Armauer Hansen Research Institute

A Diagnostic Research and Development and Local Production Roadmap in Ethiopia (2025-2030)

Version 1

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MINISTRY OF HEALTH · ETHIOPIA

Strategic Pillars

Vaccine, Diagnostics and Medical device R&D Directorate

June, 2024

Technical Working Group Members

Table 1: List of TWG participated in the development of the diagnostic roadmap

Name	Position	Affiliation	Role
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Mr. Fitsum Adnew	Director, Pharmaceuticals Directorate	AHRI	Secretary
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Abbreviations

AHRI: Armauer Hansen Research Institute
COVID: Coronavirus Diseases
DAT: Direct Agglutination Tests
ECAE: Ethiopian Conformity Assessment Enterprise
ECC: Ethiopian Custom Commission
EFDA: Ethiopian Food and Drug Administration
NRA: National Regulatory Agency
EIPA: Ethiopian Intellectual Property Authority
ELISA: Enzyme Linked Immuno-Sorbent Assay
EMI: Ethiopian Metrology Institute
ENAO: Ethiopian National Accreditation Office
EPMSMA: Ethiopian Medical Supplies Manufacturers Association
EPSS: Ethiopian Pharmaceuticals Supply Service
ESA: Ethiopian Standard Agency
GCP: Good Clinical Practice
GLP: Good Laboratory Practice
GMP: Good Manufacturing Practice
GRP: Good Research Practice
IES: Institute of Ethiopian Standard
IgG: Immunoglobulin G
IP: Intellectual property
ISO: International Standard Organization
IVD: Invitro Diagnostics
LMIC: Lower-Middle-Income Country
MInT: Ministry of Innovation and Technology
MOH: Ministry of Health
NBE: National Bank of Ethiopia
NRA: National Regulatory Authority

PH: Public Health
POC: Point of Care
PPP: Public-private partnership
SIT: Science and Innovation Technology
TTH: Technology Transfer Hub
WHO: World Health Organization

Forward

This roadmap was developed by AHRI staff assigned by the Director General, Professor Afework Kassu, considering the importance of diagnostics R&D and production as key priority areas to be exploited in Ethiopia. The strategic pillars with their corresponding strategic objectives were indicated. The four strategic pillars are: Strengthen R&D and Innovation Capacity, Build Local Production Capabilities, Strengthen Regulatory Frameworks, and Promote Collaboration and Partnership. These pillars were further analysed in relation to corresponding strategic objectives such as Strengthening local diagnostics R&D capacity, Building a Local Diagnostic Manufacturing Capability, Strengthening Regulatory Frameworks, and Promote Collaboration and Partnership. Similarly, these strategic objectives were aligned with their major activities (10- year development plan and Home-grown Economic Reforms), strategic initiatives, and measurable indicators. Following this, implementation plan, Monitoring and evaluation as well as stakeholders involved during the implementation are also indicated. Senior AHRI researchers develop this roadmap through several brain storming discussion session.

Definition of terms

Accreditation: is a process by which an authoritative organization evaluates and certifies that an entity, such as an educational institution, program, or professional body, meets predetermined standards of quality and competence.

Biomarker: Is a short for biological marker, to a measurable characteristic or substance that can indicate normal or pathological biological processes, disease presence, or response as diagnostic marker. Biomarkers can be found in various biological samples, including blood, urine, tissue, or saliva and etc.

Diagnostic ecosystem: refers to the interconnected network of stakeholders, technologies, processes, and infrastructure involved in the development, delivery, and utilization of diagnostic tests and services.

Epidemics: refer to the occurrence of a disease that spreads rapidly and affects a large number of people within a particular population or geographical area. Epidemics can be caused by various factors, including infectious agents (such as bacteria, viruses, or parasites), environmental factors, social behaviours, and population susceptibility.

Good Laboratory Practice: It is a set of principles and guidelines that ensure the quality, integrity, and reliability of non-clinical laboratory studies conducted for regulatory purposes, particularly in the fields of pharmaceuticals, chemicals, and other regulated products.

Good Manufacturing Practice: It is a set of guidelines and regulations that ensure the consistent production and quality control of pharmaceuticals, medical devices, food, and other consumer products. GMP provides a framework for the manufacturing process, quality control, documentation, and facility requirements to ensure that products are safe, effective, and of high quality.

Good Clinical Practice (GCP): is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials involving human participants.

Good Research Practice (GRP): refers to a set of principles and guidelines that promote the ethical, rigorous, and responsible conduct of research across various disciplines.

Incubation centers: is a start-up incubators or innovation hubs, are physical or virtual spaces that support the growth and development of early-stage start-ups and entrepreneurs.

Innovation: refers to the process of introducing new ideas, methods, products, or services that bring about significant improvements, advancements, or changes in various fields.

Input: refers to information, data, or signals that are provided to a system, process, or device for further processing, analysis, or output. It is the raw material or the starting point that is fed into a system to produce a response or result.

International Organization for Standardization (ISO): It is an independent, nongovernmental international organization that develops and publishes international standards.

Invitro diagnostics (IVD): refers to medical tests and procedures that are performed on samples taken from the human body, such as blood, urine, or tissue, outside of the body.

Outcome: refers to the result, consequence, or effect of a process, action, event, or situation. It is the final or observable result that occurs as a consequence or output of a particular activity or set of circumstances.

Output: refers to the result, response, or information produced by a system, process, or device after processing input data or performing operations. It is the outcome or the end result of a computation or a series of actions.

Preparedness: refers to the actions, plans, and measures taken in advance to mitigate the impact of potential disasters, emergencies, or crises.

Process: refers to a series of actions, steps, or operations performed to achieve a particular outcome or goal. It involves the systematic and organized handling of inputs to produce desired outputs.

Proof of Concept (PoC): is a process or demonstration used to validate the feasibility and potential of a concept, idea, or technology. It aims to provide evidence that a particular concept or solution can work in practice and achieve the desired results.

Prototypes: is early-stage models or representations of a product, system, or idea that is created to test and validate its design, functionality, and user experience.

Public-private partnership (PPP): is collaborative arrangements between government or public sector entities and private sector organizations or businesses. This partnership bring together the resources, expertise, and capabilities of both sectors to address societal challenges, deliver public services, and achieve shared objectives.

Quality Management System: It is a formalized framework or set of processes and procedures that an organization implements to ensure consistent quality in its products, services, and operations.

Technology adoption: refers to the process by which individuals, organizations, or societies accept and integrate new technologies into their daily lives, operations, or systems that offers improved features, functionalities, or benefits.

Technology Transfer Hub (TTH): is a specialized organization or entity that facilitates the transfer of technology and knowledge between research institutions, universities, and industry.

Technology transfer: refers to the process of sharing or disseminating knowledge, skills, and technologies from one individual, organization, or country (the "source") to another individual, organization, or country (the "recipient") through exchange of technical knowhow, intellectual property, and expertise to enable the recipient to apply and utilize the transferred technology for their own purposes. This can be through Licensing, Joint Ventures, Collaborative Research and Development, Technical Assistance and Consultancy, and Spin-offs and Start-ups.

Executive Summary

Ministry of Health (MOH), Ethiopia has identified diagnostics, production using research and development as strategic priorities. This strategic focus on diagnostics emanates from its strategic objective mitigating potential risk of losing access to essential diagnostic support from international donors once transitioning to lower-middle-income country (LMIC) status. . Additionally, Ethiopia's rapidly expanding population, and the occurrence of multiple diseases demand therapeutics, diagnostics, and vaccines. Among these a robust diagnostic infrastructure is of paramount importance to effectively manage and prevent infectious diseases.

The diagnostic market size in Ethiopia is a significant component of the healthcare industry in the country. While specific data on the diagnostic market size in Ethiopia is not readily available, the African IVD (In Vitro Diagnostics) market is expected to grow due to factors such as increasing demand for point-of-care devices, rapid diagnostics, and a growing prevalence of chronic diseases[1]. The Africa Point-Of-Care Diagnostics Market is growing at a CAGR of 5.7% and is expected to reach USD 816.12 million by 2028, with countries like Ethiopia being part of this market[2].

Currently, the average budget required nationally for pharmaceuticals is estimated to be around 500 million USD per year; on the contrary, no or very few diagnostic kit production companies are found in Ethiopia. Therefore, the national demand for diagnostics is filled through imports that need hard currency. Due to this fact, local production of diagnostics through Research & Development for import substitution is mandatory.

The overall goal of this roadmap is to achieve the development, production, and utilization of diagnostic (IVD) tools for at least three priority public health diseases through strengthened R&D capacity. These three diseases were selected based on their burden, geographical coverage, and public importance. This will significantly improve national public health outcomes and disease outbreak preparedness. In the preparation of this roadmap, situational and gap analyses (SWOT), focusing on research and development, human resources, infrastructure, funding, collaboration, and technology were performed.

[1] https://www.marketsandmarkets.com/Market-Reports/ivd-in-vitro-diagnostics-market-703.html

[2] https://www.databridgemarketresearch.com/reports/africa-point-of-care-diagnostics-market

Based on the analyses, four strategic pillars were derived .i.e., (1) Strengthen R&D and Innovation Capacity; (2) Build Local Production Capabilities; (3) Strengthen Regulatory Frameworks; (4) Promote Collaboration and Partnership. To address these strategic pillars four corresponding strategic objectives were set, i.e., (1) Strengthening local diagnostics R&D capacity, (2) Building a Local Diagnostic Manufacturing Capability, (3) Strengthening Regulatory Frameworks, and (4) Promote Collaboration and Partnership. Similarly, these strategic objectives were aligned with their strategic initiatives and measurable indicators. Following this implementation plan and implementing institutions as well as stakeholders involved during the implementation are also indicated.

In conclusion, this diagnostic roadmap is developed to be implemented in the next five years (2025-2030) to addressing the shortage of human resource, infrastructure, and maintain collaboration for successful implementation in Ethiopia in alignment with the MOH and AHRI's 10- year strategic plan.

Scope of the Roadmap:

The overall scope of this roadmap is local production of in vitro-diagnostics (IVD) supported by R&D. Specific scopes of this roadmap are

- In line with the new AHRI's/health aspects research mandate in Ethiopia related with IVD diagnostics.
- Dealing/addressing with high level strategic areas on national PH priority needs
- Involving/Engaging with innovation, adoption and technology transfer through R&D
- Strengthening local regulatory pathways for fast-track approval
- Ensuring local capacity building to enhance the skill and knowledge required for diagnostics
- Fostering strong partnership and collaboration with the relevant stakeholders

1. Background

The global in vitro diagnostics (IVD) market is forecasted to reach a revenue of $88.98 billion by 2024, growing at a CAGR of 2.91% from 2024 to 2029 to reach $102.70 billion by 2029. The United States is expected to generate the highest global IVD revenue, amounting to $30,100 million in 2024, owing to its strong research and development efforts and robust regulatory environment. The African in vitro diagnostics (IVD) market will reach a projected value of $1.68 billion by 2024, with 3.44% annual growth from 2024 to 2029, leading to a market volume of $1.99 billion by 2029. Similarly, the Ethiopian in vitro diagnostics (IVD) market is projected to have a value of $41.31 million by 2024 continues with CAGR of 5.65% from 2024 to 2029, leading to a market volume of $54.38 million by 20293. This area is one of the sectors that utilize knowledge- based economy. Ethiopia is the most populous country and located in the horn of Africa with poor health care services and lack of companies that produces diagnostics local production aimed at strengthening R&D and local production of diagnostics. This would help in detecting diseases early in one of the suspect countries and to establish an immediate response plan. Moreover, it would help to establish or introduce knowledge based economic sources like China and Korea. With above gap and the huge economic demand for diagnostic in the region, the Ethiopian Ministry of Health (MOH) has identified diagnostics research, development, and production as one of Ethiopia's five strategic priorities, reflecting its unwavering commitment to self-sufficiency in this crucial sector. Ethiopia's strategic focus on diagnostics stems from the potential risk of losing access to essential diagnostic support from international donors once transitioning to a lower-middle-income country (LMIC) status. Additionally, Ethiopia's rapidly expanding population demands a robust diagnostic infrastructure to effectively manage and prevent infectious diseases[4].

Previously, in 2018, AHRI and relevant stakeholders developed a roadmap emphasizing diagnostics R&D and development5. However, this earlier roadmap did not explicitly address the critical aspects of local production and commercialization. AHRI's current mandate acknowledges the need to bridge this gap by integrating local production and commercialization into the diagnostics development process.

Ethiopia's experience in diagnostics remains limited, with the country heavily reliant on imports for almost all diagnostic tools. The nation's current diagnostic development efforts largely focus on antigen screening, clinical evaluation, and validation stages, falling short of actual product development and commercialization.

[3] https://www.statista.com/outlook/hmo/medical-technology/in-vitrodiagnostics/worldwide?currency=usd

[4] https://www.globalfinancingfacility.org/sites/default/files/Ethiopia-HSTP-II.pdf

Despite this limited experience, AHRI has a proven track record in diagnostics, including the development of serological TB and COVID-19 diagnosis through ELISA or IgGcoated TB antigens.

When it comes to finding visceral leishmaniosis, AHRI is also good at antigen screening, biomarker identification, primer design, and making direct agglutination tests (DATs).

In addition, recently three companies (Access Bio Inc, New Millennium and BGI genomics) started production of Invitro diagnostics in Ethiopia. These companies' capacity of production is limited due to a lack of investment in R&D.

However, AHRI's advancements in diagnostics have yet to reach the stage of product development. This lack of transition from R&D to commercialization hinders Ethiopia's ability to independently address its diagnostic needs.

To achieve self-sufficiency in diagnostics, Ethiopia must invest in strengthening its local production capabilities, fostering collaboration between research institutions and industry, and providing incentives for the development and commercialization of domestically produced diagnostics. By addressing these critical aspects, Ethiopia can\ break free from its reliance on external sources and establish a self-reliant diagnostic ecosystem.

The current strategic roadmap preparation process for diagnostics in Ethiopia reflects

[5] Road Map for Research and Development of Diagnostics in Ethiopia (2018)
AHRI's new mandate, placing a strong emphasis on R&D, development, and commercialization or utilization of diagnostic tools. This roadmap builds upon the 2018 roadmap, incorporating updated insights from the current context and setting a clear vision for Ethiopia's future in diagnostics. The overall goal is to transform Ethiopia into a self-sufficient nation by producing and utilizing high-quality diagnostic tools for priority public health diseases, ultimately improving health outcomes and strengthening epidemic investigation.

2. Situation Analysis (SWOT)

Below is a SWOT analysis for making Ethiopia a self-reliant nation in diagnostic capacity through R&D and local production:

Strengths:

- A large pool of skilled scientists, engineers, and healthcare workers
- Existence of mandated Inst for diagnostics R&D, and production
- Initiatives and commitment from the government for the establishment of the new state of the art facility
- Strong International collaboration (Bilateral)
- Strong Biomedical R&D culture
- Excellent team work & committed staff

Weaknesses:

- Limited functional R&D infrastructure
- Limited experience in local production
- Inadequate senior experts on diagnostics' R&D
- External initiatives & interests
- Overreliance on foreign funding
- Constrained government funding source
- Inefficient administration, procurement and finance system
- Lack of product development
- Infrastructure challenging (Hinder manufacturing and distribution efforts)

Opportunities:

- Government commitment
- Government incentives for local pharmaceutical manufacturers
- Growing global and local demand for diagnostics
- Availability of external funding
- Emergence of new technologies such as POC
- Health biotech R&D policy
- SIT policy
- National Biotechnology Road Map

- National STI council Increased health care service utilization
- Growing population
- Dedicated Pharmaceutical Industrial Park
- Expansion of higher learning and research institutes
- Access, equity and availability of technology transfer
- Inexpensive workforce
- Public-Private Partnerships

Threats:

- Competition from established manufacturers
- High cost of imports for inputs
- Protectionism by developed countries
- Globally challenging economic climate
- Stiff competition with global biomedical research landscape
- Significantly high investment cost of diagnostics manufacturing
- Limited experience and capacity in regulatory procedures for local products
- Scarcity of biotechnology companies (Public & Private)
- Inadequate intellectual property (IP) rights protection, particularly for science & innovation
- Negative attitude and perception towards local products
- Insufficient sustainable funding
- Weak health innovation ecosystem

By addressing its weaknesses and capitalizing on its strengths and opportunities, Ethiopia can build a self-reliant diagnostic ecosystem that improves health outcomes, enhances epidemic preparedness, and contributes to economic development.

3. Stakeholder Mapping

The stakeholders that are involved directly in the diagnostic R&D and production are listed in table 2. This was analysed in function of their interest, influence/power as well as their impact. Further, their engagement strategies are also listed (table 2).

Table 2. Stakeholder analysis

	Stakeholder	Interest/Concerns	Influence/Power	Impact	Engagement Strategy
1	Government	Public health, import substitution	High	High	Policy advocacy, Resource allocation requests, Market guarantee
2	MOH	Improved Health Outcomes	High	High	Regular updates, Collaboration on policy alignment, Market Guarantee
3	EFDA	Compliance	High	High	Regular checks & consultations
4	Manufacturers	R&D support, Technology Transfer	Medium	Medium	Regular updates & collaboration
5	EPMSMA (Asso)	Advocacy, Service	Medium	Medium	Regular updates & collaboration
6	Academia &Research Institutions	Collaboration, Training, & Technology transfer	Medium	Medium	Joint research, Capacity building
7	Healthcare Workers	Access & availability to Quality diagnostics	Medium	Medium	Advocacy, Product selection (assessment)
8	Donor Organizations	Financial & Technical support	High	High	Well prepared Proposal
9	Hospital, Clinics & Laboratories	Access to quality Diagnostics	Medium	Medium	Satellite sites for clinical trials
10	Patients & Communities	Access to quality, specific & sensitive diagnostics	High	High	Public awareness campaigns & feedback mechanism
11	NBE	Hard currency	High	High	Awareness
12	ECC (Custom)	Import	High	High	Awareness
13	EPSS	Procurement	High	High	Market priority, providing raw materials
14	WHO	Partnership	Medium	Medium	Collaboration
15	ECAE	Compliance	High	High	Collaboration
16	IES	Standard	High	High	Collaboration
17	EMI	Standard	High	High	Collaboration
18	ENAO	Certification	High	High	Collaboration
19	EIPA	Patent Protection	High	High	Collaboration
20	MInT	Funding, Technology Transfer, Facilitation	High	High	Collaboration, Well prepared proposal
21	EMLA	Advocacy, Service	Medium	Medium	Regular updates & collaboration

4. Vision

By 2030, IVDs R&D, and local production will be enhanced, for high quality and timely investigations of epidemics in Ethiopia.

5. Mission

Enhancement of diagnostics R&D thereby strategic investment for domestic diagnostics manufacturing facilities, and promotion of affordable access through innovative financing schemes and public-private partnerships

6. Overall Goal

By 2030, Ethiopia aims to achieve development, production, and utilization of diagnostics (IVDs) for at least three priority public health diseases through strengthened R&D capacity. This will significantly improve national public health outcomes and disease outbreak preparedness.

7. Pillars, Strategic Objectives and Initiatives

7.1 Strategic Pillars

1) Strengthen R&D and Innovation Capacity in Diagnostics
2) Build Local Production Capabilities
3) Strengthen Regulatory Frameworks
4) Promote Collaboration and Partnership

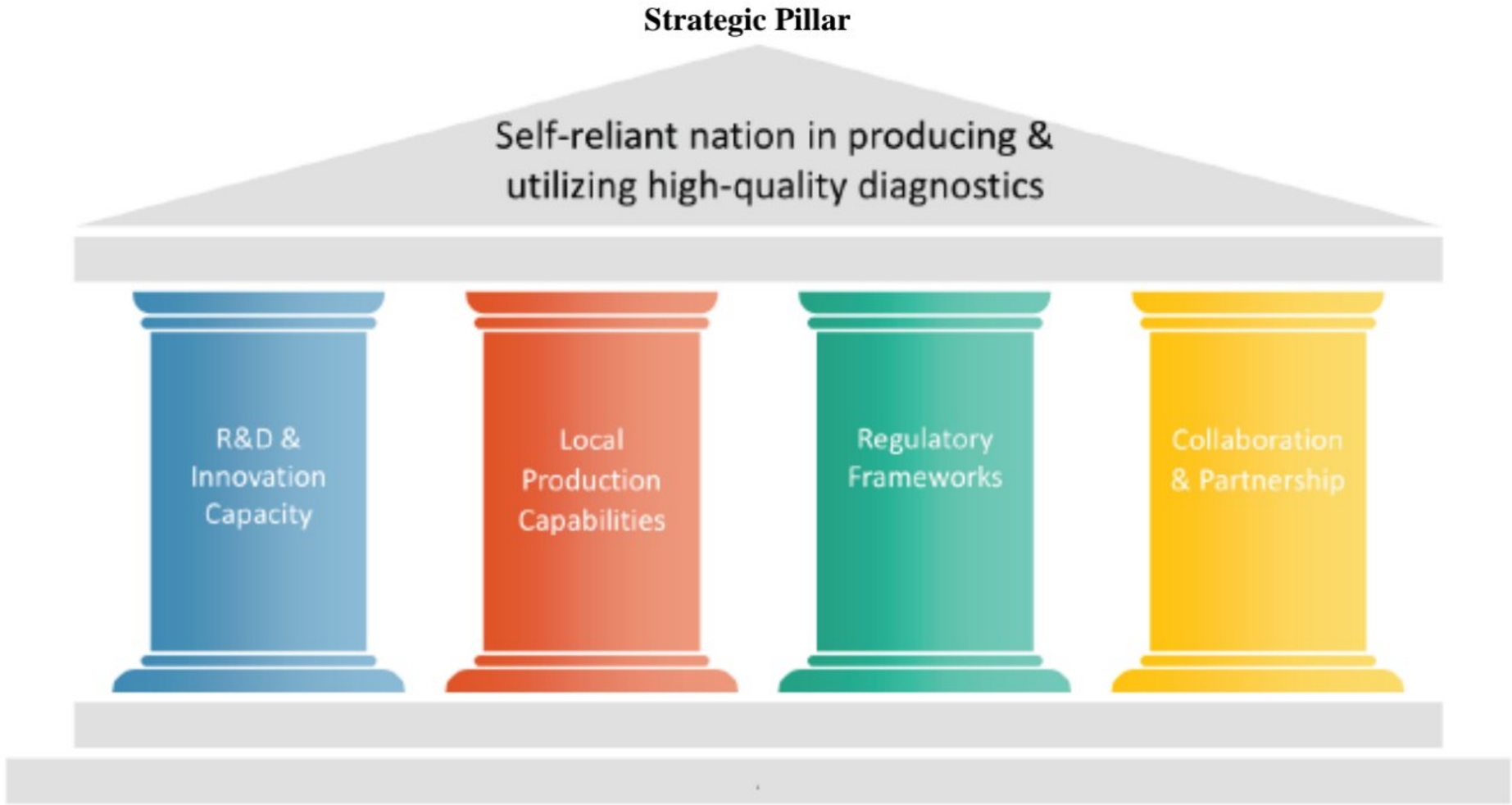

Figure: Strategic Pillars of the Diagnostic Roadmap

7.2. Strategic Objectives and Initiatives

SO1: Strengthening local diagnostics R&D capacity

Description

Establishing local diagnostics production capacity through technology transfer and research and development (R&D) is an approach to developing local diagnostics production capacity through technology transfer and R&D. It mainly encompasses identifying critical technology, infrastructure development, and capacity building from established companies to local industries. Technology transfer involves the transfer of knowledge, expertise, and know-how. The R&D aimed at developing new diagnostic technologies, improving existing ones, and adapting imported technologies to local contexts. On the other hand, local innovations are promoted for proof-of-concept design, prototype development, small scale production, and establishing incubation centers.

Further, for the purpose of quality control, the establishment of reference standards, antigens, and serum will also be considered. This will improve healthcare access, reduce costs, strengthen disease surveillance, and enable timely responses to public health emergencies.

SI -1: Strengthen R&D for Innovation and discovery of diagnostics for Public health important diseases

Major Activities:

- Identify critical technologies
- Strengthen R&D facility
- Increase personnel capacity building in diagnostic technologies
- Enhance the development of new or improve existing diagnostics
- Advertising a Call scheme for IVD grant
- Enhance production of reference antigen, serum and establishment of reference standards

Indicators

- Number of technologies identified
- Number of capacities created
- Number of functional facilities
- Number of products developed
- Number of grants advertised and granted
- Number of reference antigen, and serum produced and reference standards established

SI -2: Facilitate the transfer of established diagnostic technologies to address priority
PH diseases
Major Activities:

- Need assessment for specific priority PH diseases
- Technology acquisition
- Adopting and producing diagnostic technologies for priority diseases
- Establish and support incubation centers

Indicator

- Number of assessments done
- Number of technologies absorbed
- Number of technologies adopted
- Number of functional incubation centers

SI -3: Prototype Development, and production
Major Activities:

- Designing proof of concept
- Prototype Development and Refinement
- Optimization of the prototype and Small Scale production for industrial transfer

Indicators:

- Number of proofs of concept designed
- Number of prototypes developed
- Quantity produced

SO2: Building a Local Diagnostic Manufacturing Capability

Description

Establishing a robust local capacity means building a strong, self-sufficient capacity to make diagnostic goods locally. It has several important steps, including a feasibility study, building the facility, procuring equipment, making it operational, and soliciting funds. These steps all work together and need careful planning, organization, and investment. To keep this commitment, many people need to work together, and manufacturers need to be willing to transfer of technology. This capability enables the creation of diagnostic tools tailored to the local population's needs. The goal of this objective is to reduce dependence on imports, enhance healthcare access, foster innovation, create employment opportunities, and improve the overall health outcomes of the local population.

SI-4: Invest in manufacturing facilities

Major Activities:

- Feasibility study
- Facility development
- Solicit required finance

Indicators

- Feasibility studied
- Manufacturing facility established
- Fund secured

SO3: Strengthening Regulatory Frameworks

Description

Strengthening regulatory frameworks for diagnostics is not just about setting rules; it's about building a robust system that safeguards public health and fosters industry progress. This strategic objective focuses on strengthening the National Regulatory Agency (EFDA) to perform its critical role with efficiency and transparency. The initiative's key pillars include enhancing EFDA's capacity to invest in training and resources; Prepare a streamline guidance document for regulatory body for approval, promote international collaboration, facilitate knowledge sharing and best practices exchange among NRAs globally; modernize regulatory frameworks, and strengthen enforcement mechanisms through establishing a collaborative platform with stakeholders. Moreover, QMS, and compliance with applicable regulatory requirements (GMP, GLP, ISO) will ensure the reliability and accuracy of locally produced diagnostics.

By implementing these measures, we can build effective NRAs that protect public health, foster innovation, and promote public trust. This strategic objective is ultimately about empowering NRAs to be guardians of public health, driving innovation, and fostering a thriving diagnostics ecosystem.

SI -6: Enhance a transparent and efficient regulatory system for the approval and monitoring of diagnostic products

Major Activities:

- Review, update and follow the existing regulatory guidelines
- Prepare Streamlined Regulatory guidance for approval
- Strengthening Regulatory Authorities' Capacity
- Establish a collaborative platform with stakeholders

Indicators

- Number of regulatory guidance reviewed and updated
- Streamlined regulatory guidance prepared
- Number of Regulatory Authorities' personnel trained
- Platform established

SI-7: Implement quality control measures to ensure the reliability and accuracy of locally produced diagnostics

Major Activities:

- Implement QMS
- Ensure compliance with applicable regulatory requirements (GMP, GLP, ISO)

Indicators

- Number of labs implemented QMS
- Number of standard operating procedures (SOPs) ISO accredited

Description

In today's interconnected world, individual entities, individuals, institutes, companies, and even countries are realizing the immense potential of collaboration. Synergistic partnerships and international collaboration have become crucial for maximizing performance and achieving desired outcomes. This strategic objective recognizes the power of these collaborative efforts, specifically in the realm of technology transfer and capacity building for diagnostics development and production. Among them, public private partnerships (PPPs) emerge as a particularly innovative model, offering unique value through strategic alliances both locally and internationally.

The key to success lies in cultivating reliable partnerships with international organizations and governments. This would be through knowledge exchange and joint research. This involves actively identifying reliable collaborators, establishing robust networks, and nurturing ongoing relationships with diverse institutions, companies, and countries across various sectors. In addition, establishing a Technology Transfer Hub would be an important scenario for the sustainability and transfer of newly innovated and adopted technologies. Once these activities are all performed commercialization will follow. By fostering these synergies, we can collectively improve overall performance and unlock new advancements in the field of diagnostics.

SI-8: Strengthening Public-Private Partnerships (PPPs) for Diagnostic Development and Production

Major Activities:

- Establishing a Clear PPP Framework (guideline)
- Establishment of partnership
- Commercialization

Indicators

- PPP framework(guideline) prepared
- Number of partnerships established
- Number of products transferred to industry for commercialization.

SI-9: Leveraging International Collaboration for Technology Transfer and Capacity Building

Major Activities:

- Establish Collaborative Partnerships with International Organizations and Governments
- Enhance Knowledge Exchange and Joint Research Projects
- Establish Technology Transfer Hub

Indicators

- Number of partnerships established
- Number of individuals that gained the knowledge
- Number of joint projects won
- Number of technology transfer hubs established

SI-10: Establishing Local Multi-Sectoral Collaborative Platforms for Diagnostic Research and Development

Major Activities:

- Establish multi-stakeholder platform
- Establish research and development coordination mechanism

Indicators:

- Number of multi-sector platform conducted
- Number of R&D coordination mechanism established

8. Implementation Plan

This part of the roadmap explains the four strategic objectives, their high level respective strategic initiatives, major activities, and measurable indicators. In addition, the target is five years (2025-2029) with the estimated budget. Moreover, the main budget source to implement this roadmap are indicated as government, World Bank, and partners). The responsible institutions to implement this roadmap are mentioned, i.e., MOH, AHRI, the Ministry of Innovation and Technology, EFDA, as well as partners (detailed implementation plan is indicated in Annex).

9. Monitoring, Evaluation and Learning (MEL)

The design of this framework aims to adhere to the activities outlined in the roadmap, thereby achieving the anticipated target. The main target here is the small scale production of three invitro diagnostics. To achieve this, inputs are processed to give an output that helps to meet the target. These inputs, process, outputs, outcomes, and impacts are well analyzed in Table 3.

Table 3: Monitoring and Evaluation Framework

Inputs	Process	Output	Outcome	Impact
-Human resource -Infrastructure -Technology, -Finance -Regulatory bodies -Partnership & collaboration	-Trainings -Need assessment -Technology transfer -Designing proof of concept -Feasibility study -Implement QMS	-Established Incubation center -Trained staff -Porotype -Technologies -Small scale production -Enhanced approval -Accredited facility -Established multi-sectoral platform	- Small scale production of the three IVDs - Adoption and utilization	- Healthcare system - Economy (cost saving) - created job

Annex

Table 4: Implementation plan of the diagnostic roadmap

Strategic Objectives	Strategic Initiatives	Major Activities	Indicator	Target	2025	2026	2027	2028	2029	2030	Budget(USD)	Budget source	Responsible Institution
SO1: Establish local diagnostics production capacity through Technology transfer and R&D	SI -1: Strengthen R&D for Innovation and discovery	Identify critical technologies	#	1							5000	Govt	AHRI
		Strengthen R&D facility	#	1	X						5E+06	Govt/WB	AHRI
		Increase personnel capacity building in diagnostic technologies	#	15	3	3	3	3	3	3	500000	Govt/WB	AHRI
		Enhance the development of new or improved existing diagnostics	#	10	1	1	2	3	2	1	7E+06	Govt	AHRI
	SI -2: Facilitate the transfer of established diagnostic	Need assessment for specific priority PH diseases	#	1							5000	Govt	AHRI
		Technology acquisition	#	2	X	X					8E+06	Govt/Partners	AHRI
		Adopting diagnostic technologies for priority diseases	#	2	X	X					2E+06	Govt/Partners	AHRI

	technologies to address priority PH diseases	Establish and support incubation centers	#	1	X	X					7E+06	Govt/WB	AHRI
	SI -3: Prototype Development & production	Designing proof of concept	#	8	X	X	X	X	X	x	800000	Govt/Partners	AHRI
		Prototype Development and Refinement	#	3			X	X	X		150000	Govt/Partners	AHRI
		Small scale production	#	2				X	X		550000	Govt/Partners	AHRI
SO2: Building Local Diagnostic Manufacturing Capability	SI-4: Invest in manufacturing facilities	Feasibility study	#	1	x						200000	Govt/WB	MOH/ AHRI
		Solicit required finance	#	1					X		3E+07	Govt/WB	MOH/ AHRI
		Facility development	#	1	X						0	Govt	MOH/ AHRI
			#	2	X						0	0	AHRI
SO3: Strengthening Regul	SI -6: Enhance a transparent and efficient	Review, update and follow the existing Regulatory guidelines	#	1	X						0	0	AHRI/ EFDA

atory Frame works	regulatory system for the approval and monitoring of diagnostic products	Prepare Streamlined Regulatory guidance for approval	#	1	X	X	X	X	X		0	0	AHRI/ EFDA
		Strengthening Regulatory Authorities' Capacity	%	100	X	X	X	X	X		300000	Govt/Partners	AHRI/ EFDA
		Establish a collaborative platform with regulatory bodies	#	3	X	X	X	X	X		20000	Govt/Partners	AHRI
	SI-7: Implement control measures to ensure the reliability and accuracy of locally produced diagnostics	Implement QMS	#	1	X	X	X	X	X		500000	Govt/Partners	AHRI
		Ensure compliance with applicable regulatory requirements (GMP, GLP, ISO)	#	3		X	X	X	X		50000	Govt/Partners	AHRI
SO4: Promote Collab	SI-8: Strengthening Public-Private	Establishing a Clear PPP Framework (guideline)	#	1	X						10000	Govt/Partners	AHRI

oration and Partnership	Partnerships (PPPs) for Diagnostic Development and Production	Establishment of partnership	#	5	1	1	1	1	1		0	Govt/Partners	AHRI
		Commercialization	#	3			1	1	1		100000	Govt/Partners	AHRI
	SI-9: Leveraging International Collaboration for Technology Transfer and Capacity Building	Establish Collaborative Partnerships with International Organizations and Governments	#	3	1	1	1				50000	Govt/Partners	AHRI
		Enhance Knowledge Exchange and Joint Research Projects	#	3	1	1	1				200000	Govt/Partners	AHRI/ Partners
		Establish Technology Transfer Hub	#	1	X	X					15000	Govt/Partners	AHRI/ Partners
	SI-10: Establishing Multi-Sectoral Collaborative Platforms for	Establish multi-stakeholder platform	#	1	X						50000	Govt/Partners	AHRI/ Partners
		Establish research and development coordination mechanism	#	1	X						25000	Govt/Partners	AHRI/ Partners

	Diagnostic Research and Developme nt