People' Representatives (Parliament)	Ratification & Approval of policy, regulation Plan and performance. Follow up and support.	Implementation of policy, implementation of international standard, regulations, and strategic plan. Quality and Equity plan and implementation, good governance, Accountability, and timely accomplishments	High-bureaucracy, institutional restructuring,	Put in place a strong M&E System, increase efficiency and effectiveness.	High	High
Ministry of Health	Approval of policy, program, Plan and Performance. Follow up and support. Program Alignment,	Implementation of the strategic plan. Equity and quality laboratory plan and Implementation, timely accomplishments	Poor budget, poor-coordination	Compliance with international quality, Efficiency, effectiveness, optimization.	High	High

Stakeholders	Behaviors We desire	Their needs and interests	Resistance issues	Institutional Response	Power	Influence
		with a report				
Ministry of Finance	Resources allocation, performance follow up and support	Value for money, economic feasibility lab technologies, cost effectiveness, optimum utilization of budget	Reallocate funds, poor budget, close programs, reduce budget.	Give value for money, timely planning, and reporting	High	High
Civil Service Commission	Approval workforce size and structure, standardize jobs, incentives, and salaries	Work force estimation for laboratories, manual, standard preparation,	Not standardize the laboratory workforce accordingly. Administrative measures.	Timely preparation of directives, manuals	Medium	High
Ethiopia Pharmaceutical Supply Service and Ethiopia Food and Drug Administration.	Timely delivery of laboratory equipment and supplies, collaborative work, post and premarket assessment for lab equipment, demand analysis.	Timely equipment planning, value chain monitoring, timely request, Equipment management, evidence-based equipment management.	Untimed delivery, disruption in supply chain,	Joint planning, coordination, collaborative work	High	High

Stakeholders	Behaviors We desire	Their needs and interests	Resistance issues	Institutional Response	Power	Influence
Regional Health bureaus, regional public health institutes and Regional reference laboratories.	collaboration, coordination, participation, laboratory quality program implementation, commitment to change.	Joint agenda setting, effective coordination, supportive supervision.	Dissatisfaction,	Joint program implementation M&E	High	High
Health facilities (Government & private, regional laboratories, hospitals, and health centers)	commitments Implementation of laboratory quality program (SLPTA, EQA) LIS, BSC-calibration, maintenance, and others.	Program implementation, mentorship, follow up, budget support, technical support, policy guideline and other supports.	Lack of commitment to implementation.	Strict follow up. Embedded mentorship and monitoring	High	High
Program donor (CDC, ACDC WHO, WB, GF.....)	Harmonized & Aligned Participation More financing and Technical Support,	Laboratory program implementation, report, efficient budget liquidation,	Cut budget support,	Resource use Build financial management capacity build strengthens. M&E.	High	High
Laboratory professionals and other staff.	Perform laboratory test with quality standards. Implement laboratory protocols/policies /SOPs. Improve skill. Ensure safety of machine and equipment.	Provide capacity building. Avail IPC supplies. Motivation and recognition.	Low Commitment	Strict follow up. Embedded mentorship and monitoring.	High	High

Stakeholders	Behaviors We desire	Their needs and interests	Resistance issues	Institutional Response	Power	Influence
Manufacturers and companies (National and International)	Deliver qualified supplies and machines. Provide maintenance services according to the agreement.	Present specifications. Check the quality. Communicate early.	Low quality products. Resistance to be governed based on agreement.	Coordination and collaboration work.	Medium	High
Ethiopian Accreditation Service	Assess laboratory for accreditation (new & maintained). Provide assessment report.	Fulfil laboratory standard for accreditation. Maintain accreditation standard. Implement the feedback	Delaying accreditation.	Coordination and collaboration,	Medium	High

2.9. SWOT (Strengths, Weaknesses, Opportunities and Threats) Analysis of the National Laboratory System

SWOT analysis, one of the situational analysis methods, was used to accurately identify and define all the aspects that affect the working environment with reference to the implementation of National laboratory programs throughout the nation. It is broadly divided into internal factors (Strengths and Weaknesses) and external factors (Opportunities and Threats) to analysis the situation.

The results of the SWOT analysis, which are listed in the table below, were taken into consideration when developing the third edition of the National Laboratory Strategic Plan as enablers and challenges for enhancing the targeted performances.

Table 2: SWOT Analysis of the National Health Laboratory System

Strength	Weakness
<ul style="list-style-type: none"> • Availability of different working national guidelines, manuals, and other documents • Existence of national laboratory system with tiered laboratory network and defined functions • Commitment to introduce new diagnostic testing technologies. • Improved laboratory infrastructure at national and regional public health institutes and reference laboratories • Existence of functional regional public health institutes and reference laboratories • Experience of implementation of laboratory quality management system • Good established communication with laboratory stakeholders and partners • Presence of accredited laboratories to ISO and other standards • Improved service availability and accessibility 	<ul style="list-style-type: none"> • Inadequate implementation of quality laboratory services through the laboratory tier system • Inefficient coordination of laboratory specimens' referral system at all levels. • Shortage and improper deployment of laboratory workforce • Inadequate equipment maintenance services • Limited budget for laboratory services at facility levels • High staff turnover • Limited Laboratory ICT infrastructure • Inadequate laboratory infrastructure at peripheral health facility levels • Weak Public Private Partnership • Limited implementation of the standardized laboratory testing menu • Limited lab-clinic interface • Poorly defined core functions & structure of regional labs/Public health institutes • Inadequate capacity for the detection of emerging and reemerging diseases • Insufficient laboratory testing data management and utilization for decision-making. • Weak implementation of regulatory framework pertaining to laboratory minimum quality standard • Inadequate coordination with regulatory and accreditation bodies • Limited EQA coverage and lack of National EQA provider • Absence of regulatory framework for control of

	<p>hazardous pathogens and toxins</p> <ul style="list-style-type: none"> • Absence of high containment laboratories • Weak laboratory inventory management and procurement system
Opportunities	Threats
<ul style="list-style-type: none"> • Strong government commitment • Emphasis given for quality laboratory service in HSTP-II • Existence of partners support and collaboration • Growing private health sector • Growing interest in the public private partnership • Existence of Professional associations • Existence of dedicated regulatory and logistic bodies • Growing academic and research institutions • The existence of laboratory equipment placement initiative • Existence of national laboratory accreditation, calibration, and standard bodies 	<ul style="list-style-type: none"> • Poor community engagement • Increased natural & manmade disasters as well as internal political instability. • Declining and low predictability of donor funding • Competing local and international priorities • Effect of global economic inflation on laboratory supplies • Sub-standard reagents and supplies available in the market. • Unsustainable supplies of laboratory reagents and supplies

CHAPTER THREE

3.1 Vision and Mission of the National Health Laboratory System:

Vision:

Excellence in quality health laboratory services.

Mission:

Build the capacity of the Ethiopian/ Health Laboratory System to strengthen health care delivery services; responses to public health surveillance and emergencies; and to generate evidence by providing quality laboratory services.

Core values

- Evidence based decision.
- Responsiveness
- Transparency
- Accountability
- Professionalism
- Teamwork.
- Partnership
- Quality and excellence
- Resource conscious
- Equity
- Innovation
- Continuous learning

3.2 Strategic Objectives, Strategic Result and Strategic Directions

The national laboratory strategic plan has seven main strategic objectives to be implemented in a five-year (2023-2027) period. Each strategic objective has strategic results, strategic directions, major activities, and indicators. The strategic objectives, strategic result and strategic directions are indicated in the following table:

Table 3: Summary of Strategic Objectives, Strategic Result and Strategic Directions

S. No	Strategic objective	Strategic Result	Strategic direction
1	Provide comprehensive and standardized health laboratory testing services.	Avail comprehensive and standardized health laboratory testing services	<ul style="list-style-type: none"> ➤ Enhance laboratory testing services. ➤ Equipment standardization and implementation of innovative technologies ➤ Diagnostic Network Optimization (DNO).
2	Strengthen implementation of laboratory quality management system.	All laboratories implemented quality management system	<ul style="list-style-type: none"> ➤ Enhance implementation of quality initiatives and promote accreditation program. ➤ Ensure standardized and sustainable External Quality Assessment (EQA) program.
3	Improve biosafety, biosecurity, and hazardous waste management system.	Safe and secured laboratory system	<ul style="list-style-type: none"> ➤ Establish and implement regulatory and legal frameworks for handling of hazardous pathogens and toxins. ➤ Improve the implementation of biosafety and biosecurity programs. ➤ Improve compliance and practice of laboratory waste management system.
4	Strengthen an integrated laboratory data and information management system.	Implemented integrated laboratory data and information management system	<ul style="list-style-type: none"> ➤ Strengthen the implementation of standardized laboratory information system (LIS) ➤ Build national and regional capacities for laboratory data repository, management, sharing and use.
5	Enhance operational research, innovations, and introduction of new laboratory technologies.	Enhanced operational research, innovations, and introduction of new laboratory technologies.	<ul style="list-style-type: none"> ➤ Build the capacity of laboratories for innovation and transfer of new technologies. ➤ Promote operational research to improve laboratory services. ➤ Establish biobank/biorepository.

S. No	Strategic objective	Strategic Result	Strategic direction
6	Leadership, Governance, Partnership, and Sustainable Financing	Strong leadership and governance, partnership, and sustainable financing.	<ul style="list-style-type: none"> ➤ Strengthen Leadership and governance. ➤ Enhance Partnerships, collaboration, and coordination. ➤ Strengthen Sustainable Laboratory Financing System.
7	Workforce development and Management	Adequate, Competent, and motivated workforce at each level of the laboratory networks.	<ul style="list-style-type: none"> ➤ Ensure Human Resource Planning and Retention. ➤ Strengthen Continuous Professional Development and Knowledge Management.

3.3 Strategic Objective One: Enhance the provision comprehensive and standardized health laboratory testing services.

Strategic Result: Avail comprehensive and standardized health laboratory testing services

Description

Laboratory services are an essential and fundamental component of the health system. The purpose of laboratory services is to improve the health status of the nation through the provision of evidence-based information for disease prevention, detection, and response. Health laboratories that are associated with the primary, secondary, and tertiary tiers of the country's healthcare service delivery system assume extremely varying positions due to multiple factors. Standardizing laboratory testing at all tier levels will bring considerable impact to improve the diagnostic capacities of laboratories both at national and regional levels. It also helps to ensure laboratory services accessibility at all levels, especially those at the lower level of the health system. In Ethiopia, investments made on advanced methods and technologies to strengthen laboratory services for HIV and TB/MDR-TB brought a substantial improvement in the diagnosis and treatment of other priority diseases.

Like other aspects of the health care delivery system, the demand for laboratory services has expanded over time. The range of laboratory tests available is on the rise over the years,. Cognizant of the existing situation, ensuring laboratory services expansion to address public health priority diseases, is timely and

plays a crucial role. Concurrently, it is necessary to implement the national health laboratory infrastructure standards and upgrading laboratory infrastructure through renovation and equipping to the standard. A sustainable laboratory supply chain management system has a critical role in providing uninterrupted laboratory services. Addressing the issues of the laboratory supply chain from quality product selection up to the use of the product at the facility level and addressing issues through post-marketing surveillance will help to improve the frequent stock out and use of substandard laboratory reagents and supplies. Ethiopia has been striving to introduce multiplex testing and develop a Diagnostic Network Optimization (DNO) and efficient integrated specimen transportation & result delivery system, an undertaking that is yet to mature in all aspects during the implementation period of this strategic plan.

Strategic direction:

3.3.1 Enhance laboratory testing services.

Description

This strategic direction covers improving and standardizing laboratory tests, methods, and technologies across all tiers of the national laboratory system. It also deals with the expanding laboratory tests for the existing services and introducing innovative and state-of-the-art technologies to the laboratory system. To avail and access laboratory services to all, it needs integration and diagnostic network optimization of laboratory networks for specimen referral and testing services. Furthermore, this strategic direction guides laboratories to be prepared and respond to public health emergencies.

Health laboratories form an essential component of the health system. They serve as a foundation for disease surveillance and public health response to outbreaks and epidemics, in addition to providing test results for disease diagnosis, guiding treatment, and detecting drug resistance. The importance of health laboratories in the modern health care system is demonstrated by the fact that 70% of today's medical decisions made depend on laboratory test results. Robust clinical laboratories provide the foundation for accurate and timely disease diagnosis, prevention, and control to improve the health and safety of the community. Laboratory Systems is uniquely positioned to support clinical laboratories in several ways. Patients in rural areas often experience barriers to healthcare and laboratory services that limit their ability to receive the care they need. Efforts to strengthen health systems should therefore focus on laboratory services and systems as they provide primary information that informs decision-making for the best healthcare outcomes.

Major activities

- Standardize and implement laboratory testing menu at all tier levels.
- Ensure laboratory services accessibility at all levels.
- Ensure laboratory services expansion including public health priority diseases.
- Strengthen laboratory supply chain management system.
- Promote quality of laboratory commodities through pre- and post-market surveillance
- Strengthen implementation of national health laboratory infrastructure standards
- Upgrade laboratory infrastructure through renovation and instrumentation

Indicators

- Proportion of laboratories implementing standardized test menu
- Number of laboratories that can detect public health priority diseases.
- Proportion of diagnostic laboratories with <5% stock outs
- Type of tests for which pre- and post-market surveillance conducted.
- Proportion of laboratories meets the national infrastructure standard.

3.3.2 Equipment standardization and implementation of innovative technologies

Description

This strategic direction provides guidance on technology selection, specification, inspection, site preparation, installation, commissioning, operation, maintenance, calibration, decommissioning, and disposal of laboratory equipment. Standardization in laboratory diagnostics entails the establishment of uniform test menus appropriate for the healthcare delivery level and the selection of standard technology platforms, including instruments, reagents, and consumables for each test at each level. A national laboratory equipment management system needs the standardization of equipment platforms, implementation of equipment maintenance, and development of procedures for equipment retirement mechanisms. Implementing innovative technologies at appropriate levels to accurately and reliably diagnose diseases prioritized and targeted by global health normative agencies and International Health Regulation for control, elimination, or eradication of priority infectious diseases.

Major activity

- Develop and implement laboratory equipment management system.
- Standardize and harmonize laboratory equipment platforms across tier level.
- Implement an effective system for equipment maintenance and calibration services.

Indicators

- Number of laboratories with standardized equipment platform.
- Proportion of laboratories with <5% equipment downtime.
- Proportion of laboratory equipment calibrated.
- Proportion of equipment safely disposed.

3.3.3 Diagnostic Network Optimization (DNO)

Description

This strategic direction guides a diagnostic network that interconnects systems that comprise human resources, infrastructure, referral systems, and diagnostic testing devices, to detect, manage and monitor diseases in a clinical or public health setting. It includes both physical elements, such as sites, devices, and tests, and rules or policies that govern operations, such as sample referral linkages.

The goal of diagnostic network optimization is to deliver the right amount of testing, in the right place, at the right time, for the right people, and at an affordable and sustainable cost, ensuring that accurate test results are delivered in a timely manner to inform patient care and public health decision-making, on a scale consistent with national goals and strategies. DNO is a specific form of geospatial analysis that looks at optimizing diagnostic network design.

Major activities

- Laboratory mapping throughout the national network
- Establish functional network and communication systems among national reference, regional laboratories, private facilities, and animal health diagnostic and surveillance centers.
- Update and optimize vertical and horizontal networks of laboratories for specimen referrals and result communications.
- Ensure sustainable, safe, and quality specimen transport system.

Indicators

- Proportion of laboratories providing testing services through referral linkage per the defined network
- Proportion of networked laboratories receiving their results within acceptable turnaround time (TAT)
- Proportion of referred specimens with rejection rate of < 1%

3.4 Strategic Objective Two: Strengthen implementation of laboratory quality management system.

Strategic Result: All laboratories implemented quality management system.

Description

It is critical that health laboratories implement and maintain quality management system to effectively support and continually improve the quality of health care services, public health emergency response, and surveillance and research activities in accordance with available national and international standards. In Ethiopia, quality infrastructures such as Ethiopia standard agency (ESA), Ethiopian accreditation service (EAS) and national metrology institute (NMI) are in place which enables laboratories to achieve quality and accreditation initiatives. Likewise, Ethiopian food and drug authority (EFDA) is a regulatory body which enforces laboratories to fulfill the minimum service and quality requirements.

In laboratories, implementing quality management systems ensures the reliability and dependability of all aspects of the laboratory technical and managerial processes and operations. Poor quality management system can lead to unnecessary treatment and its complications, incorrect treatment, delayed diagnosis, and unnecessary follow-up diagnostic testing. In addition to poor patient outcomes, it can result in increased time, cost, and unnecessary work burden. Therefore, QMS in medical laboratories requires fulfilling quality standards in all practices including environment management, quality assessments (QA), record keeping, human resources, reagents, and equipment and instruments. Ethiopia has been implementing Laboratory Quality Management System (LQMS) over the past few years and great progress has been achieved in improving the quality of laboratory testing services at all levels of the laboratory system. As a result of these efforts many laboratories are currently providing relatively better quality of testing services, and a few have even achieved accreditation to ISO15189 and 17025 quality standards. However, more investments are needed to sustain the achievements gained so far and enhance the implementation of LQMS across all laboratories. This will ensure accurate, reliable, and timely results are always readily available and accessible for proper clinical management of patients, public health interventions, and research undertakings.

Strategic directions:

3.4.1 Enhance implementation of quality initiatives and promote accreditation program.

Description

Systematic and coordinated implementation of quality system essentials, is key for the provision of sustainable quality laboratory services. Implementing all essential elements of LQMS across all laboratories nationwide through undertaking various initiatives such as the Strengthening Laboratory Management Towards Accreditation (SLMTA) and the WHO-AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) will ensure that accurate, reliable, and timely results are always readily available and accessible for proper clinical management of patients, public health interventions, and research undertakings.

A task-based, practical training and mentoring program called SLMTA aims to enhance laboratories in resource limited countries. Unlike that of the conventional accreditation scheme which scores laboratories as pass or fail status, SLIPTA is a framework for auditing and monitoring laboratories through an incremental star-level recognition system. This stepwise approach recognizes where a laboratory stands currently and promotes continual improvement through positive reinforcement by rewarding progress at each step. Laboratories are evaluated based on relevant ISO standards after the implementation of LQMS, SLMTA, and different quality improvement initiatives. Upon LQMS implementation and attainment of the required quality standards and accreditation, it is possible to achieve customer's satisfaction.

Laboratory accreditation is an assurance that the laboratory has been assessed against internationally recognized standards aimed to prove the existence of a quality system, technical competence, and that the personnel are actually proficient to generate valid results and suitable information for the intended use of each test.

Following rigorous implementation of the Laboratory Quality Management System, Ethiopian laboratories have been working to achieve ISO 15189/17025 Accreditation standards. This effort has been supported by EPHI and few laboratories have achieved accreditation. However, this effort should be enhanced and promoted by all stakeholders and supporting partners to increase the number of laboratories achieving accreditation each year.

Major activities

- Strengthen and implement laboratory quality management system (LQMS) at all levels of laboratories.
- Implement SLMTA at different tier level laboratories.
- Promote accreditation to stakeholders.

- Prepare laboratories to accreditation scheme.
- Support laboratories for maintenance of accreditation and scope extension

Indicators

- Number of laboratories with SLIPTA 1–5-star levels (disaggregated into star levels)
- Number of laboratories progressively improving their SLIPTA star level at least by 1 star
- Proportion of laboratories with Basic LQMS (BLQMS) 1-5 Star levels (disaggregated into customized star levels)
- Number of laboratories progressively improving their BLQMS Star level at least by 1 star
- Number of laboratories accredited to ISO 15189/ 17025 requirements.
- Proportion of laboratories maintaining their ISO 15189/17025 accreditation status each year
- Number of laboratories with at least one accreditation scope extension each year

3.4.2 Ensure standardized and sustainable External Quality Assessment (EQA) program.

Description

External quality assessment (EQA) is a system for objectively checking the laboratory’s performance with an evidence-based comparison of a laboratory testing quality and provides a systematic performance evaluation report from a third party. Organized and coordinated management of EQA schemes are required at each level of the laboratory network across the nation using various methods (Proficiency testing, random blinded retesting/rechecking, and onsite evaluations). This could be done through International, National, and Regional EQA schemes to assure and improve testing laboratories quality service and provide an evidence-based comparison between participating laboratories.

As part of this, EPHI has designed and implemented various national EQA schemes at all tiers of the country’s laboratory network. Over the next few years, the EQA program will be strengthened through establishing EPHI as a capable national EQA service provider with PT production capacity, robust informatics and efficient logistics system in accordance with ISO 17043 standards and enhancing the national capacity for EQA program coordination. Furthermore, it is planned to strengthen the participation of Ethiopian laboratories in selected national and international EQA schemes as well as promoting the implementation of other EQA methods such as Random Blinded Rechecking, Onsite Supportive Supervision and inter-laboratory comparison at various levels as found appropriate.

Major activities

- Improve Proficiency Testing (PT) infrastructural, production, distribution, result collection and feedback provision capacity in line with ISO 17043 requirements.
- Strengthen the national and regional capacity for sustainable coordination of EQA activities.
- Strengthen the system for Random Blinded Rechecking and Onsite evaluation activities.
- Introduce and implement Inter-laboratory comparison program.

Indicators

- Established PT Production center at national level based on ISO 17043 requirements.
- Established and maintained functional EQA management software (ePT) system.
- Proportion of laboratories enrolled at least in one of the three EQA methods.
- Proportion of laboratories scored acceptable PT performance per round.
- Proportion of EQA enrolled laboratories responded within the intended timeframe.
- Proportion of laboratories enrolled in random blind rechecking (RBR) EQA program.
- Proportion of laboratories scoring acceptable performance (concordance rate) in random blinded rechecking (RBR) EQA program
- Proportion of laboratories covered through onsite evaluation EQA program.
- Number of laboratories participated in inter-laboratory comparison scheme.

3.5 Strategic Objective Three: Improve biosafety, biosecurity, and hazardous waste management system.

Strategic Result: Safe and secured laboratory system

Description

Biosafety and biosecurity describe the containment principles, technologies, and practices that are implemented to prevent unintentional exposure to pathogens and toxins or their accidental release. Proper implementation of biosafety, biosecurity principles, and waste management practices following international standards are crucial for the well-being of laboratory personnel, patients, the public, and the environment. There are limited biosafety, biosecurity, and waste management implementation initiatives across all health laboratories in Ethiopia.

To improve the biosafety, biosecurity system, and waste management, there should be guidance for evaluation containment, and control of biohazards, categorized as to the degree of risk of infection, good laboratory practices, and safe handling and disposal of hazardous wastes. Besides, there should be a formal

regulation governing the registration and certification of health laboratories for the safe storage and disposal of dangerous pathogens and toxins. Thus, systematic and coordinated implementation of Biosafety, biosecurity, and laboratory waste management program and activities across the country is key for the provision of biosafety and biosecurity and hazardous waste management system.

Strategic Directions

3.5.1 Establish and implement regulatory and legal frameworks for handling of hazardous pathogens and toxins.

Description

Hazardous pathogens and toxins can pose a significant risk to human health and safety and are capable of causing significant illness or death in humans. To improve the handling of select hazardous pathogens and toxins in Ethiopia, establishing a national regulatory and legal framework for the safe handling of the select hazardous pathogens and toxins, and provide assurance that individuals with access to a prescribed list of security-sensitive human pathogens and toxins would hold an appropriate security clearance. To achieve this, a risk-based licensing process for facilities conducting controlled activities with the pathogens and toxins. The Regulator will also identify and publish a list of Ethiopians select hazardous pathogens and toxins and regulate the possession, use, and transfer of select hazardous pathogens and toxins that pose the highest risk of misuse and will set out security clearance requirements and enforce regulatory and legal frameworks for on laboratories who have access to these agents.

Major Activities

- Establish regulatory and legal frameworks for handling hazardous pathogens and toxins.
- Implement regulatory and legal frameworks for laboratories that possess, use, and transfer hazardous pathogens and toxins.
- Enforce regulatory and legal frameworks on laboratories that possess, use, and transfer hazardous pathogens and toxins.

Indicators

- Established regulatory and legal framework for handling of hazardous pathogens and toxins.
- Number of health facilities fulfilling the regulatory and legal requirements for handling hazardous pathogens and toxins.
- Number of licensed health facilities for handling hazardous pathogens and toxins.

3.5.2 Improve the implementation of biosafety and biosecurity programs.

Description

Biosafety and Biosecurity activities are fundamental to protecting the laboratory workforce and the wider community against unintentional exposures or releases of pathogenic biological agents. These activities are implemented through the development of a safety culture which is needed to ensure a safe workplace where adequate measures are applied to minimize the likelihood and severity of any potential exposure to biological agents.

EPHI has made considerable progress in the implementation of laboratory biosafety and biosecurity programs nationwide, however there are still several outstanding challenges that hinder the comprehensive implementation of the programs to the level of institutes expectations as amenable with pertinent international standards and recommendations.

The biosafety cabinet is the principal containment device used to protect the laboratory worker and surrounding environment from infectious biological materials. Despite this central role, many biosafety cabinets in use are not routinely tested and verified for correct functional operation and integrity. This process, referred to as certification, must be carried out by trained individuals and requires the use of calibrated testing equipment.

Using biosafety cabinets that have not been properly certified not only presents a risk to infection among laboratory workers, but also presents a risk of release of infectious agents back into the surrounding community and environment preventing global efforts to contain and control infectious diseases.

EPHI have been support biomedical engineers and enhance equipment maintenance capacity for the routine certification of biosafety cabinets. Additional, EPHI will establish a system for verification and certification program for clean room and high containment laboratories.

Major Activities

- Strengthen the implementation of biosafety program and biosecurity program.
- Strengthen bio-risk management system across the laboratory system.
- Establish negative pressure system verification and certification program.
- Strengthen biosafety cabinets certification program.

Indicators

- Number of laboratories implemented biosafety program.
- Number of laboratories implemented biosecurity program.
- Number of laboratories implemented bio-risk management system.
- Number of negative pressure laboratory facilities certified.
- Number of biosafety cabinets certified.

3.5.3 Improve compliance and practice of laboratory waste management system.

Description

Health laboratories produce different types of waste, and up to 25% of that waste is hazardous and may pose a variety of environmental and health risks. Poor waste management affects waste, waste generators, handlers, the public, and the environment. One of the revealed effects of the mishandling of waste is the alarming incidence of laboratory-associated infections and the transmission of emerging diseases. However, we can prevent or minimize health and safety risks in the laboratories, community, and environment by reducing the amount of waste generated, ensuring proper handling, treating hazardous waste, and disposing of it.

Major Activities

- Strengthen laboratory biohazardous waste management system
- Improve compliance and practice of chemical and other laboratory waste management system.

Indicators

- Number of laboratories implemented biohazardous waste management system.
- Number of laboratories practiced chemical and other waste management system.

3.6 Strategic Objective Four: Strengthen an integrated laboratory data and information management system.

Strategic Result: Implemented integrated laboratory data and information management system.

Description

Robust Laboratory Information System (LIS) is key for the effective management of information and data to improve work processes, traceability, turn-around time, data security, and accountability in health laboratories. Proper collection, storing, analyzing, and transferring of health laboratory data is a vital component of laboratory programs and is a valuable source of information for surveillance, M&E activities, and continuous laboratory quality improvement undertakings. LIS is an essential tool to manage the flow of

information between health care providers, patients, and laboratories and should be designed to optimize not only laboratory operations but also clinical services.

The Ethiopian Public Health Institute, in collaboration with its stakeholders and partners, has been making tremendous efforts to standardize paper-based LIS (test request and result reporting forms and laboratory registers) to ensure uniform capturing of laboratory data across the laboratory system in a way it accommodates all clinical and laboratory requirements. However, data capture using this method is cumbersome, prone to transcriptional errors, and does not lend itself to easy analysis and communication. Despite all these shortcomings, laboratories in Ethiopia, including the national and regional reference laboratories, are using paper-based LIS.

Considering the multitude of data, a laboratory generates daily and recognizing the importance of these for informed decision-making and policy formulations needed for improving clinical services and public health response actions, EPHI has introduced and implemented electronic LIS for data management systems at a minimal number of health facilities. The development of electronic LIS to the level the nation has long aspiring has been hampered by a lack of financial resources to pay costs associated with software, hardware, and equipment interfacing/configuration, especially for installations of Local area network (LAN) and wide area network (WAN) as well as other ICT infrastructures. During the implementation of this strategic plan over the next coming years, EPHI envisions strengthening the standardization of paper-based LIS further to be implemented at primary healthcare unit laboratories and mobilize adequate resources for the expansion of electronic LIS at national and regional reference laboratories as well as secondary and tertiary hospital laboratories across the nation. Major strategic activities will also be implemented to build capacity at all levels to ensure seamless bidirectional data and information flow between laboratories in the national system but particularly across a cascade of laboratories starting from health centres to the national level where a national laboratory data repository and management are anticipated to be strengthened. EPHI, in collaboration with the MOH, will also invest in initiatives to interface LIS to hospital Electronic Medical Records (EMR) and other hospital information managing systems. Development of implementation guidelines and manuals for standardized laboratory data repository, data management, data sharing and use is mandatory. This can be achieved by building infrastructural capacity, designing a system for multi-sectoral laboratory data sharing, and enhancing data use for evidence-based policy intervention.

Strategic directions

3.6.1 Strengthen the implementation of standardized laboratory information system (LIS)

Description

To manage information and data effectively and to enhance work processes, traceability, turnaround times, data security, and accountability in health laboratories, a robust LIS is essential. Proper collection, storage, analysis, and transfer of health laboratory data is useful for surveillance, M&E, and ongoing laboratory quality improvement projects. LIS should be created to optimize not only laboratory operations but also clinical services, since it is a crucial instrument for managing the information flow between healthcare professionals, patients, and laboratories.

Major Activities

- Develop and implement standardized guidelines, manuals, and forms for LIS.
- Develop/adapt and implement eLIS.
- Build human and ICT infrastructure capacities for the implementation of electronic LIS (eLIS)
- Network laboratories to the national laboratory data repository and management center through eLIS
- Develop and implement interoperability protocols to integrate eLIS with health facility information systems, such as EMR, DHIS-2.
- Develop eLIS maintenance system.

Indicators

- Number of Developed implementation guidelines and manuals for LIS
- Proportion of laboratories using standardized paper-based LIS
- Number of laboratories using robust eLIS
- Proportion of laboratories with functional electronic network with the national data management center
- Proportion of laboratories with functional eLIS interface with healthcare facility EMR or DHIS-2

3.6.2 Build national and regional capacities for laboratory data repository, management, sharing and use .

Description

Building the national and regional capacity for laboratory data repository and use is one of the key areas identified to be addressed in this strategic plan. To realize this strategic direction, the development of guidelines and manuals for standardized laboratory data repository, data management, data sharing and use is critical to implement and benefit from the data. A system needs to develop to manage multi-sectoral laboratory data sharing. There should be proper data synthesis to give evidence for informed decision making and intervention.

Major Activities

- Upgrade the infrastructure to standardize laboratory data repository.
- Build human capacity for management, and use of laboratory data repository.
- Develop and implement guidelines and operational manuals for standardized laboratory data repository, management, sharing and use.
- Develop a system for multi-sectoral laboratory data sharing for program improvement.
- Enhance data use for evidence-based policy intervention.

Indicators

- Established capacity for laboratory data repository and management system.
- Developed national guideline for data sharing.
- Developed system for multi-sectoral data sharing.
- Number of policy brief/issue brief generated.

3.7 Strategic Objective Five: Enhance operational research, innovations, and introduction of new laboratory technologies.

Strategic Result: Enhanced operational research, innovations, and introduction of new laboratory technologies

Description

Health laboratories play a vital role in the diagnosis of diseases, treatment monitoring, survey, surveillance, research, and response to outbreaks. These functions have been given due consideration in the previous laboratory strategic plan and the current EPHI's SPM, even though implementation has been limited. Laboratory systems and networks for the diagnosis of disease and treatment monitoring have been strengthened, especially for priority diseases like HIV, TB, and malaria. Although the system is still weak in

laboratory diagnostic services such as microbiology because of insufficient attention given to setting up the services and upgrading the existing technologies, training of human resources, and other necessary factors, it has recently been recognized that serious attention needs to be paid to building the capacity of the laboratory system better to perform diagnosis and confirmation of public health priority diseases.

Laboratory system in Ethiopia, as described above, has focused on providing clinical service and the attention given to building the capacity of laboratories to effectively address increasing demands of research is very weak. The role of a laboratory in research is twofold: On one hand, laboratories through continuous engagement in operational research improve laboratory practices by designing better methodologies and introduction of better diagnostic technologies.

The core elements of laboratory systems for technological advancement include having a biorepository, implementing suitable clinical and laboratory practices, creating laboratory infrastructure, and training human resources. This enables laboratories to participate in cutting-edge research, clinical trials, and thorough program effect evaluations. Significant strategic initiatives will be implemented to achieve this, such as regular engagement with laboratory systems, capacity building for innovation and the introduction of improved diagnostic technologies, capacity building for centres of excellence, and establishing biobanking for repositories.

Strategic directions

3.7.1 Build the capacity of laboratories for innovation and transfer of new technologies.

Description

The capacity of laboratories needs to build to conduct operational research improve laboratory practices by designing better methodologies and introduction of better diagnostic technologies. Laboratory system should be designed and strengthened to be able to develop, evaluate and introduce new technologies. Evaluation guidelines and protocols should be developed to be engaged in evaluation of new technologies, manufacturing of in vitro diagnostics and create collaboration with higher education and institutions to evaluate and validate new technologies.

Major Activities

- Develop validation, evaluation guidelines and protocols for new technologies at national and regional reference centers of excellence laboratories.

- Develop collaboration agreements with major companies for evaluation and validation of new technologies (test kits, equipment)
- Develop human resource capacity for evaluation of technologies (hiring competent staff, training, and mentoring and coaching)
- Promote streamlined registration process for new technologies.
- Strengthen documentation of best practices and dissemination

Indicators

- Developed guidelines for new laboratory technology evaluation and operational research.
- Number of new methods and technologies evaluated and/or validated.

3.7.2 Promote operational research to improve laboratory services.

Description

The use of operational research data helps laboratory system to benefit from technological advancements and keep laboratory processes and practices up to date. On the other hand, laboratory system should be designed and strengthened with the intention to put laboratories at the heart of evaluation and development of new technologies and promotion of laboratory-industry linkage. This requires deliberate attempt of developing capacity of centers of excellence to be engaged in manufacturing of in vitro diagnostics and create collaboration on fast evaluation and validation of technologies. The role of laboratories in collaborating with the manufacturing sector and university establishments is insufficient and many opportunities have been lost. For example, Ethiopia in the last fifteen years has been conducting more than 10 million HIV rapid tests every year on average. However, there has not been any attempt of the national laboratory system to collaborate with leading manufacturers to build capacity for local manufacturing of in vitro HIV diagnostics.

Major Activities

- Strengthen collaborations among health laboratories, higher education, and research institutions on operational research.
- Capacitate laboratories for in-vitro diagnostics research and development.
- Conduct operational research to improve laboratory services.

Indicators

- Number of capacitated for in-vitro diagnostics research and development.
- Number of national and regional reference laboratories capacitated and engaged in advanced research, evaluation of technologies and in vitro diagnostics manufacturing.

3.7.3 Establish biobank/biorepository.

Description

Biobank establishment is to support diagnostic development and health research to improve the population's health, by providing access to biological specimens and data for diagnostic test development, evaluation, and research. The facility facilitates the development and evaluation of diagnostic tests for diseases of epidemic potential, antimicrobial resistance and other global health priorities, and facilitating genomic surveillance and epidemiological research. Biobank enables to have well-characterized specimens collected from different parts of the country.

Major Activities

- Develop and implement guidelines and protocols to manage biobank based on international safety and biosecurity standards.
- Establish infrastructure and provide services (collection, annotation/catalog, storage and redistribution) at selected regional and centers of excellences laboratories for biobank.

Indicators

- Number of biobanks/bio-repository established at centers of excellence laboratories.

3.8 Strategic Objective Six: Leadership, Governance, Partnership, and Sustainable Financing

Strategic Result Six: strong leadership and governance, partnership, and sustainable financing

Description

Providing high quality testing services within the national laboratory networks and meeting the needs of clinical care services, public health emergencies, and laboratory-based health research, fundamentally depends on the demonstrated capacities and qualities of leadership and management. Strengthening the laboratory networks through effective leadership, management, and governance is thought to ensure functional partnership, collaboration, coordination, and long-term funding in the country. The funding for Ethiopia's laboratory system comes from the public treasury and financial grants from international donors or secured through bilateral agreements. It is essential for the country to design and put into action

acceptable plans for the sustainable financing of the laboratory system because donor financing choices have a limited lifespan and funding may drastically fall or be completely removed at any time.

The EPHI regularly met with RHBs, Regional Laboratories, donors, and developing partners using various interface platforms to monitor the effectiveness of the laboratory strategies, system implementation, technical and operational issues, and coordinate activities through mutual understanding. However, the implementations have been impacted by the introduction of new strategies and initiatives without adequate consideration of the structure, leadership, and governance capabilities at all levels. This is explained in terms of limited institutional leadership capacities at all levels, lack of clear accountability, transparency, evidence-based decisions, shared vision and ownership, conducive regulatory environment, suboptimal integration of vertical and horizontal components of the laboratory system, and inadequate stakeholders' engagement. Therefore, it is critical to have a strong capability in leadership, governance, and management system at all levels of the laboratory networks to ensure the attainment of the strategic objectives and exert synergistic influence on the performance of the overall health system in the country.

Strategic directions:

3.8.1 Strengthen Leadership and governance

Description

A well-designed internal policies and procedures for efficient, equitable, and accessible services, conducive regulatory environment, institutionalized implementation mechanisms and platforms, and capable human resource in leadership are critical enablers for desirable outcomes of the laboratory system. Understanding the limited knowledge and capacity of subject matter experts in leadership, management, and governance, EPHI has been providing in-service trainings and refresher courses.

This strategic direction is about ensuring a responsive, accountable, transparent, inclusive, and institutionalized leadership and governance system for the successful implementation of strategies. This addresses proper resource utilization and optimal health laboratory services provision for the best interest of the public.

Major Activities

- Develop and implement guidelines and directives that supports the laboratory network governance and leadership and ensure public trust and satisfaction.
- Mainstream the interests of youth, women, and people with special need into laboratory program implementations.

- Strengthen harmonization and alignment for health laboratory system planning, budgeting, and reporting.

Indicators

- Number of policies/ guidelines/directives developed.
- Customers/stakeholders satisfaction rate.
- Proportion of women and people with special need in the laboratory leadership at all levels.

3.8.2 Enhance Partnerships, Collaboration, and Coordination.

Description

Improving partnership, collaboration, and coordination is critical for the successful implementation of strategic objectives. Strong alliance is crucial with national, regional, and international stakeholders including private organizations who have interest and influence in the country's laboratory system and service delivery. As a coordination platform with RHBs, the EPHI conducts review meetings and supervisions periodically and identifies specific technical and operational issues for improvement.

Different mechanisms that include public-private partnership benefit the health laboratory system through technical and financial approaches. This can be achieved through well-designed stakeholders mapping, segmentation, and active engagements of key stakeholders in priority issues and contribute for in the decision-making processes. The following major activities are prioritized to achieve a strong partnership, collaboration, and coordination.

Major activities

- Establish national and regional level stakeholders (Public, Private, CSOs, Professional associations, and other Non-Governmental Organizations) network forums.
- Develop/strengthen Technical Working Groups at different levels of the laboratory networks.
- Strengthen national and regional joint planning and M&E
- Increase the engagement of private sectors through Public Private Partnership (PPP) arrangements.

Indicators

- Proportion of “active stakeholders” supporting the health laboratory system.
- Proportion of resources mobilized through partnership agreement.

- Number of new partnerships signed per year (this includes partnership with international laboratory services providers).
- Number of projects implemented through PPP arrangement.
- Number of private sector organizations invested in the national diagnostic business opportunities.

3.8.3 Strengthen Sustainable Laboratory Financing System

Description

This strategic direction is about ensuring sufficient resources from domestic and international sources for sustainable financing of the country's health laboratory system and programs. This strategic initiative can be achieved through robust and risk-based resource mobilization efforts, including gap analysis and resource mapping, fostering partnerships, advocating for increased government spending, and fostering international cooperation. Moreover, enhancing the grant management system, including regular and timely fund liquidation, creating effective procurement and supply chain management system, and seamless financial management systems are among the significant areas identified to be improved in this strategic period.

Therefore, this strategic direction aims to ensure sustainable financing through the gradual replacement of resources from external funding by domestic resources and an effective grant management system. Furthermore, it is expected to have an organized resource management action plan that includes timely tracking, monitoring, auditing, and documenting improvements. The process will ensure accountability and transparency in managing and utilizing financial resources.

Major activities

- Develop and implement innovative resource mobilization strategies and effective and efficient resources utilization.
- Strengthen public laboratories revenue generation capacity (cost-recovery mechanism)
- Promote the implementation of community-based health insurance/social health insurance system across the country.

Indicators

- The proportion of resources mobilized per year from different domestic from the total resource required.
- Annual budget utilization rate.
- Proportion of laboratory service fees covered by health insurance.

3.9 Strategic Objective Seven: Workforce Development and Management

Strategic Result: Adequate, Competent, and motivated workforce at each level of the laboratory networks

Description:

A professional, knowledgeable, competent, and multidisciplinary laboratory workforce is essential for strong and efficient health laboratory system at all levels. The workforce must be prepared and responsive in identifying, assessing, and responding to public health threats, as well as cope with regional, national, and global health priorities.

This strategy is aimed to ensure adequate, competent, and motivated laboratory workforce through proper human resources planning, development, and management (training, capacity building, recruitment, deployment, performance management, and motivation).

Strategic directions:

3.9.1 Ensure Human Resource Planning and Retention

Description:

It's crucial to estimate the need for workers properly and frequently, taking into account external factors like economic, social, and technological developments. There is currently a large imbalance between the supply and demand of laboratory workers. As a result, some healthcare facilities have been adversely affected and are unable to reliably offer crucial diagnostic services. Additionally, the situation is made worse by a lack of incentive systems and the quick turnover of a trained personnel, which has an impact on service delivery access at every level of the network.

Therefore, this strategic direction is aimed at improving the technical and managerial human resources adequacy, availability, and retention across the system.

Major activities

- Implement Laboratory Workforce Information Management System/Database Management system.
- Conduct annual laboratory workforce survey and forecasting and share with stakeholders.
- Develop Laboratory work force strategy that allows deployment, retention of highly qualified and competent professionals in the national laboratory system.
- Facilitate long term education for laboratory professionals.

Indicators

- Turnover rate of trained laboratory workforce at each level
- Workforce satisfaction rate

3.9.2 Strengthen Continuous Professional Development and Knowledge Management**Description:**

Knowledge, skills, and experiences can be transferred generation to generation and proper succession in the health laboratory workforce can be realized through well-designed Knowledge Management System and professional development activities. In support of the Continuous Professional Development programs, it is essential to develop and implement knowledge management system across the health laboratory networks.

This strategic direction is about ensuring the availability of knowledgeable and competent health laboratory workforce through continuous professional development activities and knowledge management system. This can be achieved through improving the quality of pre-service and in-service training programs and promoting ethics, professionalism, and competency. Furthermore, this direction addresses the promotion of women in the health laboratory leadership at different levels.

Major Activities:

- Promote the use of CPD in the country.
- Increase the number of CPD accredited laboratory courses.
- Propose courses to pre-service education curriculum to higher education institutions that fosters need based skills.
- Establish “knowledge management system *” at national and regional levels to support CPD.

Indicators:

- Number of proposed courses to pre-service education curriculums
- Number of professionals certified in continuous professional development program.
- Number of laboratory courses accredited for CPD.
- Number of accredited CPD providers that can provide health laboratory courses.

4 Implementation Arrangement and Risks and Mitigations

4.1 Implementation Arrangement

The following factors are considered as enablers for the smooth and full-fledged implementation of this Strategic Plan:

- Government policy, commitment, and support
- Involvement and ownership of FMOH, RHBs, RLs/RPHIs, Health facility management and other stakeholders
- Community engagement and ownership
- Strong collaborations and support from professional associations and partners
- SMART annual planning and implementation over the plan years at levels
- Multi-sectoral one health approach implementation
- Adequate financial and human resource
- Strong Monitoring and Evaluation, data analysis and use for continual program improvement.

4.2 Risks and Mitigations

During the implementation of National Laboratory Strategic plan 3rd edition, the laboratory program may encounter risks that impede achievement of results. The risks are identified through SWOT and stakeholder analysis.

The following table shows the risks identified through SWOT and stakeholder analysis, and the strategies identified to address or mitigate them.

Table 4: Risks and mitigation strategies

S.N	Risk	Mitigation Strategy
1	Absence of Quality enforcement regulatory standard	<ul style="list-style-type: none"> • Prepare regulatory standard for LQMS and endorse by EFDA. • Promote Laboratory quality management implementation
2	Delay international procurement.	<ul style="list-style-type: none"> • Strengthen institutional procurement system through developing and implementing automated supply chain management. • Encourage the EFDA and the Custom Authority to pay proper attention to imported supplies of reagents and consumables. • Collaborate with international NGOs to secure reagents and supplies. • Timely request of reagents and supplies before stockout
2	Weak inter-sectorial collaboration	<ul style="list-style-type: none"> • Work closely with line agencies and other stakeholders to collaborate in addressing challenges in laboratory equipment & supplies required for infectious disease outbreak management. • Development of forum for discussion of stakeholders
3	Weak implementation of biosecurity and biosafety	<ul style="list-style-type: none"> • Establishing and implementing good Biosafety, Biosecurity, and biocontainment practices. • Provide training on biosafety, biosecurity, and biocontainment practices, and implement monitoring of its implementation.
4	Inadequacy of financial Resource, reduction of donor funding.	<ul style="list-style-type: none"> • The Laboratory Program should put more emphasis on domestic financing to close the funding gap that will be needed during the NLSP implementation period. • Strengthen collaboration with the private health sectors.

5 Monitoring and Evaluation Framework

Strong monitoring and evaluation system should be developed and implemented to assure the practical implementation of this Strategic Plan. Targets for all performance measurement indicators detailed in the implementation matrix (Annex I) will be meticulously tracked and schematically evaluated to assess the effectiveness of implementation.

The following activities will be implemented:

- Develop M&E framework and tools.
- Implement biannual supportive supervision and corrective action plans.
- Implement annual joint planning and review platforms with all stakeholders.
- Use National Laboratory Forum for close follow-up and review of progress.
- Engage the community through the public wing meetings.
- Conduct periodic customers' satisfaction surveys.
- Implement requirements for quarterly and annual reporting by all key players.
- Undertake mid-term review and final evaluation of the SP.

5.1 Target

The five years Strategic plan targets are outlined in Table-5, respectively, reflecting targets of activities and the cost needed to implement and fully achieve the planned main and specific activities. A bottom-up costing approach followed by identifying the lowest level appropriate activities to create a range of estimates, covering the scope based on the activity definition available to align their targets.

5.2 Indicators

In this Strategic plan, 69 core indicators are identified to evaluate the progress change and have Impact, Outcome, Output, and Input indicators which selected based on selecting criteria (Annex I). These criteria include relevance, availability of data source, measurability, sensitivity, national and international priority health interventions, and requirements. The period for data collection and analysis varies for each indicator,

ranging from a quarterly up to 5 years. Some indicators are collected and analyzed on a monthly basis while others are collected and analyzed on a quarterly, annually, 2-3-years, and 5-years basis.

5.3 Data sources

The common data sources used to measure and inform NLSP include administrative records, laboratory records, facility-based assessments, research, and others.

5.4 Data quality

Improving the quality of laboratory data for a meaningful decision-making process will be a focus in this NLSP. Interventions will be designed and implemented in order to tackle technical, organizational, and behavioral factors affecting the quality of laboratory data. Improving laboratory data quality requires the effort of every actor in the health sector as well as the comprehensive implementation of techniques for improving data quality. Data quality-assurance techniques will be implemented holistically at each level of the health laboratory tier system. As part of the external verification process and to enhance reliability and credibility, a data quality audit (DQA) will be conducted regularly.

5.5 Reporting

NLSP will regularly be assessed and reported the implementation status using different mechanisms to ensure accountability for quarterly based annual administrative and approved evaluation reports.

5.6 Use of information for action

Improving data demand, information culture, knowledge management, learning, and the capacity to change data into meaningful information and use it for action will be a priority.

5.7 Performance review

A consistent and participatory performance review will be undertaken annually at different levels. In the performance review session, all relevant stakeholders will be invited to review the national laboratory program implementation performance.

5.8 Evaluation

Evaluation of the NLSP will be undertaken at mid-term and end-term to assess the status of attainment of set objectives and targets. The mid-term evaluation will assess progress towards achievement of results and generate lessons learned, while the end-term will inform the development of the subsequent strategic plan.

5.9 Dissemination and communication

Monitoring and evaluation findings will be disseminated to stakeholders using different platforms. Quarterly and annual reports will be produced and submitted to the relevant stakeholders.

CHAPTER SIX

6 Implementation activity target and cost

The total cost estimation is \$201,522,532.45 USD for the next five years. As indicated in the table below (table 6). The estimate is divided as follows across the seven strategic objectives \$85,908,197.40 USD for Provide comprehensive and standardized health laboratory testing services, \$44,800,000.00 USD Strengthen implementation of laboratory quality management system, \$23,622,939.51USD for Improve biosafety, biosecurity, and hazardous waste management system \$26,819,692.30 USD for Establish an integrated laboratory data and information management system, \$14,956,703.24 USD for Enhance operational research, innovations, and introduction of new laboratory technologies, \$2,010,000.00 USD for Strengthen Leadership, Governance, Partnership, and Sustainable Financing, \$3,405,000.00 USD Enhance Workforce development and Management System. After the endorsement of this NLSP, a separate document will be prepared to map the budget source and utilization strategies.

Table 5: Activity target

No	Strategic Directions	Major Activities	Specific Activity	Unit	Baseline	Total target	Target					
							2023	2024	2025	2026	2027	
1	Enhance laboratory testing services	Standardize and implement laboratory testing menu at all tier levels	Conduct baseline assessment (desk review, laboratory assessment)	Number		1						
			Preparation of EDL	Number		1						
			Launch workshop and endorse the EDL	Number		1						
			Develop implementation strategy	Number		1						
		Ensure laboratory services accessibility at all levels	Implement essential diagnostic list at all tier levels	Percent			100		50	75	85	100
			Conduct monitoring and evaluation for the implementation of EDL	Number			4		1	1	1	1
			Update the EDL based on country demand and international guidance	Number			1			1		
			Improve Sample transportation coverage	Percent		75	100		80	95	100	100
			Ensure all inaccessible laboratories are networked	Percent		75	100		85	90	95	100
		Ensure laboratory services expansion to address emerging and reemerging priority diseases	Conduct monitoring and evaluation of sample transportation and referral networking system	Number		1	5		1	1	1	1
			Building capacity of laboratories to diagnosis emerging and reemerging priority diseases	Number		5	13		2	3	4	4
			Introduce Multiplex testing technology in different laboratories	Number			3		1		1	1
			Develop standardized procurement and supply management guideline	Number			1		1			
Sustain laboratory supply chain management system	Involve in the laboratory commodities quantification and supply chain management	Number			5		1	1	1	1		
	Strengthening inventory management system (provide	Percent		60	100		85	95	100	100		

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target			
			Laboratory Commodity management, IPLS trainings)							
		Promote quality of laboratory commodities through pre- and post-market surveillance	Participate in post market surveillance of laboratory commodities	Number		5	1	1	1	1
			Disseminate post market surveillance results	Number		5	1	1	1	1
		Strengthen implementation of national health laboratory infrastructure standards	Promote health laboratories have implanted national infrastructure standard	Percent		75	40	55	60	75
			Support the implementation of National Laboratory infrastructure standard	Round		5	1	1	1	1
		Upgrade laboratory infrastructure through renovation and instrumentation, including equipping new laboratories.	Upgrade laboratory infrastructure	Number		28	6	5	5	7
			Renovate existing Regional reference laboratory infrastructure	Number		5			3	2
		Standardized and harmonized laboratory equipment platforms	Develop a guideline for Standardization and harmonization of laboratory equipment	Number		1	1			
			Implement the Standardization and harmonization of laboratory equipment guideline at all levels	Percent		100	75	85	100	100
		Implement an effective system for equipment maintenance and calibration services	Develop Laboratory equipment management guidelines and manuals	Number		1		1		
2	Equipment standardization and technologies		Improve regional Equipment maintenance and calibration centers	Number		15	8	10	12	15
			Avail Equipment maintenance contract agreement for major equipment type	Number		4		2		2
		Develop and	Establish equipment disposal system	Number		1		1		

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target											
3	Diagnostic Network Optimization (DNO)	implement laboratory equipment management system	guideline															
			Collect data for non-functional equipment	Number		5		1	1	1	1	1	1	1	1	1		
			Facilitate the establishment of equipment disposal center	Number		1											1	
			Conduct baseline assessment on the availability of laboratory equipment, type of test and human power	Number		1						1						
			Develop laboratory mapping with diagnostic network optimization	Number		1						1						
			Conduct assessment of the existing referral network.	Number		5			1	1	1	1	1	1	1	1	1	
			Establish functional network and communication systems among national reference laboratories, regional laboratories, private facilities, and animal health diagnostic and surveillance centers		Implement Diagnostic Network Optimization (DNO)	Percent		100					50			75	85	100
			Update and optimize vertical and horizontal networks of laboratories for specimen referrals and result communications		Review the functionality of referral network and result communication within pre-defined TAT	Percent		85					50			75	80	85
			Ensure sustainable, safe and quality specimen transport system		update the functionality of specimen referral network and communication for each facility based on the findings	Number		4					1			1	1	1
					Assess alternative specimen courier system in the country	Number		5					1			1	1	1
			Establish a sustainable specimen courier system for hard to reach areas	Percent		100					75			85	95	100		

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target					
4	Enhance implementation of quality initiatives and promote accreditation program	Strengthen and implement laboratory quality management system (LQMS) at all levels	Monitor and evaluate the performance for the established specimen courier systems	Number		5	1	1	1	1		
			Provide training on LQMS for all health facilities	Percent	75	85	78	80	82	83	85	
			Provide support on the implementation of LQMS for all health facilities	Percent		100	100	100	100	100	100	100
			Conduct final assessment to evaluate the implementation status of LQMS for all health facilities	Percent		100	100	100	100	100	100	100
			Support Hospital laboratories to implement SLMTA and achieve 4- & 5-star levels in SLIPTA	Number	10	50	10	20	30	40	50	
		Implement strengthening laboratory quality management towards accreditation (SLMTA)	Support Hospital laboratories to implement SLMTA and achieve 3- star levels in SLIPTA	Number	50	155	30	60	90	120	155	
			Support Hospital laboratories to implement SLMTA and achieve 2- star levels in SLIPTA	Number	65	185	35	70	105	145	185	
			Support laboratories to implement SLMTA and achieve 1- star levels in SLIPTA	Number	70	130	25	50	75	100	130	
		Promote accreditation to stakeholders	Awareness creation workshop for stakeholders	Number		5	1	1	1	1	1	
			Prepare annual accreditation recognition forum	Number		5	1	1	1	1	1	
Prepare and laboratories to accreditation scheme	Mentor and technically support health laboratories for limited scope accreditation to pertinent ISO standards	Number	44	100	44	65	75	85	100			
	Mentor and technically support health laboratories for full scope accreditation to pertinent ISO standards	Number	4	12	6	7	8	10	12			

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target					
5	Ensure standardized and sustainable External Quality Assessment (EQA) program	Support laboratories for maintenance of accreditation and scope extension	Mentor and technically support laboratories to maintain their accreditation status	Percent		100	100	100	100	100		
			Mentor and technically support laboratories to expand their scope of accreditation at least by one test	Number	30	100	10	15	20	25	30	
		Improve Proficiency Testing (PT) infrastructural, production, distribution, result collection and feedback provision capacity in line with ISO 17043 requirements	Establish PT production center	Number		1				1		
			Develop PT production protocol, manual, per ISO 17043 standards	Number		1		1				
			Prepare Panels as per ISO 17043 standards for selected tests	Number		3				1	2	3
			Develop national ePT (EQA Software) program establishment	Number		1			1			
			Develop ePT user's manual, per ISO 13528 standards	Number		1			1			
			Follow up the proper implementation of ePT (EQA Software) program	Percent		100			100	100	100	100
			Coordinate the enrollment, distribution, result submission, and proper utilization of PT panels (IEQAS, NEQAS, REQAS)	Percent		40	100		90	95	98	100
			Provide support for strengthening the utilization and implementation of regional EQA schemes	Percent					70	75	85	100
Strengthen national and regional capacity for sustainable coordination of EQA activities	Provide support for the strengthening of random blind rechecking, retesting, and onsite evaluation EQA schemes for regions	Percent		100		70	75	85	95	100		
	Capacity building training on Random Blinded Rechecking and onsite evaluation activities for all health facilities	Percent										
Strengthen the system for Random Blinded Rechecking and Onsite evaluation activities	Capacity building training on Random Blinded Rechecking and onsite evaluation activities for all health facilities	Percent		100		65	75	85	95	100		
	Implement integrated EQA for TB and Malaria	Percent		85		55	60	75	80	85		
		Conduct regional onsite evaluation	Percent			60	75	85	90	95		

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target			
			Establish malaria Slind bank	Number	1	5	1	2	3	5
		Introduce and implement Inter-laboratory comparison program	Develop protocol for Inter-laboratory comparison for rare disease	Number		1	1			
			Implement Inter-laboratory comparison for rare disease	Number		4	1	1	1	1
			Prepare guideline for the establishment of regulatory body for enforcement of Biosafety and biosecurity proclamation	Number		1	1			
		Establish regulatory and legal frameworks for handling of hazardous pathogens and toxins	Develop Biosafety and biosecurity directives and procedures for the implementation of biosafety and biosecurity proclamation	Number		1	1			
			Provide services for certification of Labs for using and housing Ethiopia's selected hazardous pathogens and toxins (ESHPT)	Number		1	1			
6	Establish and implement regulatory and legal frameworks for handling of hazardous pathogens and toxins	Implement regulatory and legal frameworks for laboratories that possess, use, and transfer of hazardous pathogens and toxins	Conduct workshop on the Biosafety and biosecurity proclamation implementation	Number		340		100	200	340
			Provide training for safety officers on the implementation of Biosafety and biosecurity proclamation	Number		250		100	150	250
			Support laboratories and research centers to get a license for using and housing Ethiopia's selected hazardous pathogens and toxins (ESHPT)	Number		25		5	15	25
			Implement regulatory and legal frameworks on selected laboratory	Percent		15		5	10	15
			Establish Laboratory assessment team for hazardous pathogens and toxins (ESHPT)	Number		3		1	1	1

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target					
7	Improve the implementation of national biosafety and biosecurity programs	pathogens and toxins	Provide capacity building on Biosafety and Biosecurity infrastructure for Public Health Institutes /Regional, sub regional/center of excellence laboratories and hospitals	Number		55	5	10	15	20	25	
				Percent		100	55	60	75	85	100	
		Establish negative pressure system verification and certification program	Develop Negative pressure system verification capacity at National Level	Number		150	30	30	30	30		
				Number		1		1				
				Percent		100		100		100		100
				Number		3			1	2	3	
				Percent		100		100		100		100
Strengthen bio-risk management system across the laboratory system	Provide training on bio risk management	Number		150	30	30	30	30	30	30		
		Percent		100		60	75	85	100			
		Number		1		1						
Improve compliance and practice of laboratory waste management system	Develop biohazardous waste management manual	Number		740	100	120	150	170	200			
		Percent		100		60	70	85	100			
		Number		100		60	70	85	100			

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target							
8	Strengthen the implementation of standardized laboratory information system (LIS)	Improve compliance and practice of chemical and other laboratory waste management system	Provide technical support health facilities for the development of laboratory chemical hygiene plan	Percent		100	50	60	70	85	100			
		Develop and implement standardized guidelines, manuals and forms for LIS	Provide training on chemical and hazardous material handling and disposal	Number		650		160	160	150	180			
		Develop and implement standardized guidelines, manuals and forms for LIS	Develop guidelines and implementation manuals for standardized LIS	Number		1		1						
		Standardize and implement forms for laboratory data management system	Standardize forms for laboratory data management system	Number		1		1						
		Build human and ICT infrastructure capacities for the implementation of electronic LIS (eLIS)	Implement standardized forms for laboratory data management system	Percent		100				60	75	100		
		Network laboratories with eLIS to the national laboratory data repository and management center	Provide training on ICT capacity for the implementation of eLIS	Provide training on ICT capacity for the implementation of eLIS	Number		650		75	85	160	150	180	
			Develop one comprehensive diagnostic connectivity tool to network eLIS implementing laboratories with national data repository and management system	Support the implementation of ICT infrastructure for eLIS at Regional reference laboratories and Hospital laboratories	Number	25	100		25	25	25	25	25	25
				Network eLIS implementing Regional reference laboratories and Hospital laboratories with national data repository and management system for data transfer	Number		1					1		
			Develop and implement	Develop interoperability protocol to integrate lab eLIS with health	Number		1				1			

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target				
9	Build national and regional capacities for laboratory data repository, management and use	interoperability protocols to integrate laboratory eLIS with health facility EMR and HMIS	facility EMR and HMIS								
		Develop a system for eLIS maintenance	Integrate lab eLIS with health facility EMR and HMIS based on the interoperability protocol	Percent		100	30	50	75	100	
			Develop manual for eLIS maintenance	Number		1					
		Upgrade the infrastructure for standardized laboratory data repository, management and use	Develop a system for eLIS maintenance team at Regional level	Number		13	2	3	3	5	
			Build infrastructural capacity for standardized laboratory data repository, management and use	Number		1		1			
		Build human capacity for management, and use of laboratory data repository	Provide training on management, and use of laboratory data repository	Number		150	30	30	30	30	
			Develop and implement guidelines and operational manuals for standardized laboratory data repository, management, sharing and use	Number		1			1		
		Develop a system for multi-sectoral	Implement standardize laboratory data repository, management, sharing and use based on the developed guidelines and operational manuals	Percent		100			50	75	100
			Develop a system for multi-sectoral	Number		1			1		

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target	Target			
10	Build the capacity of laboratories for innovation and transfer of new technologies	laboratory data sharing for program improvement	sharing for program improvement								
		Enhance data use for evidence-based policy intervention	Implement multi-sectorial laboratory data sharing based on the guideline	Percent		100		60	75	100	
			Analyze laboratory data collected from different health facilities and generate report	Number		4		1	1	1	
		Develop validation, evaluation guidelines and protocols for new technologies at national and regional reference laboratories	Share the output of data for leadership for evidence-based policy intervention	Number		4		1	1	1	
			Develop validation, evaluation guidelines and protocols for new laboratory diagnostics technologies at national and regional reference laboratories	Number		3		1	1	1	
		Develop collaboration agreements with major companies for evaluation and validation of new laboratory diagnostics technologies (test kits, equipment)	Develop collaboration agreements with major companies for evaluation and validation of new laboratory diagnostics technologies (test kits, equipment)	Number		3		1	1	1	
			Collaborate with major companies for evaluation and validation of new laboratory diagnostics technologies based on the agreement	Number		3		1	1	1	
		Develop human resource capacity for evaluation of technologies (hiring more competent staff, training and mentoring and coaching)	Provide training for professionals to evaluate new laboratory diagnostics technologies	Number		240		20	40	60	80
			Perform the evaluation of new laboratory diagnostics technologies	Number		3			1	1	1

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target						
11	Promote operational research to improve laboratory services	Promote streamlined registration process for new technologies	Work closely with regulatory agency to streamline registration process for new technologies	Number		3			1	1	1		
		Strengthen documentation of best practices including publication in peer reviewed journals	Document best practices in evaluation of new technologies including publication in peer reviewed journals	Number		3			1	1	1		
		Strengthen collaborations with higher education and research institutions on operational research	Collaborate with higher education and research institutions on operational research	Number		6			1	1	2	2	
12	Establish bio-banking for bio-repository	Capacitate laboratories for in-vitro diagnostics research and development	Provide training for lab professionals in in-vitro diagnostics research and development	Number		150			30	30	30		
		Develop and implement guidelines and protocols to manage bio-bank/bio-repositories based on international safety and biosecurity standards	Mobilize resources to conduct operational researches	Number		6			1	1	2	2	
		Develop and implement guidelines and protocols to manage bio-bank/bio-repositories based on international safety and biosecurity standards	Develop guidelines and protocols to manage bio-bank/bio-repositories based on international safety and biosecurity standards	Number		1			1				
		Implement bio-bank /bio-repositories for selected organisms based on the guidelines and protocols at selected health laboratories	Implement bio-bank /bio-repositories for selected organisms based on the guidelines and protocols at selected health laboratories	Number		21			1	3	5	5	7
		Establish infrastructure and provide services	Develop infrastructure at selected centers of excellences for bio-repository	Number		5			1	1	1	1	1

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target								
13	Strengthen Leadership and governance	(collection, annotation/catalog, storage and redistribution) at selected regional and centers of excellences laboratories for bio-bank/biorepository	Provide bio-banking/bio-repository services (collection, annotation/catalog, storage and redistribution)	Number		5	1	1	1	1	1	1	1		
		Develop and implement guidelines and directives that supports the laboratory network governance and leadership, and ensure public trust and satisfaction	Develop guideline and directive the laboratory network governance and leadership	Number		1				1					
		Mainstream the interests of youth, women, and people with special need into laboratory program implementations	Establish laboratory professional ethics council that ensures transparency, accountability, and professional ethics	Number		1						1			
		Strengthen harmonization and alignment for health laboratory system planning, budgeting, and reporting	Ensure the implantation of mainstream the interests of youth, women, and people with special need into laboratory program implementations	Percent		100						100	100	100	100
			Promote joint planning and reporting mechanism with all laboratory stakeholders	Percent		100					80	85	95	100	

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target					
14	Enhance Partnerships, collaboration, and coordination	Establish national and regional level stakeholders (Public, Private, CSOs, Professional associations, and other Non-Governmental Organizations) network forums	Develop and implement stakeholders' engagement and management guideline	Number		1			1			
			Strengthen collaboration and networking with national and international stakeholders	Percent		100	80	85	95	100	100	
		Develop/strengthen Technical Working Groups at different levels of the laboratory networks	Strengthen of Technical working group management guideline	Percent		100	80	85		95	100	
			Monitor performance of Established TWG	Percent		100	100	100		100	100	
		Strengthen national and regional joint planning and M&E	Organize joint planning workshops	Number		4		1		1	1	
			Conduct assessment on partnership, collaboration and coordination	Number		4		1	1	1	1	
		Increase the engagement of private sectors through PPP arrangements	Strengthen public-private partnerships and community engagement	Strengthen public-private partnerships and community engagement	Percent		80	45	60	70	75	80
				Develop resource mobilization and utilization guideline	Number		1		1			
				Implement resource mobilization and utilization guideline	Number		1			1		
		15	Strengthen Sustainable Laboratory Financing System	Strengthen public laboratories	Improve domestic financing system to sustain laboratory capacity	Percent		85	60	70	75	80

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target							
16	Ensure Human Resource Planning and Retention	revenue generation capacity (cost-recovery mechanism)	Generate internal revenue through providing laboratory services	Percent		100	100	100	100	100	100	100	100	
		Implement Laboratory Workforce Information Management System/Database Management system	Develop workforce information management database	Number		1				1				
		Conduct annual laboratory workforce survey and forecasting and share with stakeholders	Conduct annual survey to collect laboratory workforce data	Number		2		1						1
		Develop Laboratory work force strategy that allows deployment, retention of highly qualified and competent professionals in the national laboratory system	Provide training for health laboratory workforce on pertinent skills including high containment laboratory operation and leadership	Number		500		150	150	150	150	150	150	100
		Facilitate long term education for laboratory professionals	Establish a system for long term training program for lab professionals	Number		200		40	40	40	40	40	40	40
			Promote conducive working environment and improve benefit packages for laboratory workforce	Percent		100		85	85	95	95	100	100	100
		Strengthen Continuous Professional Development and Knowledge Management	Collaborate with universities for long term education for laboratory professionals	Number		200		40	40	40	40	40	40	40
			Promote the use of CPD in the country	Number		13		1	2	3	3	4	4	4
			Increase the number of health laboratory accredited courses	Number		20		5	5	5	5	3	3	1

No	Strategic	Major Activities	Specific Activity	Unit	Baseline	Total	Target					
			Provide trainings based on Continuous Professional Development (CPD) requirements	Number		2500	500	500	500	500	500	
		Propose courses to pre-service education curriculum to higher education institutions that fosters need based skills	Identify and propose curriculum development of pre-service education to higher education institutions that fosters need based skills	Number		2				1	1	
			Develop and implement health laboratory professionals farming (internship) program through university-Industry linkage	Number		1				1		

Table 6: Implementation Cost

No	Strategic Objectives	Strategic Directions	Major Activities	Total cost in USD	Cost per year in USD				
					2023	2024	2025	2026	2027
1	Provide comprehensive and standardized health laboratory testing services	Enhance laboratory testing services	Standardize and implement laboratory testing menu at all tier levels	\$60,000.00	\$12,000.00	\$12,000.00	\$12,000.00	\$12,000.00	\$12,000.00
			Ensure laboratory services accessibility at all levels	\$1,000,000.00	\$200,000.00	\$200,000.00	\$200,000.00	\$200,000.00	\$200,000.00
			Ensure laboratory services expansion to address emerging and reemerging priority diseases	\$3,000,000.00	\$600,000.00	\$600,000.00	\$600,000.00	\$600,000.00	\$600,000.00
			Sustain laboratory supply chain management system	\$500,000	\$100,000.00	\$100,000.00	\$100,000.00	\$100,000.00	\$100,000.00
			Promote quality of laboratory commodities through pre- and post-market surveillance	\$400,000	\$80,000.00	\$80,000.00	\$80,000.00	\$80,000.00	\$80,000.00
			Strengthen implementation of national health laboratory infrastructure standards	\$9,047,252.65	\$1,809,450.53	\$1,809,450.53	\$1,809,450.53	\$1,809,450.53	\$1,809,450.53
			Upgrade laboratory infrastructure through renovation and instrumentation, including equipping new laboratories.	\$49,721,000.00	\$16,573,666.67	\$16,573,666.67	\$16,573,666.67	\$16,573,666.67	\$16,573,666.67
			Standardized and harmonized laboratory equipment platforms	\$1,969,843.75	\$393,968.75	\$393,968.75	\$393,968.75	\$393,968.75	\$393,968.75
			Implement an effective system for equipment maintenance and calibration services	\$1,150,000.00	\$230,000.00	\$230,000.00	\$230,000.00	\$230,000.00	\$230,000.00

No	Strategic	Strategic	Major Activities	Total cost in	Cost per year in USD				
2	Strengthen implementation of laboratory quality management system	Strengthen Diagnostic Network Optimization (DNO)	Develop and implement laboratory equipment management system	\$700,000	\$140,000.00	\$140,000.00	\$140,000.00	\$140,000.00	\$140,000.00
			Laboratory mapping throughout the national network	\$2,000,000	\$400,000.00	\$400,000.00	\$400,000.00	\$400,000.00	
			Establish functional network and communication systems among national reference laboratories, regional laboratories, private facilities, and animal health diagnostic and surveillance centers	\$5,260,101.00	\$1,052,020.20	\$1,052,020.20	\$1,052,020.20	\$1,052,020.20	\$1,052,020.20
			Update and optimize vertical and horizontal networks of laboratories for specimen referrals and result communications	\$1,100,000.00	\$220,000.00	\$220,000.00	\$220,000.00	\$220,000.00	
			Ensure sustainable specimen courier system, safety, and quality of specimen transport	\$10,000,000.00	\$2,000,000.00	\$2,000,000.00	\$2,000,000.00	\$2,000,000.00	
			Strengthen and implement laboratory quality management system (LQMS) at all levels	\$3,000,000.00	\$600,000.00	\$600,000.00	\$600,000.00	\$600,000.00	
			Implement strengthening laboratory quality management towards accreditation (SLMTA)	\$3,000,000.00	\$600,000.00	\$600,000.00	\$600,000.00	\$600,000.00	
			Promote accreditation to stakeholders	\$600,000.00	\$120,000.00	\$120,000.00	\$120,000.00	\$120,000.00	
			Prepare laboratories to accreditation scheme	\$700,000.00	\$140,000.00	\$140,000.00	\$140,000.00	\$140,000.00	
			Support laboratories for maintenance of accreditation and scope extension	\$1,500,000.00	\$300,000.00	\$300,000.00	\$300,000.00	\$300,000.00	

No	Strategic	Strategic	Major Activities	Total cost in	Cost per year in USD						
		Ensure standardized and sustainable External Quality Assessment (EQA) program	<p>Improve Proficiency Testing (PT) infrastructural, production, distribution, result collection and feedback provision capacity in line with ISO 17043 requirements</p> <p>Strengthen national and regional capacity for sustainable coordination of EQA activities</p> <p>Strengthen the system for Random Blinded Rechecking and Onsite evaluation activities</p> <p>Introduce and implement Inter-laboratory comparison program</p>	\$16,000,000.00	\$5,333,333.33	\$5,333,333.33	\$5,333,333.33	\$5,333,333.33	\$2,000,000.00	\$1,800,000.00	\$200,000.00
		Improve biosafety, biosecurity, and hazardous waste management system	<p>Establish and implement regulatory and legal frameworks for handling of hazardous pathogens and toxins</p> <p>Implement regulatory and legal frameworks for laboratories that possess, use, and transfer of hazardous pathogens and toxins</p> <p>Enforce regulatory and legal frameworks on laboratories that possess, use, and transfer hazardous pathogens and toxins</p>	\$1,843,505.49	\$368,701.10	\$368,701.10	\$368,701.10	\$368,701.10	\$260,000.00	\$260,000.00	\$260,000.00
3			<p>Strengthen the implementation of biosafety and biosecurity program</p>	\$250,000.00	\$50,000.00	\$50,000.00	\$50,000.00	\$50,000.00	\$50,000.00	\$50,000.00	\$50,000.00
			Improve the implementation of national biosafety and	Strengthen the implementation of biosafety and biosecurity program	\$2,800,000.00	\$560,000.00	\$560,000.00	\$560,000.00	\$560,000.00	\$560,000.00	\$560,000.00

No	Strategic	Strategic	Major Activities	Total cost in	Cost per year in USD					
4	Establish an integrated laboratory data and information management system	biosecurity programs	Strengthen bio-risk management system across the laboratory system	\$600,000.00	\$120,000.00	\$120,000.00	\$120,000.00	\$120,000.00	\$120,000.00	\$120,000.00
			Establish negative pressure system verification and certification program	\$5,765,258.22	\$1,153,051.64	\$1,153,051.64	\$1,153,051.64	\$1,153,051.64	\$1,153,051.64	\$1,153,051.64
			Strengthen biosafety cabinets certification program	\$1,325,000.00	\$265,000.00	\$265,000.00	\$265,000.00	\$265,000.00	\$265,000.00	\$265,000.00
			Strengthen laboratory biohazardous waste management system	\$5,843,505.50	\$1,168,701.10	\$1,168,701.10	\$1,168,701.10	\$1,168,701.10	\$1,168,701.10	\$1,168,701.10
			Improve compliance and practice of chemical and other laboratory waste management system	\$3,895,670.30	\$779,134.06	\$779,134.06	\$779,134.06	\$779,134.06	\$779,134.06	\$779,134.06
		Strengthen the implementation of standardized laboratory information system (LIS)	Develop and implement standardized guidelines, manuals, and forms for LIS	\$1,311,146.98	\$262,229.40	\$262,229.40	\$262,229.40	\$262,229.40	\$262,229.40	\$262,229.40
			Standardize and implement forms for laboratory data management system	\$6,622,293.96	\$1,324,458.79	\$1,324,458.79	\$1,324,458.79	\$1,324,458.79	\$1,324,458.79	\$1,324,458.79
			Build human and ICT capacity for the implementation of eLIS	\$5,244,587.91	\$1,048,917.58	\$1,048,917.58	\$1,048,917.58	\$1,048,917.58	\$1,048,917.58	\$1,048,917.58
			Network laboratories with eLIS to the national laboratory data repository and management center	\$3,111,469.76	\$622,293.95	\$622,293.95	\$622,293.95	\$622,293.95	\$622,293.95	\$622,293.95
			Develop and implement interoperability protocols to integrate laboratory eLIS with health facility EMR and HMIS	\$2,622,293.96	\$524,458.79	\$524,458.79	\$524,458.79	\$524,458.79	\$524,458.79	\$524,458.79
			Develop a system for eLIS maintenance	\$1,311,146.98	\$262,229.40	\$262,229.40	\$262,229.40	\$262,229.40	\$262,229.40	

No	Strategic	Strategic	Major Activities	Total cost in	Cost per year in USD				
5	Enhance operational research, innovations, and introduction of new laboratory technologies	Build the capacity of laboratories for innovation and transfer of new technologies	Upgrade the infrastructure for standardized laboratory data repository	\$2,250,000.00	\$450,000.00	\$450,000.00	\$450,000.00	\$450,000.00	\$450,000.00
			Build human capacity for management, and use of laboratory data repository	\$1,800,000.00	\$360,000.00	\$360,000.00	\$360,000.00	\$360,000.00	
			Develop and implement guidelines and operational manuals for standardized laboratory data repository, management, sharing and use	\$600,000.00	\$120,000.00	\$120,000.00	\$120,000.00	\$120,000.00	
			Develop a system for multi-sectoral laboratory data sharing for program improvement	\$1,146,752.75	\$229,350.55	\$229,350.55	\$229,350.55	\$229,350.55	
			Enhance data use for evidence-based policy intervention	\$800,000.00	\$160,000.00	\$160,000.00	\$160,000.00	\$160,000.00	
			Develop validation, evaluation guidelines and protocols for new technologies at national and regional reference laboratories	\$786,688.20	\$157,337.64	\$157,337.64	\$157,337.64	\$157,337.64	
			Develop collaboration agreements with major companies for evaluation and validation of new technologies (test kits, equipment)	\$1,573,376.36	\$314,675.27	\$314,675.27	\$314,675.27	\$314,675.27	
			Develop human resource capacity for evaluation of technologies (hiring more competent staff, training and mentoring and coaching)	\$1,573,376.36	\$314,675.27	\$314,675.27	\$314,675.27	\$314,675.27	
			Promote streamlined registration process for new technologies	\$2,360,064.56	\$472,012.91	\$472,012.91	\$472,012.91	\$472,012.91	

No	Strategic	Strategic	Major Activities	Total cost in	Cost per year in USD				
			Strengthen documentation of best practices including publication in peer reviewed journals	\$1,146,752.75	\$229,350.55	\$229,350.55	\$229,350.55	\$229,350.55	\$229,350.55
		Promote operational research to improve laboratory services	Strengthen collaborations with higher education and research institutions on operational research	\$2,146,752.75	\$429,350.55	\$429,350.55	\$429,350.55	\$429,350.55	\$429,350.55
			Capacitate laboratories for in-vitro diagnostics research and development	\$1,146,752.75	\$229,350.55	\$229,350.55	\$229,350.55	\$229,350.55	\$229,350.55
		Establish bio-banking for bio-repository	Develop and implement guidelines and protocols to manage bio-bank/bio-repositories based on international safety and biosecurity standards	\$1,933,440.93	\$386,688.19	\$386,688.19	\$386,688.19	\$386,688.19	\$386,688.19
			Establish infrastructure and provide services (collection, annotation/catalog, storage, and redistribution) at selected regional and centers of excellences laboratories for biobank/biorepository	\$2,289,498.58	\$457,899.72	\$457,899.72	\$457,899.72	\$457,899.72	\$457,899.72
		Strengthen Leadership, Governance, Partnership, and Sustainable Financing	Develop and implement guidelines and directives that supports the laboratory network governance and leadership, and ensure public trust and satisfaction	\$350,000.00	\$70,000.00	\$70,000.00	\$70,000.00	\$70,000.00	\$70,000.00
6			Mainstream the interests of youth, women, and people with special need into laboratory program implementations	\$260,000.00	\$52,000.00	\$52,000.00	\$52,000.00	\$52,000.00	\$52,000.00

No	Strategic	Strategic	Major Activities	Total cost in	Cost per year in USD					
			Strengthen harmonization and alignment for health laboratory system planning, budgeting, and reporting	\$250,000.00	\$50,000.00	\$50,000.00	\$50,000.00	\$50,000.00	\$50,000.00	\$50,000.00
		Enhance Partnerships, collaboration, and coordination	Establish national and regional level stakeholders (Public, Private, CSOs, Professional associations, and other Non-Governmental Organizations) network forums	\$125,000.00	\$25,000.00	\$25,000.00	\$25,000.00	\$25,000.00	\$25,000.00	\$25,000.00
			Develop/strengthen Technical Working Groups at different levels of the laboratory networks	\$225,000.00	\$45,000.00	\$45,000.00	\$45,000.00	\$45,000.00	\$45,000.00	\$45,000.00
		Sustainable Laboratory financing System	Strengthen national and regional joint planning and M&E	\$175,000.00	\$35,000.00	\$35,000.00	\$35,000.00	\$35,000.00	\$35,000.00	\$35,000.00
			Increase the engagement of private sectors through ppp arrangements	\$150,000.00	\$30,000.00	\$30,000.00	\$30,000.00	\$30,000.00	\$30,000.00	\$30,000.00
		Strengthen Human Resource Planning and Retention	Develop and implement innovative resource mobilization strategy and effective and efficient resources utilization	\$325,000.00	\$65,000.00	\$65,000.00	\$65,000.00	\$65,000.00	\$65,000.00	\$65,000.00
			Strengthen public laboratories revenue generation capacity (cost-recovery mechanism)	\$150,000.00	\$30,000.00	\$30,000.00	\$30,000.00	\$30,000.00	\$30,000.00	\$30,000.00
7	Enhance Workforce development and Management		Implement Laboratory Workforce Information Management System/Database Management system	\$1,425,000.00	\$285,000.00	\$285,000.00	\$285,000.00	\$285,000.00	\$285,000.00	\$285,000.00

No	Strategic System	Strategic	Major Activities	Total cost in	Cost per year in USD				
			Conduct annual laboratory workforce survey and forecasting and share with stakeholders	\$875,000.00	\$175,000.00	\$175,000.00	\$175,000.00	\$175,000.00	\$175,000.00
			Develop Laboratory work force strategy that allows deployment, retention of highly qualified and competent professionals in the national laboratory system	\$175,000.00	\$35,000.00	\$35,000.00	\$35,000.00	\$35,000.00	\$35,000.00
			Facilitate long term education for laboratory professionals	\$280,000.00	\$56,000.00	\$56,000.00	\$56,000.00	\$56,000.00	\$56,000.00
		Strengthen Continuous Professional Development and Knowledge Management	Promote the use of CPD in the country	\$375,000.00	\$75,000.00	\$75,000.00	\$75,000.00	\$75,000.00	\$75,000.00
			Propose courses to pre-service education curriculum to higher education institutions that fosters need based skills	\$275,000.00	\$55,000.00	\$55,000.00	\$55,000.00	\$55,000.00	\$55,000.00

ANNEXES

Annex I. Strategic plan Implementation Matrix

S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
1	SO1: Provision of comprehensive and standardized health laboratory testing services	Enhance laboratory testing services	<p>Proportion of laboratories implementing standardized test menu</p> <p>Number of laboratories that can detect emerging and reemerging priority infectious diseases</p> <p>Proportion of diagnostic laboratories with <5% of working hour stock outs</p> <p>Proportion of tests for which pre- and post-market surveillance conducted</p> <p>Proportion of laboratories meets the national infrastructure standard</p>	<p>Process</p> <p>Input</p> <p>Input</p> <p>Process</p> <p>Input</p>	<p>%</p> <p>Number</p> <p>%</p> <p>Number</p> <p>%</p>	<p>(Number of laboratories implementing standardized test menu/total number of function laboratories) *100%</p> <p>Number</p> <p>(Number of laboratories have <5% of working hour stock outs/Total number of diagnostics laboratories</p> <p>(Number of tests for which pre- and post-market surveillance conducted/Total number of tests planned for pre- and post-market surveillance)*100%</p> <p>(Number laboratories meets the national infrastructure standard /Total number of laboratories)*100%</p>	<p>Assessment report (annually)</p> <p>Assessment report (annually)</p> <p>Assessment report (annually)</p> <p>Assessment report (annually)</p> <p>Assessment report (within 3 year)</p>	<p></p> <p></p> <p></p> <p>Pre and Post market surveillance will be done by EFDA/EPSS A</p> <p></p>

S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
		Equipment standardization and implementation of innovative technologies	Number of laboratories with standardized equipment platforms	Input	Number	Number	Assessment report (annually)	
	Proportion of laboratories with <5% equipment downtime		Output	%	(Number of laboratories have <5% of working hour equipment downtime/Total number of diagnostics laboratories)	Assessment report (annually)		
	Proportion of laboratory equipment calibrated		Output	%	(Number of laboratories with equipment calibrated/Total number of laboratory equipment that require calibration) * 100%	Assessment report (annually)		
	Proportion of equipment safely disposed		Output	%	(Number of laboratories with equipment safely disposed/Total number of obsolete equipment) * 100%	Assessment report (annually)		
		Strengthen Diagnostic Network Optimization (DNO)	Proportion of laboratories providing testing services through referral linkage per the defined network	Output	%	(Number of laboratories providing testing services through referral linkage/Total number of laboratories within the network) * 100%	Assessment report (annually)	
			Proportion of networked laboratories receiving 90% of their results within acceptable turnaround time (TAT)	Output	%	(Number of laboratory test results within acceptable TAT/Total number of laboratory results within the network) * 100%	Assessment report (annually)	
			Proportion of referred specimens with rejection rate of < 1%	Process	%	(Number of referred specimens rejected/Total number of referred specimens) * 100%	Assessment report (annually)	Needs further discussion
2	Implementation of laboratory quality	Enhance implementation	Number of laboratories with SLIPTA 1-5-star levels	Output	%	Number	Assessment report (annually)	

S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
		n of quality initiatives and promote accreditation program	(disaggregated into star levels)					
			Number of laboratories progressively improving their SLIPTA star level at least by 1 star	Output	Number	Number	Assessment report (annually)	
			Proportion of laboratories with Basic LQMS (BLQMS) 1-5 Star levels (disaggregated into customized star levels)	Output	Number	(Number of laboratories with BLQMS 1-5 star level /total number of laboratories implementing BLQMS)*100%	Assessment report (annually)	
			Number of laboratories progressively improving their BLQMS Star level at least by 1 star	Output	Number	Number	Assessment report (annually)	
			Number of laboratories accredited to ISO 15189/ 17025 requirements	Output	%	Number	Assessment report (annually)	
			Proportion of laboratories maintaining their ISO 15189/17025 accreditation status each year	Output		(Number of laboratories maintaining their ISO 15189/17025 accreditation status/Total number of laboratories ISO 15189/17025 accredited)*100%	Assessment report (annually)	
			Number of laboratories with at least one accreditation scope extension each year	Output	Number	Number	Assessment report (annually)	
	Ensure sustainable and standardized External Quality		Established PT Production center at national level based on ISO 17043 requirement	Output	Number	Number	Once in 5 year	
			Established and maintained functional EQA management software (ePT) system	Output	Number	Number	Once in 5 year	

S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
		Assessment (EQA) program	Proportion of laboratories enrolled at least in one of the three EQA methods	Process	%	(Number of laboratories enrolled at least in one of the three EQA methods /Total number of laboratories)*100%	Assessment report (annually)	
			Proportion of laboratories scored acceptable PT performance per round	Output	%	(Number of laboratories scored acceptable PT performance per round)*100%	Assessment report (annually)	
			Proportion of PT enrolled laboratories responded within the intended timeframe (Response rate)	Output	%	(Number of laboratories responded PT results within the deadline/Total number of laboratories enrolled in PT schemes)*100%	Assessment report (annually)	
			Proportion of facilities enrolled in random blind rechecking (RBR) EQA program	Output	%	(Number of laboratories enrolled in random blind rechecking EQA/Total number of laboratories)*100%	Assessment report (annually)	
			Proportion of laboratories scoring acceptable performance (concordance rate) in random blinded rechecking (RBR) EQA program	Output	%	(Number laboratories scoring acceptable performance (concordance rate) in random blinded rechecking (RBR) EQA program /Total number of laboratories enrolled in random blind rechecking EQA program)*100%	Assessment report (annually)	
			Proportion of laboratories covered through onsite evaluation EQA program	Output	%	(Number of laboratories covered through onsite evaluation/Total number of laboratories)*100%	Assessment report (annually)	
			Number of laboratories participated in inter-laboratory	Output	Number	Number	Assessment report (annually)	

S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption		
3	SO3: Improve biosafety, biosecurity, and hazardous waste management system	Establish and implement regulatory and legal frameworks for handling of hazardous pathogens and toxins	comparison							
			Established regulatory and legal framework for handling of hazardous pathogens and toxins	Output	Number	Number	Once in 5 year			
			Number of health facilities fulfilling the regulatory and legal requirements for handling of hazardous pathogens and toxins	Output	Number	Number	Assessment report (annually)			
		Improve the implementation of biosafety and biosecurity programs	Number of licensed health facilities for handling of hazardous pathogens and toxins	Output	Number	Number	Assessment report (annually)			
			Number of laboratories implemented biosafety program	Output	Number	Number	Assessment report (annually)			
			Number of laboratories implemented biosecurity program	Output	Number	Number	Assessment report (annually)			
		Improve compliance and practice of laboratory waste management system	Number of laboratories implemented bio-risk management system	Output	Number	Number				
			Number of negative pressure laboratory facilities certified	Output	Number	Number				
			Number of biosafety cabinets certified	Output	Number	Number	Assessment report (annually)			
					Number of laboratories implemented biohazardous waste management system	Output	Number	Number	Assessment report (annually)	
					Number of laboratories practiced chemical and other waste management system	Output	Number	Number	Assessment report (annually)	

S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
4	SO4: Establish an integrated laboratory data and information management system	Strengthen the implementation of standardized laboratory information system (LIS)	Number of Developed implementation guidelines and manuals for LIS	Output	Number	Number	Once in 5 year	
			Proportion of laboratories using standardized paper-based LIS	Output	%	(Number of laboratories using standardized paper-based LIS/Total number of laboratories)*100%	Assessment report (annually)	
			Number of laboratories using robust eLIS	Output	Number	Number	Assessment report (annually)	
			Proportion of laboratories with functional electronic network with the national data management center	Output	%	(Number of laboratories with functional electronic data management center / Total number of laboratories)*100%	Assessment report (annually)	
			Proportion of laboratories with functional eLIS interface with healthcare facility EMR or DHIS-2	Output	%	(Number of laboratories with functional eLIS interface with healthcare facility EMR or HMIS system / Total number of laboratories) *100%	Assessment report (annually)	
		Build national and regional capacities for laboratory data repository, management and use	Established capacity for laboratory data repository and management system	Output	Number	Number	Once in 5 year	
			Developed national guideline for data sharing	process	Number	Number	Once in 5 year	
			Developed system for multi-sectoral data sharing	process	Number	Number	Once in 5 year	
			Number of policy brief/issue brief generated	Output	Number	Number	Assessment report (annually)	

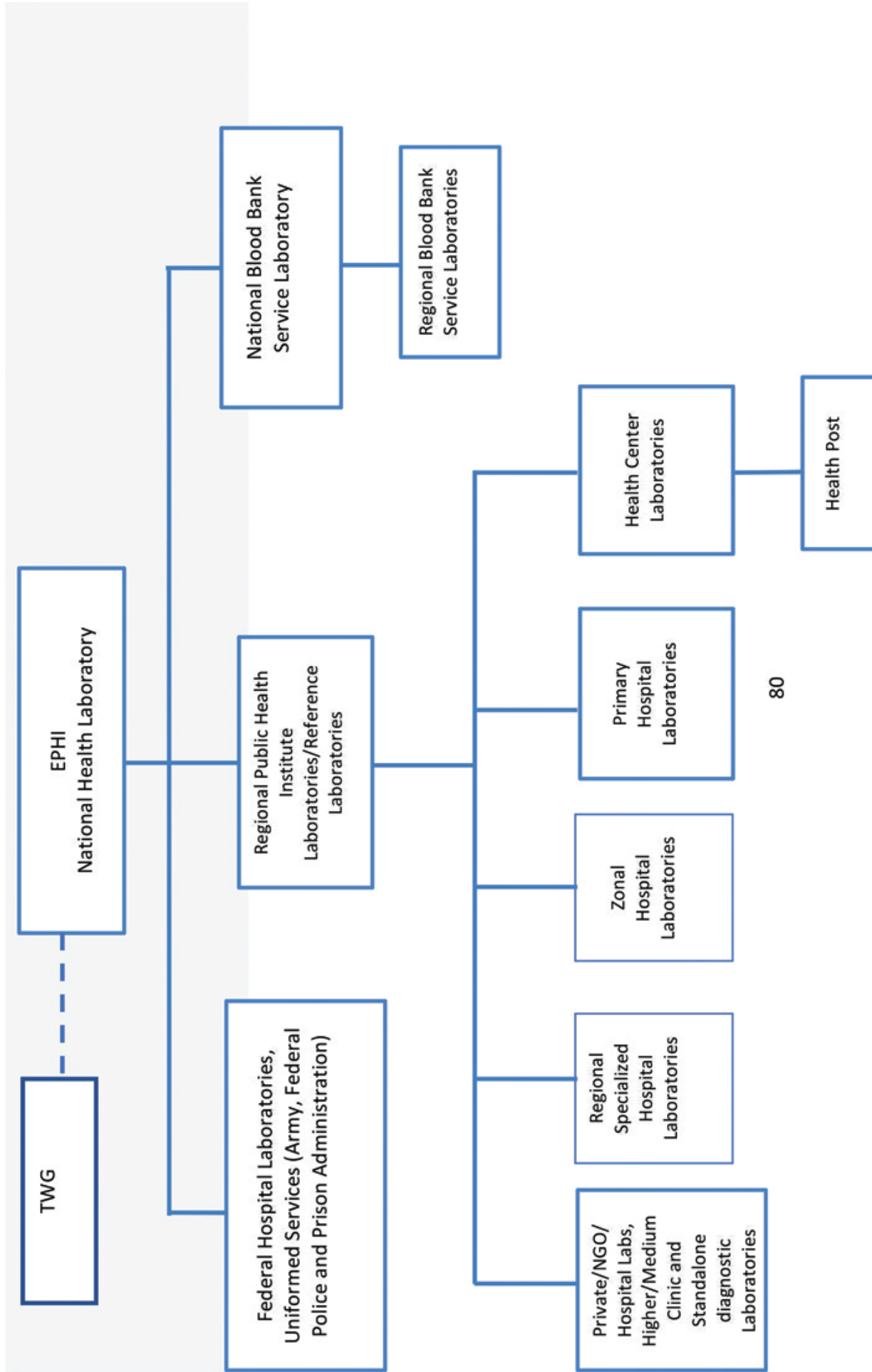
S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
5	SO5: Enhance operational research, innovations, and introduction of new laboratory technologies	Build the capacity of laboratories for innovation and transfer of new technologies	Developed guidelines for new laboratory technology evaluation and operational research	Output	Number	Number	Assessment report (annually)	
			Number of new methods and technologies evaluated and/or validated	Output	Number	Number	Assessment report (annually)	
			Number of capacitated for in-vitro diagnostics research and development	process	Number	Number	Assessment report (annually)	
		Promote operational research to improve laboratory services	Number of national and regional reference laboratories capacitated and engaged in advanced research, evaluation of technologies and in vitro diagnostics manufacturing	process	Number	Number	Assessment report (annually)	
			Number of centers of excellence laboratories established bio-banking center	Output	Number	Number	Assessment report (annually)	
SO6: Partnership, Governance, Financing	Strengthen Leadership and governance	Number of policies/directives developed	Input	Number	Number	Assessment report (annually)		
		Customers/stakeholders satisfaction rate	Output	%	(Number of customers/stakeholders satisfied on laboratory leadership /Total number of customers) * 100%	Assessment report (annually)		
		Proportion of women and people with special need in the laboratory leadership at all levels	Process	%	(Number of women and people with special need in the laboratory leadership at all levels/total number of women or people with	Assessment report (twice in 5 year)		

S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
						disability or youth in the Laboratory program)*100%		
			Proportion of “active stakeholders” supporting the health laboratory system	Process	%	(Number of “active stakeholders” supporting the health laboratory system/Total Number of stakeholders supporting the health laboratory system)*100%	Assessment report (twice in 5 year)	
			Proportion of resources mobilized through partnership agreement	Process	%	(Number of resource mobilized / through partnership agreement/Total Number of resources mobilized)*100%	Assessment report (annually)	
		Enhance Partnerships, collaboration, and coordination	Number of new partnerships signed per year (this includes partnership with international laboratory services providers)	Process	Number	Number	Assessment report (annually)	
			Number of projects implemented through PPP arrangement	Process	Number	Number	Assessment report (annually)	
			Number of private sector organizations invested in the national diagnostic business opportunities	Process	Number	Number	Assessment report (annually)	
		Strengthen Sustainable Laboratory Financing	Proportion of resources mobilized per year from different domestic from the total resource required	Process	Number	Number	Assessment report (annually)	

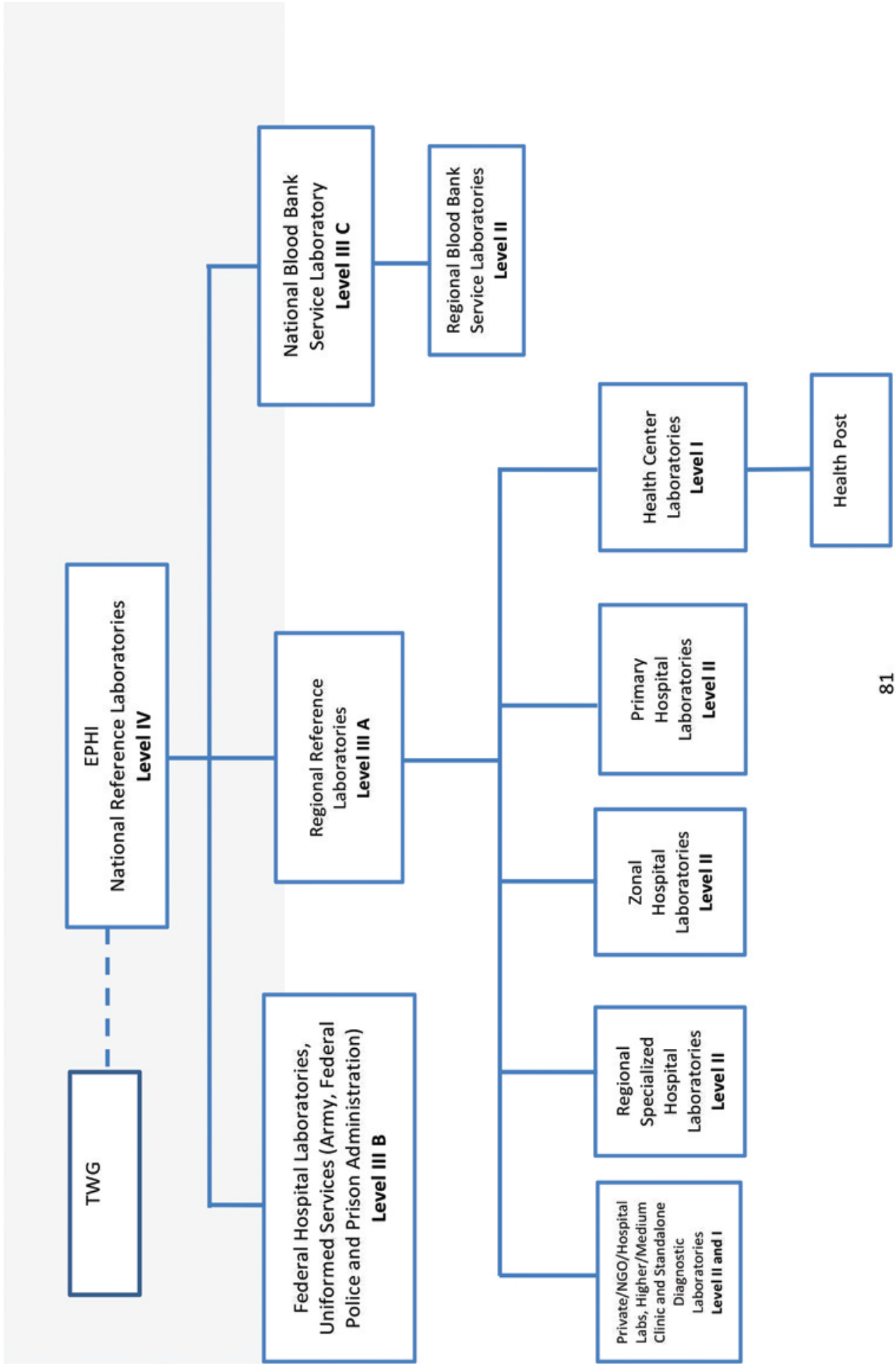
S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
		System	Annual budget utilization rate	Process	Number	(Number of domestic resource mobilized for laboratory services / Total number of Resource mobilized)*100%	Assessment report (annually)	
			Proportion of laboratory service fees covered by health insurance	Process	Number	(Number of laboratory service covered by health insurance/total number of services provided) *100%	Assessment report (annually)	
	SO:7 Workforce development and Management	Ensure Human Resource Planning and Retention	Turnover rate of trained laboratory workforce at each level	Process	Number	(Number of laboratory workforce left the organization / Total number of laboratory workforce working)*100%	Assessment report (annually)	
7		Strengthen Continuous Professional Development and Knowledge	Workforce satisfaction rate	Process	Number	(Number of Laboratory workforce satisfied / Total number of laboratory workforce)*100%	Assessment report (annually)	
			Number of proposed courses to pre-service education curriculums	Process	Number	Number	Assessment report (annually)	

S. N	Strategic Objective	Strategic Direction	Indicators	Type of Indicator	UoM	Formula	Means of verification	Risk and Assumption
		Management	Number of professionals certified in continuous professional development program	Process	Number	Number	Assessment report (annually)	
			Number of laboratory courses accredited for CPD	Process	Number	Number	Assessment report (annually)	
			Number of accredited CPD providers that can provide health laboratory courses	Process	Number	Number	Assessment report (annually)	

Annex 2: NATIONAL HEALTH LABORATORIES SYSTEM TECHNICAL SUPPORT STRUCTURE



Annex 3: NATIONAL HEALTH LABORATORIES TIER LEVEL



Annex 4: List of National Laboratory Technical Working Group members

S.N	Name	Organization	Role
1	Mr. Daniel Melese	EPHI	Chair
2	Mr. Markos Paoulos	MOH	Member
3	Dr. Yared Tedela	US CDC	Secretary
4	Dr. Yenew Kebede	Africa CDC	Co-Secretary
5	Dr. Geremew Tasew	EPHI-Research	Member
6	Mr. Gonfa Ayana	EPHI NLCBD	Member
7	Mr. Achamyeleh Mulugeta	EPHI NLCBD	Member
8	Dr. Eyob Abera	EPHI NLCBD	Member
9	Mrs. Feven Girmachew	EPHI NLCBD	Member
10	Mr. Wondimenh Liknaw	EPHI NLCBD	Member
11	Mr. Muluken Moges	EPHI PME	Member
12	Mr. Ashenafi Habtewold	EPHI NLCBD	Member
13	Mr. Feyisa Challa	EPHI NRL	Member
14	Mr. Kassahun Endale	EPSS	Member
15	Dr. Redeat Belaineh	AHI	Member
16	Mr. Abebe Edao	AAU	Member
17	Dr. Birhanu Seyoum	EMLA	Member
18	Dr. Amha Kebede	EPHLA	Member
19	Mr. Adisu Kebede	ASLM	Member
20	Mr. Zelalem Messele	CHAI	Member
21	Mr. Dessie Adugna	ICAP	Member
22	Mr. Kirubel Eshetu	MSH	Member
23	Mr. Endale Mengesha	KNCV	Member

Annex 5: List of Consultative workshop participants

S/N	Name	Name of Organization
1	Abdi Dangi	Benishangul Gumuz Regional lab
2	Abdi Haybe Musse	Somali Regional Lab
3	Abdu Kassaw	Diredawa Public Health Research and Reference Laboratory
4	Abebe Edao	Addis Ababa University
5	Achamyelch Mulugeta	EPHI
6	Adato Adela	Sidama Public Health institute
7	Adugna Gedefa	Benishangul Gumuz Regional lab
8	Awad Mohammed	EPHI
9	Ayana Teshale	EPHI
10	Dr. Birhanu Seyoum	Ethiopian Medical Laboratory Association
11	Dr. Daniel Garcia	US-CDC
12	Daniel Damtew	Addis Ababa Health Bureau
13	Daniel Melese	EPHI
14	Engida Gizaw	Harer Regional Laboratory
15	Ephrem Alemu	EPHI
16	Eyob Abera	EPHI
17	Feven Girmachew	EPHI
18	Girma Wondimu	SNNPR Public Health institute
19	Hamedu Ahmed	Afar Public Health institute
20	Hiwot Abebe	EPHI
21	Hiwot Amare	UK HSA
22	Hulemenaw Delelegn	US-CDC
23	Kassayenew Amare	AAHB
24	Kefene Kelbesa	Afar Public Health institute
25	Markos Paulos	MOH

S/N	Name	Name of Organization
26	Minel Sead	EPHI
27	Mintesinot Melka	SNNPR PHI
28	Muluken Moges	EPHI
29	Oute Reta	South West Ethiopia Public Health Institute
30	Simeneh Ayalew	Amhara Public Health Institute
31	Usheta Dasiso	Oromia Region Health Bureau
32	Wondmeneh Liknaw	EPHI
33	Yemisrach Alemu	Amhara Public Health Institute
34	Ziad Amin	Harer Regional Laboratory



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