Ministry of Health

MALAWI GENOMICS SURVEILLANCE IMPLEMENTATION PLAN FOR 2023-2030

First edition

PHIM | PUBLIC HEALTH INSTITUTE of MALAWI

Contents

Acronyms/Abbreviations 2

Foreword 4

Preface 5

Acknowledgements 6

1. Background 9

1.1 Introduction 9

1.2 Global and National Situational Analysis 9

1.3 SWOT Analysis 10

1.4 Guiding Principles for the Implementation Plan 11

1.5 Implementation of the Plan 12

1.6 The Role of PHIM in the Implementation of the Plan 12

1.7 Rationale 13

1.8 Overall Goal 13

1.9 Specific Objectives 13

1.10 Linkage with Policy Documents 13

2. Thematic Areas 14

2.1 Research and Surveillance 14

2.2 Health Systems Strengthening 17

2.3 Capacity Building for Human Resources 19

2.4 Data Management 20

2.5 Resource Mobilization, Financing, and Sustainability 21

2.6 Governance, Regulation, and Policy 22

2.7 Stakeholder Engagement 23

3. Appendices 25

Appendix 1: SWOT Analysis of Genomics implementation in Malawi 25

Appendix 2: Financing and Costing 34

Appendix 3: Monitoring and Evaluation Framework 42

Acronyms/Abbreviations

Acronym/Abbreviation	Full Version
Africa CDC	Africa Centre for Disease Control and Prevention
ASLM	African Society for Laboratory Medicine
CDC	US Centers for Disease Control and Prevention
CE-IVD	Conformité Européenne-In Vitro Diagnostics
CHAI	Clinton Health Access Initiative
COVID-19	Corona Virus Disease of 2019
EQA	External Quality Assurance
GoM	Government of Malawi
HEU	Health Education Unit
HIV	Human Immunodeficiency Virus
HSSP III	Health Sector Strategic Plan III
ICT	Information and Communication Technology
IRB	Institutional Review Board
I-TECH	International Training and Education Center for Health
IVD	In-vitro Diagnostics
KUHeS	Kamuzu University of Health Sciences
MBS	Malawi Bureau of Standards
MCM	Medical Council of Malawi
MLW	Malawi Liverpool Wellcome Trust
MoEST	Ministry of Education, Science and Technology
MoH	Ministry of Health
NGC	National Genomics Committee

NGRN	National Genomics Research Network
NHRL	National HIV Reference Laboratory
NHSRC	National Health Sciences Research Committee
NSP	National Strategic Plan
NTP	National Tuberculosis Control Program
PAM	Physical Assets Management
PGI	Pathogen Genomics Initiative
PHIM	Public Health Institute of Malawi
PMRA	Pharmacy and Medicines Regulatory Authority
R4H	Riders for Health
SOPs	Standard Operating Procedures
SWOT	Strengths, Weaknesses, Opportunities, and Threats
TB	Tuberculosis
UMB	University of Maryland Baltimore
USAID	United States Agency for International Development
WHO	World Health Organization

Foreword

This plan provides guidance on the implementation of genomics for pathogens of pandemic and epidemic potential in Malawi. It is crucial in time of unprecedented health challenges such as cholera, COVID-19, and other emerging and re-emerging infectious diseases.

Genomics has been instrumental in combating diseases across the world. It has provided valuable insights to inform public health response. This plan provides a comprehensive overview of genomics and its role in disease prevention, surveillance, and management in Malawi.

Malawi is determined to advance genomics research and practice in healthcare. We will use cutting-edge sequencing and surveillance technologies to identify, prevent, and control disease outbreaks. We will also use genomics to accelerate discoveries of vaccines, diagnostics, and therapeutics. We also intend to use genomic surveillance to improve our general awareness and understanding of health and diseases.

This plan is a result of multi-sectoral collaboration. We had conducted extensive consultations with experts in health, agriculture, and homeland security. We collaborated with both the public and private sectors to develop the plan and also engaged researchers, policymakers, the public, and other stakeholders. then plan represents a shared vision of how we will responsibly integrate genomics into healthcare for the benefit of patients, healthcare providers, and society.

I would like to express my sincere gratitude to all those who contributed to the development of this plan. This includes individuals and organizations that provided financial support, technical expertise, and time towards the development of this plan. I applaud the Malawi Government for recognizing the importance of genomics in public health and taking steps towards strengthening the capacity and infrastructure for genomics applications in the country. This plan serves as a critical tool in addressing the current and future health challenges in Malawi. I am therefore, pleased to present this Malawi Genomics Implementation Plan for 2023-2030.

Hon. Khumbize Kandodo Chiponda, MP
Minister of Health

Preface

The Ministry of Health (MoH) through the Public Health Institute of Malawi (PHIM) initiated the process of developing the Malawi Genomics Implementation Plan 2023-2030. This is in line with one of the key recommendations of the PHIM Strategic Plan 2023-2030 which recommends development of a genomics implementation plan to guide Malawi's prevention and response to disease outbreaks, epidemics, and pandemics. The need for genomics to inform public health response cannot be over-emphasized. The recent global success in the fight against the COVID-19 pandemic is sufficient proof.

The genomics plan has been developed through a consultative process. Stakeholders such as government departments, implementing partners, and academic institutions immensely contributed to its development. This is the first implementation plan for genomics in Malawi. It has the following 7 thematic areas: Research and Surveillance; Health Systems Strengthening; Capacity Building for Human Resources; Data Management; Resource Mobilization, Financing, and Sustainability; Governance, Regulation, and Policy; and Stakeholder Engagement. These are priority areas that Malawi is committed to advance in genomics.

This is the most critical phase for the development of genomic surveillance in Malawi. It requires the support and contribution of all government agencies, donors, implementing partners, research and academic institutions. The government is committed to facilitating the successful implementation of the plan.

Dr. Samson Mndolo
Secretary for Health

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1. Background

1.1 Introduction

Genomics is the study of the total or part of the genetic or epigenetic sequence information of organisms and attempts to understand the structure and function of these sequences and of downstream biological products[1]. Genomic surveillance is the process of constantly monitoring pathogens and analysing their genetic similarities and differences. Genomic sequencing is a method used by scientists in the laboratory to decipher the genetic material found in a pathogen or organism[2]. Closely related to genomic sequencing and surveillance is bioinformatics. Bioinformatics is a subdiscipline that utilizes computer technology to store, analyse, and disseminate genomic data and information[3].

Surveillance of changes in the genetic makeup of pandemic and epidemic-causing pathogens remains critical in informing timely responses, for both emerging and re-emerging pathogens and diseases. Genomic surveillance provides the scientific evidence required for health systems to identify, prevent, and track disease transmission and outbreaks like COVID-19, Tuberculosis (TB), HIV/AIDS, Ebola, and others. It also informs data-driven public health actions that are tailored to local needs. Genomics is critical in the development of valuable medical commodities such as vaccines, diagnostics, and therapeutics.

This plan intends to provide guidance on the national implementation of genomics for pathogens of pandemic and epidemic potential.

1.2 Global and National Situational Analysis

Over hundred disease outbreaks are reported across the world each year[4]. Despite the increasing availability of genomic sequencing technology across the world, there are still significant inequalities in access to genomic sequencing technology between countries. This was more evident during the COVID-19 pandemic. Only 13 out of 189 countries (6.8%) were able to sequence 5% or more of their total confirmed cases in the first 2 years of the COVID-19 pandemic (2020 -

[1] World Health Organization. (2020, November 12). Genomics. Newsroom.https://www.who.int/news-room/questions-and-answers/item/genomics

[2] US Centers for Disease Control and Prevention. (2022, December 2). What is genomic surveillance?. Science. Genomics is for diagnosis and surveillance https://www.cdc.gov/coronavirus/2019-ncov/variants/genomic-surveillance.html

[3] National Human Genome Research Institute.(2023, July 24). Bioinformatics. Genetics Glossary. https://www.genome.gov/genetics-glossary/Bioinformatics

[4] World Health Organization. (2023, March 17). Disease Outbreak News. Emergencies. https://www.who.int/emergencies/disease-outbreak-news

2022)[5]. Eighty-six (86) out of 189 countries sequenced 0.5% of their COVID-19 confirmed cases and the rest were unable to do any sequencing[4]. A higher percentage of countries that were able to sequence more than 0.5% of their confirmed COVID-19 cases were high-income countries. Low and middle-income countries were less likely to do so.

Key contributors to the current disparities in genomic sequencing globally include varied investment priorities in national health, research, and development programs[6]. High-income countries have used previously established networks and infrastructure to conduct genomic surveillance. Most low-and-middle-income countries lack such existing south-to-north and north-to-north networks and infrastructure[7].

The Africa Center for Disease Control (Africa CDC) reported in September 2022 that 78% (42/54) of African countries, which include Malawi, had the capacity to produce SARS-CoV-2 genomes[8]. Only 8 of the 42 countries were able to generate all the genomes in-country. The rest, which included Malawi, had some genomes generated in-country and others outside.

There is limited policy guidance and funding for genomic sequencing in Malawi. The Government of Malawi (GoM) has expressed interest to increase investments in genomics and capacity building. The World Health Organization (WHO) has recently published the Global Genomic Surveillance Strategy for Pathogens with Pandemic and Epidemic Potential 2022-2023[9], which will support the government's efforts to expand its capacities and bring harmonized approaches to robust local-to-global genomics implementation.

1.3 SWOT Analysis

The GoM through the Public Health Institute of Malawi (PHIM) provided national leadership in developing the Malawi Genomics Implementation Plan 2023-2030. Eight (8) thematic areas were identified in line with WHO's Global Surveillance Strategy for Pathogens with Pandemic and Epidemic Potential 2022-2032[10] . A SWOT analysis was conducted to identify the strengths,

[5] Brito, A.F., Semenova, E., Dudas, G. et al. Global disparities in SARS-CoV-2 genomic surveillance. Nat Commun 13, 7003 (2022). https://doi.org/10.1038/s41467-022-33713-y

[6] Fatumo, S., Chikowore, T., Choudhury, A. *et al.* A roadmap to increase diversity in genomic studies. *Nat Med* **28**, 243–250 (2022). https://doi.org/10.1038/s41591-021-01672-4

[7] Stark, Z., Dolman, L., Manolio, T. A., Ozenberger, B., Hill, S. L., Caulfied, M. J., ... & North, K. N. (2019). Integrating genomics into healthcare: a global responsibility. *The American Journal of Human Genetics*, *104*(1), 13-20.

[8] Tegally, H., San, J. E., Cotten, M., Moir, M., Tegomoh, B., Mboowa, G., Martin, D. P., Baxter, C., Lambisia, A. W., Diallo, A., Amoako, D. G., Diagne, M. M., Sisay, A., Zekri, A.-R. N., Gueye, A. S., Sangare, A. K., Ouedraogo, A.-S., Sow, A., Musa, A. O. et al. The evolving SARS-CoV-2 epidemic in Africa: Insights from rapidly expanding genomic surveillance. Science 378, eabq5358, doi:doi:10.1126/science.abq5358 (2022)

[9] World Health Organization (2022). Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032. Geneva.

[10] Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

weaknesses, opportunities, and threats of genomics in Malawi (See Appendix 1). Each of the 7 thematic areas was analysed. Issue statements, strategic objectives, and activities for this plan were derived from the outcomes of the SWOT analysis.

1.4 Guiding Principles for the Implementation Plan

The GoM will maximize the benefits of genomics by adhering to the following guiding principles:

1.4.1 Commitment and Ownership: The GoM will set priorities for genomics through the National Genomics Committee (NGC) with its secretariat at PHIM. The GoM will lead the development of activities, work plans, and outputs for genomics applications. It will integrate genomics into the national laboratory and surveillance systems. The GoM will also drive fundraising efforts for genomics. This includes securing domestic financing through the Treasury. The GoM will also source international funding from donors. It will also strengthen and maintain links with the national, regional, and international networks for genomics.

1.4.2 Maximizing Return on Investment: The GoM will take WHO's five-dimensional approach to maximizing return on investment. The dimensions are economy, efficiency, effectiveness, equity, and ethics[11]. The GoM will ensure effectiveness of genomics through strong quality assurance systems. It will drive equity in genomics by prioritizing the most vulnerable and hard-to-reach populations. The GoM will implement an ethical genomics program by ensuring that the inputs, outputs, and outcomes of the program uphold respect, goodwill, and justice, and do not cause any harm.

1.4.3 Sustainability: The GoM will take a stepwise approach to build capacity in genomic. It will continually assess needs and opportunities to optimize and align with Malawi's priorities for the surveillance of pathogens of pandemic and epidemic potential. It will promote partnerships that invest and support the sustainability of genomics.

1.4.4 Shared Responsibility: The GoM will collaborate with national, regional, and global partners to achieve the goals and objectives of the genomics program. Key partners include Africa CDC, U.S. Centers for Disease Control and Prevention (CDC), WHO, academia, private sector, civil society, non-governmental organizations (NGOs), and others.

1.4.5 Local and Global Outlook: The GoM will set up Malawi's genomics with a local and international interface. Public health actions at the sub-national and national levels have ripple effects at the regional and global levels. Pathogens with pandemic and epidemic potential know no borders. The GoM will participate in local, regional, and global efforts to respond to emerging and re-emerging pathogens of pandemic and epidemic potential.

[11] Executive Board, 142. (2018). WHO reform: better value, better health Strategy and implementation plan for value for money in WHO: report by the Director-General. World Health Organization. https://apps.who.int/iris/handle/10665/273978 accessed 9 March 2022.

1.4.6 Ethics Consideration and Management: The GoM will implement ethical genomics by ensuring that the inputs, outputs, and outcomes of the program uphold respect, goodwill and justice, and do not cause any harm. The NGC will collaborate with the National Health Sciences Research Committee (NHSRC) and other local institutional review boards (IRBs) to ensure ethical conduct of genomic research. The GoM will maintain open dialogue with the public, patients, patient interest groups, and other stakeholders to ensure ethical implementation of all genomic activities.

1.5 Implementation of the Plan

Successful implementation of the genomic surveillance plan will require the following enabling factors:

1.5.1 Building on and aligning with existing assets: The GoM recognizes that genomics is cross-cutting and requires a wide range of expertise. MoH will work with donors, implementing partners, research and academic institutions, and other sectors to identify priority areas, available resources and assets for genomics in human, animal and environmental health.

1.5.2 PHIM's leadership: PHIM will provide overall leadership in the implementation of this plan and ensure that end-to-end surveillance and laboratory systems are strengthened and sustained.

1.5.3 Partnerships and networks: Genomics requires local and international multisectoral engagements. The GoM will promote partnerships that will strengthen Malawi's ability to detect, analyze, and utilize genomic data for public health action. The GoM will leverage local and international partnerships to meet the large-scale need for sequencing and bioinformatics.

1.5.4 Financing: Genomic sequencing and surveillance requires substantial investments in human resources, infrastructure, supply chain, and other areas. The GoM, the private sector, and donors will collaboratively finance this implementation plan (See Appendix 2).

1.6 The Role of PHIM in the Implementation of the Genomics Plan

PHIM will be the central coordination unit for the implementation of this plan. It will:

1. Coordinate resource mobilization activities.
2. Lead capacity building for genomics.
3. Develop and maintain a national, regional, and global genomics network.
4. Monitor the progress of stakeholders in the implementation of the plan (See Appendix 3).

1.7 Rationale

Building genomics capacity requires a well-coordinated plan. The GoM developed this plan to provide direction for the implementation of genomics in Malawi. It will provide direction on the allocation of human resources, equipment, and other investments. The plan also proposes sustainable systems strengthening activities for genomics in the country.

1.8 Overall Goal

The goal is to develop and strengthen local genomics capacity for quality, timely, and appropriate public health actions.

1.9 Specific Objectives

The specific objectives of the plan are to:

1. Highlight priority areas for strengthening towards building world-class genomics capacity in Malawi.
2. Harmonize genomics efforts of different stakeholders towards achievement of national public health goals.
3. Set out a high-level approach on the implementation of genomic activities in Malawi.
4. Act as a tool for resource mobilization for genomics in Malawi.

1.10 Linkage with Policy Documents

Pillar 7 of the Health Sector Strategic Plan III 2023-2030 (HSSP III)[12] is health research. One of the strategies under this pillar is to achieve the development of evidence-based policies in the health sector. This will be achieved through the intensification of knowledge generation, translation, and utilization of research. Genomics will generate knowledge through the sequencing and surveillance of pathogens of epidemic and pandemic potential. It will also compile and analyse disease and events surveillance data to support the detection of outbreaks and implementation of international health regulations. The HSSP III also highlights the multisectoral nature of health and by extension genomics. It intends to strengthen vector and vermin control, pandemic, disaster preparedness response and surveillance of diseases. It encourages collaboration between the health sector and other sectors in conducting disease surveillance and response.

[12] Ministry of Health (2022). Health Sector Strategic Plan III 2023-2030. Lilongwe, Malawi

PHIM's Strategic Plan 2023-2030 recognizes advances in genomics as an opportunity to guide public health practice. PHIM is committed to advancing public health surveillance and epidemiology in Malawi under objective 3 of its strategic plan.

This plan is also in line with the Malawi National Strategic Plan for HIV and AIDS 2020-2025[13]. It refers to HIV drug resistance monitoring as one of the game-changing strategies in the fight against HIV. Genomics is the backbone of HIV drug resistance monitoring. The HIV program is determined to use HIV drug resistance monitoring to achieve its set targets in the next five years. This will set Malawi on the path to reaching Sustainable Development Goal Target 3.3 to end the AIDS epidemic by 2030 and contribute to National Health and Development goals.

Implementation of genomics in Malawi is also linked to the National Tuberculosis and Leprosy Control Strategic Plan 2021-2025[14]. The National TB Program has a strategy to expand the coverage of new TB diagnostics and drug resistance detection. Genomics will support these efforts. Genomic surveillance will help the TB program to effectively detect, track, and treat cases of drug resistant and multi-drug resistant TB in Malawi.

Genomics is a cross-cutting service. The GoM will coordinate efforts across different disease control programs to identify priority pathogens for surveillance. The GoM will remain flexible to plan and respond to emerging pandemics (e.g., COVID-19) and epidemics (e.g., Cholera) as the situation demands.

2. Thematic Areas

2.1 Research and Surveillance

2.1.1 Research on pathogen genomics

Research on pathogen genomics requires careful planning, resource allocation, and stakeholder engagement. To strengthen stakeholder partnership and collaboration, PHIM will extend membership of the NGC to include experts in genomic sequencing and surveillance, healthcare providers, patient advocacy groups, and government agencies. The committee will identify research priorities that align with the national health agenda and will develop a set of criteria for prioritizing research areas based on disease prevalence, morbidity, mortality, and social impact. Due to limited resources the committee will use the established criteria to identify research priorities and allocate resources based on the identified priority areas.

Government through the NGC will also engage with healthcare providers, patient advocacy groups, and government agencies to gain support and collaboration for the research program. A

[13] National AIDS Commission (2020). National Strategic Plan for HIV and AIDS 2020-2025. Lilongwe, Malawi.
[14] Ministry of Health (2021). National Tuberculosis and Leprosy Control Strategic Plan 2021-2025. Lilongwe, Malawi.

monitoring and evaluation plan will be developed and used to track progress and ensure the delivery of desired research outputs.

2.1.2 Collaboration with partners

Collaboration with established research institutions can help leverage resources and expertise, lower costs, and accelerate research progress. The GoM will identify potential partners for collaboration in genomic research. These include academic institutions, government agencies, healthcare providers, and the private sector. A National Genomics Research Network (NGRN) will be established to conduct research in line with the national research agenda.
The GoM in collaboration with its stakeholders will co-develop research proposals, standard operating procedures for specimen, data and information sharing. Regular meetings and workshops will be conducted to promote collaboration and information sharing.

2.1.3 Timely detection of emerging pathogens and variants

Emergence of new pathogens/variants is a significant public health challenge. Early detection of these emerging pathogens/variants is critical for understanding their potential impact on public health and developing effective countermeasures. To strengthen the timely detection of emerging pathogens variants there is a need to increase genomic surveillance efforts, cross-border collaboration, and monitoring of high-risk populations.

The GoM will leverage its partnerships with academic institutions and research organizations to increase the capacity for sequencing and will expand the geographic coverage of genomic surveillance efforts by establishing more strategic sequencing centres and networks across the country. Surveillance systems will be established to monitor high-risk populations including healthcare workers, vulnerable populations, immunocompromised individuals, and frequent travellers. Protocols for timely reporting cases of emerging pathogens/variants and targeted interventions in high-risk populations will be developed and implemented to prevent the spread of emerging pathogens/variants.

A cross-border working group will be established with neighbouring countries to share information on genomics efforts and emerging pathogen discovery. The working group will develop protocols for the exchange of data, samples, and expertise. It will also conduct joint investigations to identify and respond to potential outbreaks of emerging pathogens. The working group will develop and implement data sharing policies that ensure the protection of sensitive data and patient privacy.

2.1.4 Preparedness and readiness for emergencies

Genomic research and surveillance are valuable tools. They also come with risks and challenges including possibilities of release of hazardous/infectious materials, breaches of privacy, and ethical concerns about genetic data collection and use. This may compromise biosafety and biosecurity standards. To ensure the safety of both personnel and the wider community, genomic sequencing

and surveillance facilities must develop comprehensive emergency plans and regularly update them. These plans will encompass various scenarios, including natural disasters, accidental releases of hazardous or infectious materials, cyber-attacks, and other emergencies.

The facilities will also conduct regular risk assessments to identify potential hazards and vulnerabilities. They will use this data to prioritize preparedness activities and tailor emergency plans to specific risks. The facilities will establish effective communication protocols that allow for the rapid dissemination of information to relevant stakeholders such as employees, emergency responders, and the public. They will train all staff in emergency procedures and protocols. The facilities will also maintain emergency supplies on hand to ensure that essential operations can continue in the event of an emergency.

2.1.5 Capacity of genomic surveillance systems in emergencies

Surge exercises will be conducted to test the capabilities of genomic surveillance systems. The exercises will simulate an increase in the number of cases of a specific pathogen or the emergence of a new disease to test the system's ability to keep up with the rapid or increased demand for sequencing and analysis in a timely manner. PHIM will design surge exercises to simulate an outbreak of a specific pathogen, or a new pathogen guided by SOPs that will stipulate how genomic sequencing will be implemented during outbreaks.

PHIM will use the surge exercises to identify any weaknesses or bottlenecks in the genomic surveillance system. These may include sequencing capacity limitations or data analysis delays. The GoM will develop and implement strategies to address these weaknesses/bottlenecks. The exercises will be repeated on a regular basis to assess the effectiveness of the genomic surveillance system's improvements.

2.1.6 Inclusion of genomics in routine surveillance

The GoM will include genomics in routine disease prevention, preparedness, and response. This will help to quickly identify the source of outbreaks, track the transmission of pathogens, and develop targeted interventions to prevent further spread.

The GoM will develop and implement a data-sharing platform to facilitate the exchange of genomic data among public health agencies and researchers. The NGRN will conduct pilot studies to assess the feasibility and effectiveness of incorporating genomic sequencing into routine surveillance practices. It will develop guidelines and standard operating procedures for the routine use of genomic surveillance in disease surveillance, prevention, preparedness, and response.

2.1.7 Promote ethical practices.

Genomics raises ethical issues about privacy, data ownership, and the responsible use of genetic information. The National Health Sciences Research Committee (NHSRC) and other local institutional review boards (IRBs) will review from time to time and update guidelines on the ethical collection, storage, and use of genomic data. The IRBs will consult with stakeholders such as patient advocacy groups, healthcare providers, and government agencies to ensure that the guidelines reflect a wide range of perspectives.

The IRBs will also conduct public education and awareness programs. The programs will provide information about genomic research and its ethical implications. The IRBs and all stakeholders will conduct public forums, educational campaigns, and outreach activities that engage the public and promote a better understanding of the science behind genomic research.

2.2 Health Systems Strengthening

2.2.1 Infrastructure and equipment for genomic sequencing

The GoM will invest in infrastructure and equipment for genomic sequencing. Periodic needs assessments will be conducted to determine the state of infrastructure and equipment. The GoM will collaborate with stakeholders to develop budgets and secure funding for the equipment and infrastructure. The GoM will procure appropriate next-generation sequencing platforms based on need and will construct and refurbish sequencing laboratories to house the equipment.

The GoM will invest in dry and cold storage equipment, power backup, and water supply at all the sequencing laboratories.

The GoM will also invest in ICT infrastructure such as data storage systems, computers, servers, networking equipment, and bioinformatics platforms.

2.2.2 Collaboration with local and international partners

The GoM will collaborate with other institutions both locally and internationally to increase access to equipment and expertise as needed. The GoM will engage with private laboratories, academic institutions, and industry partners to share knowledge, expertise, and best practices.

2.2.3 Sustainable equipment maintenance plans

The GoM through the Physical Asset Management (PAM) Unit will conduct thorough assessments of equipment inventory for genomic sequencing to identify the types of equipment and their specific maintenance needs. Equipment that requires regular maintenance and ones that require more infrequent maintenance will be listed. A maintenance schedule that outlines the frequency and type of maintenance required for each piece of equipment will be developed based on a

prioritized list. The GoM will continuously monitor and evaluate the effectiveness of the maintenance plan, identify areas for improvement, and adjust as needed.

The GoM will also develop an equipment donation policy to ensure that the country receives appropriate equipment that can be easily maintained and sustained. The GoM will establish equipment maintenance contracts with equipment manufacturers and train local engineers on maintenance of the equipment.

2.2.4 External quality assessment programs for genomic sequencing

All genomic sequencing laboratories will be required to participate in external quality assurance (EQA) programs coordinated by PHIM. The EQA programs will include software validation and evaluation besides the wet lab processes.

The GoM will identify local or international EQA providers that offer EQA. The EQA program will include the types of genomic sequencing tests included, reporting of results, and the provision of feedback.

Institutions performing genomic sequencing will develop and implement improvement plans to address any identified areas for improvement.

The GoM will track EQA progress to ensure that the program is effective and that any improvements are sustained over time. This will include ongoing monitoring of EQA results and participant feedback.

2.2.5 Supply chain management and logistics

Supply chain is an integral part of genomic sequencing. A well-coordinated supply chain system helps to have the right commodity in the right quantity at the right place, at the right time, and in the right condition which is key to avoiding service interruption due to stockouts and expiries.

The GoM will oversee the supply chain through national diagnostics supply chain specialists who collect data, quantify the needs, and procure the commodities. These specialists will also distribute the commodities, monitor consumption, and storage. They will also conduct regular physical inventories. The GoM will train facility focal persons for genomic sequencing commodities management.

A list of reagents and consumables based on equipment and targeted organisms will be developed and revised from time to time. Despite careful planning and management, unexpected events such as supplier delays, equipment breakdowns, and natural disasters can disrupt the supply of reagents and consumables. The genomic sequencing laboratories will develop contingency plans that will outline how the laboratory will respond to such events and ensure that the plan is regularly reviewed and updated.

The GoM will standardize equipment to simplify its supply chain and will procure WHO prequalified or CE-IVD marked equipment and reagents. Two to three types of pre-qualified next-generation sequencing equipment will be in use to encourage competition among suppliers. The sequencing equipment will be selected based on price, usability, and other factors.

The GoM will invest in improved storage capacity in all laboratories providing genomic sequencing services to safeguard the quality of reagents. The GoM will procure and install appropriate laboratory refrigerators and freezers. The GoM will also invest in on-site dry storage facilities.

2.2.6 Sample collection, transportation and storage

Good quality samples, well-designed sample transport systems and optimal sample storage conditions are essential for the delivery of quality centralized genomic sequencing services. The GoM will train adequate staff to collect samples at all genomic surveillance sentinel sites. All sentinel sites will be equipped with adequate sample collection materials and storage equipment.

The GoM will train couriers on sample transportation and safety. It will also monitor the couriers' adherence to the sample transportation procedures.

2.3 Capacity Building for Human Resources

2.3.1 Staffing, training, and certification

The GoM will advocate for the recruitment of sufficient laboratory scientists, bioinformaticians, epidemiologists, and other staff. These will support sequencing, analysis, reading, and interpretation of findings for different disease pathogens.

Trained laboratory staff will be required to periodically participate in EQA and inter-laboratory comparison to maintain quality and consistency in delivering results.

Training for genomics personnel will be a priority. The GoM will ensure that its staff are trained and certified accordingly. The GoM will ensure that its staff are up to date on novel genomic sequencing and surveillance techniques. The GoM will also advocate for adequate training and certification of staff working in other genomic sequencing laboratories and surveillance institutions. It will leverage its partnerships with CDC Malawi, Pathogen Genomic Institute (PGI) at Africa CDC, the African Society for Laboratory Medicine (ASLM), local academic institutions, and other partners to provide relevant training.

The GoM will engage partners and academic institutions to develop comprehensive curricula and SOPs for on-the-job training. The GoM will ensure master trainers are identified to train others. The master trainers will also provide mentorship as needed. The mentorship will include sequencing, troubleshooting of EQA, data collection, reporting, and other areas.

2.3.2 Training programs in genomics

The GoM will routinely assess training needs and provide appropriate training opportunities to employees. The GoM intends to attract, develop, and retain a highly skilled, motivated, and dedicated genomics workforce to achieve Malawi's vision for genomic surveillance. The GoM will clearly define career paths for scientific and clinical roles in genomics. It will specify the number of higher specialist scientist training positions in bioinformatics and genomics in the HSSP.

It will also collaborate with academic institutions in establishing genomics courses and providing scholarships for employees. The courses shall be a combination of classroom modules, e-learning modules, workshops, and hands-on training.

2.3.3 Knowledge exchange programs

The GoM will identify partners for knowledge exchange programs. The GoM and partners will clearly define the goals of the knowledge exchange programs. They will plan knowledge exchange activities that will include workshops, conferences, webinars, and online forums. The GoM will routinely assess the impact of the exchange programs on the target audiences. The GoM will secure funding from various sources to evaluate the effectiveness of the programs as needed. The GoM will make appropriate changes to improve the effectiveness of the programs based on participant feedback.

2.3.4 Genomics curricula in professional training institutions

The GoM will engage local academic institutions to include genomics in their training curricula. This will include genomics for human and animal health. It will also include updating content of existing bioinformatics programs. The GoM will also work with academic institutions to update curricula for biomedical engineers to include maintenance of genomic sequencing equipment.

2.4 Data Management

Data management is a very important aspect in genomics. The GoM will adopt strategies and methodologies that will ensure optimal utilization of genomic data.

2.4.1 Data and information management systems

The GoM will implement digital systems for capturing, storing, processing, and utilizing data. The GoM will ensure that the data management systems are secure, easy-to-use, scalable, interoperable, and sustainable.

2.4.2 Hardware, software, and networking equipment

The data management systems will require advanced hardware, software, and networking equipment. The GoM will regularly assess its ICT infrastructure to establish needs. The assessments will cover computer hardware, software, and networking equipment. Private and research institutions will be required to do the same. The GoM will standardize hardware, software, and networking equipment used for genomics.

2.4.3 SOPs for data management

The GoM will develop SOPs to guide the setup, use, and maintenance of data management systems. The SOPs will ensure uniformity of systems among all stakeholders.

2.4.4 Data sharing agreements

The GoM will develop data sharing agreements with both local and international partners. This will be intended at enhancing data sharing and use. The GoM will use these agreements to safeguard the privacy and security of the data.

The GoM will develop a framework that provides guidance and consensus on data and meta-data standards. These standards will uphold privacy, security, and national sovereignty. They will also regulate the sharing of contextual information to accompany genomics data.

2.5 Resource Mobilization, Financing, and Sustainability

Implementation of comprehensive genomics requires large investments in human resources, infrastructure, supply chain, and other areas. The required resources cannot be met by the government alone. The GoM will explore partnerships at the national, regional, and global levels to mobilize resources for the implementation of genomics.

2.5.1 Funding from the government

PHIM will lobby for government funding for genomics through the Treasury. PHIM will collaborate with different government departments and ministries to plan and prioritize resources for genomics. PHIM will also collaboratively plan with the government departments and ministries to mobilize resources for any identified gaps.

2.5.2 Funding from donors and partners

The GoM will continue to collaborate with donors and implementing partners to secure funding and other resources for genomics.

2.5.3 Collaboration with regional and global institutions in mobilizing resources

The GoM will strengthen its collaboration with regional and global partners such as the CDC, Africa CDC, and WHO in mobilizing resources for genomics. The GoM will collaborate with these institutions to apply for regional and global grants to strengthen genomics in Malawi.

2.5.4: Collaboration with private sector, research, and higher learning institutions

The GoM will collaborate with both the private sector and research institutions to maximize available resources for genomics. The GoM will co-apply for grants with local research institutions to finance research in priority areas for genomics.

2.5.5: Public-private partnerships

The GoM will strengthen public-private partnerships for the benefit of genomics. The GoM will negotiate pricing agreements with manufacturers and suppliers of reagents, laboratory equipment, ICT equipment, software, and other resources.

2.5.6: Income generating activities

PHIM will leverage its infrastructure to support sustainability goals through income generating activities. Part of the generate income will be allocated to genomics.

2.6 Governance, Regulation, and Policy

Genomics requires strong governance, policy, and regulations to safeguard the interests of the general public and improve health outcomes. Successful implementation of governance, policy, and regulations will require multi-sectoral collaboration.

2.6.1 National genomics committee

The NGC will set priorities for genomic surveillance in Malawi. This will ensure that the country realizes the benefits of genomics. It will also govern and regulate genomics in Malawi. The NGC will govern and regulate genomics for public, private, and academic institutions. The committee will be chaired by the highest officer within PHIM and all PHIM and the secretariat. for the committee will be hosted by PHIM.

The GoM will ensure that the secretariat is adequately staffed and funded to carry out its activities.

The secretariat will provide quarterly updates to the national committee to keep members - up to date with ongoing genomic surveillance activities in the country. This will be done in line with PHIM's objective of improving coordination and collaboration in the implementation of international health regulations.

2.6.2 Multi-sectoral policy on genomics

The GoM will develop a multi-sectoral policy on genomics in line with the One Health approach. All stakeholders including PHIM and all government departments will follow the same national policy on genomics. The policy will also set out rules of engagement for the different government ministries involved.

2.6.3: Regulation

Implementation of regulatory activities for genomics will require interagency collaboration within the government. The Pharmacy and Medicines Regulatory Authority (PMRA) will regulate the registration of genomic sequencing equipment and reagents. The Medical Council of Malawi (MCM) will certify laboratory staff and infrastructure for sequencing. The Malawi Bureau of Standards (MBS) will enforce compliance with standards for genomic sequencing laboratories as may apply. Academic institutions will certify bioinformaticians and other staff involved in genomics.

2.6.4 Quality management systems for genomics HIM will lead the implementation of quality management systems for genomics in Malawi. This includes sample collection and transportation, sequencing, data management, interpretation, and use of genomic information.

2.6.5: Biosafety and biosecurity

The GoM will adhere to stringent international biosafety and biosecurity guidelines on the management of pathogens. This will ensure the protection of laboratory staff and containment of the pathogens.

2.7 Stakeholder Engagement

2.7.1 Updates to relevant technical working groups

PHIM will provide quarterly updates on genomics to relevant technical working groups of disease programs as the need arises.

2.7.2 Sensitization of the public, patients, and healthcare providers

The GoM will conduct sensitization activities for the public, patients, and healthcare providers. The Health Education Unit (HEU) will lead these activities. HEU will develop materials and organize activities for sensitization. HEU will also collaborate with the media in these activities.

The aim of the sensitization activities will be to increase awareness and understanding of the potential benefits of genomics. The GoM will engage in open and honest conversation about what is involved in genomics.

2.7.3 Support from implementing partners

There is need to increase awareness of genomics in the country. The GoM will require support from implementing partners. The GoM will advocate for inclusion of budgets on sensitization activities in the annual plans of implementing partners. Implementing partners will support the government with conducting the activities in their geographic areas of support.

2.7.4 Basic genomics information in the curricula of primary and secondary schools

The GoM will intensify awareness of genomics in primary and secondary schools. The Ministry of Education, Science and Technology (MoEST) will include basic information about genomics in the primary and secondary school curricula. This is aimed at increasing awareness and understanding of genomics among primary and secondary school students. It is also aimed at helping students consider pursuing careers in genomics.

3. Appendices

Appendix 1: SWOT Analysis of Genomic Surveillance in Malawi

No.	Thematic Area	Strengths	Weaknesses	Opportunities	Threats	Statements on the issues	Strategies/objectives for addressing identified issues
1	Research and surveillance	1. Existing disease ecific surveillance i.e V,Sentinel COVID-19/Influenza), TB, CHOLERA 2. Availability of IDSR structures 3. Availability of trained t district y levels. of FETP 5. Existence of FETP Program that can train surveillance staff 6. Availability of HIMS (DHIS2) platform 7. Availability of LIMS 8. Staff from animal d in nce is n animal health and human health 10. Availability of mple transportation stem 11. Availability of research laboratories	1. Integration of animal iman health lance not fully 2. Low research pacities at district el 3. Poor transmission of ality data to national el 4. Few sequencing uipment, no national tabase for genomic system 5. No fully established MS in district hospital Isolated LIMS 7. Limited surveillance systems in government structures 8. Limited expertise 9. Inadequate resources 10. Limited funding 11. Lack of capacity to rvice the sequencing uipment 12. Reliance on external support 13. Lack of funding for ecific disease rveillance	1. Availability of ers, SLM etc, f licy 3. Renewed global erest to build llaborative surveillance systems 4. Presence of other partners 5. Availability of stitutions to partner th MLW, John Hopkins, KUHES 6. Availability of global rveillance data atforms 7. Availability of grants	1. Global economic crisis 2. Emerging or re-emerging of new diseases 3. Donor fatigue 4. Competing priorities Misaligned interest in rveillance 6. Funding for disease specific surveillance,	1. Lack of awareness 2. Genomic surveillance	1. Implement priority search on genomic quencing 2. Include genomic ncing research in tional research a 3. Improve access to rgencies 5. Strengthen timely tection of emerging riants 6. Implement targeted 8. Support and strengthen national

		12. Availability of ures at at ained t genomic 13. Availability of ıipment ent of it at PHIM of la					networks in routine, idemic and pandemic ntexts 9. Test the ability of ce cy es -sized capacity levels during utine and acute event riods 10. Make the use of genomics routine in surveillance
2	Health Systems thening: ructure and nent	1. Availability of uipment for quencing 2. Availability of storage uipment for samples d reagents 3. Available data computation and e infrastructure overnment tions 4. Availability of upport for : service and ce within the	1. Poor infrastructure ıge and eripheral 3. Lack of collaboration with other countries 4. Individual GS laboratories have a separate data server 5. Slow internet network Lack of calibration of ıuipment & ancillary 7. Lack of reliable back up power	1. Available networks r collaboration or joint ojects 2. Space available for nstruction of new rastructure 3. Funders available to 'ation of ɔs and nore : 4. Basic infrastructure available for scale up of GS services 5. Availability of uipment on the arkets 6. Availability of ructure that can ovated to Gene ncing labs	1. No service contracts for equipment 2. No plan for upgrade of equipment 3. Reliance on donors chase of : and ure ent 4. Manufactures not committed to all-inclusive deals 5. Expensive to maintain hence difficult to sustain	1. Sequencing nents available in facilities within y 2. Lack of a centralized bio-bank for different samples 3. Reliable and nable back up is required in institutions 5. Need for a standalone national referral genomic sequencing lab. ıge and ł n s. 7. Lack of collaboration th others within the gion and beyond. 8. Lack equipment for ɔrage of large volumes data.	1. To have in place long lans for nent service and enance 2. Increase and centralize the storage capacity of biorepositories. 3. Link genomic quencing labs to the tional data centre 4. Install reliable and nable power ɔ to support ions. 5. Strengthen ɔoratories to conduct ulti-pathogen genomic ough f high est nd plies 6. To lobby for provision of storage and transportation nent and ructure in eral sites.

							7. To enhance good collaboration within Africa and beyond 8. Increase laboratory space (renovation and construction)
3	Capacity Building (Human Resources)	1. Laboratory personnel trained in genomic sequencing 2. Availability of staff across all cadres 3. Establishment of bioinformatics training at KUHeS 4. Availability of FETP program 5. Availability of trained sample collectors in sentinel sites	1. Limited capacity to conduct genomic research 2. Limited personnel specialized in genomic sequencing 3. Reliance on partner supported staff 4. Lack of trained bioinformaticians 5. Lack of staff retention 6. Lack of funding to recruit more laboratory and computational personnel	1. Availability of committed fund to train more people 2. Committed leadership to provide and train more people 3. Good collaboration with teaching institutions 4. Availability of specialized training in Gene sequencing in the country and outside	1. Reliance on external training institutions 2. Availability of international jobs 3. Slow absorption of trained staff in the system. 4. Reprogramming of committed funding due to other priority needs including reagents	1. The country has enough HR to support the GS but there is need to train the available human resource 2. There is increasing demand for genomic sequencing coming up which calls for more human resource 3. A huge governance drive to have GS activities to kick and support from MoH and donor community, a drive which will make sure that the country has all specialized people to support GS.	1. To have all well-trained staff to support Gene sequencing testing services 2. To recruit and train data staff to support data quality and management 3. To have an NSP with costed HR and capacity building activities 4. Support the development of SoPs and curriculum for sample collection and testing trainings
4	Supply Chain Management and Logistics	1. Availability of Supply Chain Management System 2. Availability of genomic sequencing reagents on the market 3. Capacity to quantify supplies in country using appropriate tools 4. Trained staff available 5. Availability of partners (CDC, WHO, UNICEF, Global Fund) for funding of supply chain management and logistics 6. Availability of national transportation system 7. Availability of national	1. Lack of storage Space at the Laboratory level 2. Lack of capacity in-country to meet cold or frozen transportation conditions (Dry ice, Liquid nitrogen) 3. Weak distribution system of commodities at national level and inability to re-distribute 4. No clear policy for disposition of commodities and equipment 5. Unavailability of rapid and response transportation system 6. Donor dependency	1. Supply chain management trainings available for staff 2. Availability of paper-based Inventory management systems 3. Funding for more commodities procurement to scaling up GS. 4. More commodities becoming available which will make commodities cheaper 5. Political will supporting the Genomic Sequencing 6. Availability of qualified personnel who	1. Unforeseen program or policy changes which would affect the scaling up of Genomic surveillance 2. Effects of travel restrictions on the importation of commodities due to pandemics or natural disasters 3. High cost of reagents making it difficult to sustain 4. Inconsistency of available and committed funding 5. Change in priority of policy or donor	1. Though the country has an existing system with confirmed funding, it is important to consider evaluation of the system to accommodate the following: a. How best does the current supply chain system accommodate genomic sequencing b. How much funding is required c. What areas in supply chain need investment d. What innovations should be supported by the GS NSP.	1. Have defined and costed NSP with commodity budgeted 2. Standardize equipment to be used of GS in the country 3. Train more lab supply chain specialists and pharmacist to understand GS commodities 4. Support quality data availability for proper quantifications of commodities

		storage space for Cold chain freezer and room temperature	7. Lack of equipment harmonization which affects commodity procurement 8. Lack of quality data to be used for quantifications exercises	could be trained in Genome sequencing 7. Availability of specialized trainings where more staff could be trained. 8. Genome Sequencing gic plan d which cale up tation.	commitment due to aks and mics of different es. 6. Discontinuation of the different nes available in untry 7. Unavailability of commodities with the manufacturers	e. What commodities are used/needed based on the available existing platforms	
5	Data Management	1. Availability of Digital Health Division to support implementation of Digital Health Solutions 2. Availability of government's well-equipped Data Centers for data storage, processing and management 3. Availability of reliable and stable internet (Fibre, Broadband, mobile, etc) 4. Availability of Laboratory Information Management System that is scalable and can accommodate genomic sequencing workflows 5. Availability of surveillance Data Management System OHSP in DHIS2 6. Availability of legal framework to help protect patient data (Access to information Act 2016, Electronic Transactions Act 2016, Malawi National Health Information Policy 2015,	1. Limited expertise for bioinformatics 2. Siloed Data management systems 3. Disease specific data management systems 4. None existent of integrated national Health Information Management system for all diseases	1. Collaboration amongst institutions 2. Opportunities for funding from partners 3. Political will and government commitment to prioritize Genomic sequencing 4. With impact of Covid-19, genomics has been one of the priorities to improve data management in managing epidemics 5. Availability of governance system in alignment to digital health	1. High costs in purchasing and sustaining the data management equipment 2. Limited Financial resources to train staff in data management 3. Heavy reliance on donor-funding compromising sustainability	1. There is a need for sufficient funding to train more bioinformaticians. 2. There is need to utilize the newly constructed and equipped data centres in order to host MoH systems that must include genomic sequencing system 3. There need to develop genomic sequencing workflows, test and results management in existing LIMS 4. There is need to improve LIMS to create a multi-disease system that must include genomic sequencing 5. Standards must be applied to genomic surveillance systems to ensure that data is effectively interpreted and shared, and that essential meta data is captured for maximum utility. 6. There is need to	1. Train more bioinformaticians 2. Buy more servers or opt to use cloud-based storage facilities 3. Expand the capacity and scope of the existing Laboratory Information Management System to become multi-disease system 4. Develop consensus on data and metadata standards that respect data privacy and national sovereignty while balancing the importance of contextual information to accompany genomic sequencing data 5. Establish explicit data sharing and access principles that are widely agreed-upon to promote transparency and rapid and equitable dissemination 6. Ensure that data sharing agreements are already in place prior to acute events to promote

		SOP on Data Access and lease, Digital Health rategy 2020-2025) 7. Availability of partners supporting plementation of gital health solutions 7. Availability of personnel training and on data ent				provide strong for proper ent of digital itions in	timely collaboration and coordination

6	Resource mobilization, ıancing and stainability	1. Existing donor encies and plementation Partners (CDC, USAID, -ı, UMB, CHAI, DAPP, PIEGO) 2. Government political :lusion of the ırveillance :he PHIM lan	1. Lack of overall tional budget for nomic sequencing 2. Lack of dedicated ıment funding ds genomic ıcing 3. Lack of national strategic plan 4. No existing policy on genomic sequencing 5. National disease ıave d approach enomic ;	1. Existing potential s: ASLM, BMGF, CDC, World Bank, Fund, UNITAID, USAID, US CDC, European Union, etc 2. Africa CDCs lize ber level ces 4. Involve SADC in nomic sequencing and ease surveillance 5. Partnerships with ademic and research stitutions 6. Leverage resources for NCDs and One Health 7. Multi-sectoral accountability ımework :countability, data sharing)-next meeting to om rs ICT, olicy vel 8. Industry partners e.g. stic equipment acturers, ICT nies, banks, etc 9. Conduct local acturing of stics and eutics	1. Balance between 2. Unequitable sharing resources (e.g. low ioritization for the Africa region, unfavourable pricing structure for supplies)	1. Robust local donor and implementing partner community 2. Strong government political will 3. Unavailable 5. Strong international partner's willingness to nd genomic quencing 6. Moderate collaboration with local ademic and research stitutions 7. Weak One Health approach towards akers, etc) 8. Weak collaboration of gional and global stitutions	1. Lobby for genomic quencing funding om the government 2. Collaborate with ıl ing partners resources for equencing 3. Develop multi-sectoral policy on genomic sequencing 4. Collaborate with M and Africa bilizing or genomic ; 5. Strengthen vith local esearch ooling enomic 6. Strengthen the One Health approach in bilizing resources for nomic sequencing 7. Strengthen collaboration of local, nd global s in sharing of or genomic ;

7	Governance, Regulation and Policy	1. Availability of the national One Health committee 2. Availability of the ɛnomic Sequencing cretariat 3. Availability of the s and Medicines ɪtory Authority ɹ) 4. Availability of the edical Council of alawi 5. Availability of Malawi Bureau of Standards 6. Availability of the National Quality Assurance Framework	1. Lack of overarching tional policy for nomic sequencing 2. Inadequate nt of laws, ɪd regulations to medical es 3. Fragmented ɜation of e and activities for ɛquencing	1. Availability of support gulation, ɡenomic m Africa l WHO 2. Presence of ɜtional quality nce programs for ɪic sequencing	1. Introduction of ɛd equipment ɪts for ɛquencing by 2. Access to and export ɪuencing 3. Access to and sharing genomic sequencing ta by unauthorized institutions or individuals	1. Active One Health committee 2. Active Genomic g Secretariat ɪal regulatory ɜ (PMRA, BS) 4. Weak national ms ɲcing ɪomic 6. Poor enforcement of ɔolicies, and ɪions for medical ɔlogies 7. No integrated ɜation of e and activities for ɛquencing 8. Strong support from ɜ (ASLM, /HO) on gulation, ɡenomic 9. Strong international assurance ms for genomic ɲcing 10. Weak biosecurity of nomic sequencing ecimens 11. Weak data ɪance systems for ɪic sequencing	1. Strengthen the capacity of the One Health committee to ɪ and regulate ɪic sequencing es in Malawi 2. Strengthen the ɛncing upport n of ɛncing lawi 3. Implement integrated gulatory activities for nomic sequencing in collaboration with 6. Enrol in international ɪory quality nce programs for ɪic sequencing 7. Improve the ɔsecurity for genomic quencing specimens 8. Strengthen data ɪance systems for ɪic sequencing

8	Diagnostics	1. Availability of equipment 2. Availability of human resources 3. Availability of the national biorepository	1. Inconsistency in the agents ue to lack budget, elays and 2. Limited number of competent staff 3. Limited funding for trainings	1. Availability of nomic diagnostics aining institutions 2. With impact of Covid- ostics e 3. Availability of diagnostic governance system 4. Availability of the mples with the isting pandemic/epidemic 5. Internal and external Collaboration among institutions in genomic diagnostics 6. An opportunity to panding the scope of creditation	1. Heavy reliance on donor-funding 2. Challenges in rvicing the diagnostics uipment 3. Lack of water and power back up 4. Lack of local manufacturers of reagents and supplies 5. Unavailability of products due to global demands	1. There is need to prove trainings for agnostics staff and funding for sustained on of reagents aintenance of nent, 2. There is need to g quality in all genomic g to ensure f the data	1. Lobby for more trainings and f reagents es and ce of equipment 2. Develop and roll-out ckages in iagnostics to kills and cision-making d nd ss-national collaboration 4. Implement external ality assessment ograms for genomic sequencing

9	Stakeholders ement nts/General	1. Political willingness and buy-in from the government on genomic sequencing 2. Presence of various uctured forums of gagement at national s, steering with good r tion) 3. Inclusion of the quencing n the al training s 4. Presence of the nit for 5. nd ith	1. Inadequate n on genomic g and e to the 2. Genomic sequencing a new initiative to the blic 3. Most stakeholders d -going age groups due to adequate information aring 6. Lack of basic ics information in y and secondary ion levels 7. Lack of a nsive list of rs for e mapping ch 8. Little involvement of edia and civil r in genomics ness 9. Weak coordination ong the stakeholders: orking in silos 10.Weak information security systems	1. Availability of global d advocacy takeholders , ASLM, CDC, DC, USAID)	1. Spread of false ormation among the neral public	1. Strong government t on mentation of ic sequencing 2. Strong national ures for older ement 3. Inadequate ation on genomic ncing surveillance general public 4. Moderate inclusion of omic g elements in al training s 5. A reliable health education unit for MoH 6. Robust media titutions 7. Little to no inclusion omic sequencing ness activities in of stakeholders 8. No engagement of primary and secondary ts in basics of ic sequencing and lance 9. No comprehensive list pe omic ation ent omic 11. Poor coordination of olders in zation activities of ic sequencing 12. Weak privacy and y systems for ing genomic lance information	1. Provide quarterly MOH senior nt on equencing and e 2. Provide quarterly omic rough cal s 3. Conduct public aigns ncing the nit 4. Strengthen inclusion nensive equencing professional titutions 5. Advocate for inclusion sequencing activities in ns of rs 6. Lobby for inclusion of ormation of condary 7. Develop a nsive list of rs to be with genomic g information 8. Str cy s for

Appendix 2: Financing and Costing

Inputs	Key Activities	Status	2023	2024	2025	2026	2027	2028	2029	2030	Available Funding	Funding Gap	Total cost per section
2.1 Research and Surveillance	*2.1.1: Conference to develop priority research activities*		$8,060		$8,060		$8,060		$8,060		$0	$32,241	
	2.1.2: Establish new genomic sequencing centers		$50,000		$50,000		$50,000		$50,000		$0	$200,000	
	2.1.3 Quarterly cross-border working group meetings		$36,036	$36,036	$36,036	$36,036	$36,036	$36,036	$36,036	$36,036	$0	$288,287	
	2.1.4: Workshop to develop emergency plans for genomic research and surveillance		$15,206	$15,206	$15,206	$15,206	$15,206	$15,206	$15,206	$15,206	$0	$121,649	**$642,178**
2.2: Health Systems Strengthening	*2.2.1: Infrastructure Assessment*		$11,227		$11,227		$11,227		$11,227		$0	$44,909	
	2.2.2: Procurement of ultra-low freezers		$50,000				$50,000			$50,000	$0	$150,000	
	2.2.3: Training of Genomic sequencing Personnel		$16,011	$16,011	$16,011	$16,011	$16,011	$16,011	$16,011	$16,011	$0	$128,088	**$12,843,039**

Inputs	Key Activities	Status	2023	2024	2025	2026	2027	2028	2029	2030	Available Funding	Funding Gap	Total cost per section
	2.2.4 Semi-Annual Conference to share genomic sequencing best practice		$7,614	$7,614	$7,614	$7,614	$7,614	$7,614	$7,614	$7,614	$0	$60,909	
	2.2.5 Conduct needs assessments for genomic sequencing laboratories		$3,757			$3,757			$3,757		$0	$11,270	
	2.2.6 Train laboratory personnel on equipment maintenance		$16,282	$16,282	$16,282	$16,282	$16,282	$16,282	$16,282	$16,282	$0	$130,257	
	2.9.7 Develop an equipment donation policy				$59,221						$0	$59,221	
	2.2.8 Establish equipment maintenance contracts with equipment manufacturers		$60,000	$60,000	$60,000	$60,000	$60,000	$60,000	$60,000	$60,000	$0	$480,000	
	2.2.9 Train local engineers on maintenance of genomic sequencing equipment			$15,943							$0	$15,943	
	2.2.10 Enroll genomic		$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$0	$48,000	

Inputs	Key Activities	Status	2023	2024	2025	2026	2027	2028	2029	2030	Available Funding	Funding Gap	Total cost per section
	sequencing labs in EQA												
	2.2.11 Monitor EQA results and participant feedback		$5,292	$5,292	$5,292	$5,292	$5,292	$5,292	$5,292	$5,292	$0	$42,334	
	2.2.12 Implement knowledge exchange activities with local and international partners		$9,150	$9,150	$9,150	$9,150	$9,150	$9,150	$9,150	$9,150	$0	$73,200	
	2.2.13 Evaluate the effectiveness of the knowledge exchange programs		$3,224			$3,224			$3,224		$0	$9,673	
	2.2.14: Procure new Genomic Sequencing instruments			$400,000			$400,000			$400,000	$0	$1,200,000	
	2.2.15 Procure supplies for genomic sequencing		$1,250,000	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$0	$10,000,000	
	2.2.16 Train sample collectors in sentinel sites		$37,928	$37,928	$37,928	$37,928	$37,928	$37,928	$37,928	$37,928	$0	$303,420	
	2.2.17 Training of sample couriers on proper		$10,727	$10,727	$10,727	$10,727	$10,727	$10,727	$10,727	$10,727	$0	$85,815	

Inputs	Key Activities	Status	2023	2024	2025	2026	2027	2028	2029	2030	Available Funding	Funding Gap	Total cost per section
	transport methods and safety.												
2.3 Capacity Building for Human Resources	*2.3.1: Recruitment of HR (Laboratory scientists, molecular epidemiologists)*		$32,400	$32,400	$32,400	$32,400	$32,400	$32,400	$32,400	$32,400	$0	$259,200	
	2.3.2 Conduct workshops to determine workforce's training needs in genomics		$16,011			$16,011			$16,011		$0	$48,033	
	2.3.3 Provide appropriate training opportunities to employees		$10,000	$10,000	$10,000	$10,000	$10,000	$10,000	$10,000	$10,000	$0	$80,000	
	2.3.4 Assist academic institutions in establishing genomics courses			$6,715					$6,715		$0	$13,430	
	2.3.5 Training of Bioinformatics Specialists		$0	$14,000		$14,000			$14,000		$0	$42,000	**$442,664**
2.4 Data Management	*2.4.1: Development of computerised genomic sequencing data and information management systems*		$73,540								$0	$73,540	**$386,985**

Inputs	Key Activities	Status	2023	2024	2025	2026	2027	2028	2029	2030	Available Funding	Funding Gap	Total cost per section
	2.4.2: Procurement of hardware, software and network equipment and printers		$39,554								$0	$39,554	
	2.4.3: Develop SOPs for general genomic sequencing data and information management system		$6,505								$0	$6,505	
	2.4.4: Development of framework for data and metadata standard		$6,505								$0	$6,505	
	2.4.5: SOP Genomic Sequence SOPs review meetings		$6,505		$6,505		$6,505		$6,505		$0	$26,020	
	2.4.6: Replacement of Desktops					$22,044					$0	$22,044	
	2.4.7: Annual Support for Computerised Genomic Sequencing Data and Information System			$20,423	$20,423	$20,423	$20,423	$20,423	$20,423	$20,423	$0	$142,958	

Inputs	Key Activities	Status	2023	2024	2025	2026	2027	2028	2029	2030	Available Funding	Funding Gap	Total cost per section
	2.4.8: Cost of Annual printing		$8,732	$8,732	$8,732	$8,732	$8,732	$ 8,732	$8,732	$8,732	$0	$69,859	
2.5 Resource Mobilization, Financing, and Sustainability	*2.5.1 Collaborate with different government ministries to plan and prioritize resources for genomic sequencing and surveillance*		$16,587	$16,587	$16,587	$16,587	$16,587	$16,587	$16,587	$16,587	$0	$132,700	**$132,700**
2.6 Governance, Regulation, and Policy	*2.6.1: Quarterly meetings for One Health committee*		$24,153	$24,153	$24,153	$24,153	$24,153	$24,153	$24,153	$24,153	$0	$193,221	
	2.6.2: Development of a multi-sectoral policy on genomic sequencing and surveillance			$59,221							$0	$59,221	
	2.8.3 Organize monthly meetings for the Genomics Committee		$54,702	$54,702	$54,702	$54,702	$54,702	$54,702	$54,702	$54,702	$0	$437,618	
	2.6.4: Quarterly visits to genomic sequencing laboratories to check compliance with local regulations		$7,938	$7,938	$7,938	$7,938	$7,938	$7,938	$7,938	$7,938	$0	$63,500	**$3,710,341**

Inputs	Key Activities	Status	2023	2024	2025	2026	2027	2028	2029	2030	Available Funding	Funding Gap	Total cost per section
	2.6.5: Bi-annual QMS training for all staff in genomic sequencing laboratories.		$54,597	$54,597	$54,597	$54,597	$54,597	$54,597	$54,597	$54,597	$0	$436,780	
	2.6.6: Enrollment of the laboratories in local, regional, and global accreditation programs		$195,000	$195,000	$195,000	$195,000	$195,000	$195,000	$195,000	$195,000	$0	$1,560,000	
	2.6.7 Transport and dispose of the pathogens		$120,000	$120,000	$120,000	$120,000	$120,000	$120,000	$120,000	$120,000	$0	$960,000	
2.7 Stakeholders engagement (Patients/General Public)	*2.7.1: Provide monthly updates to PHIM senior leadership on genomic sequencing and surveillance*		$2,028	$2,028	$2,028	$2,028	$2,028	$2,028	$2,028	$2,028	$0	$16,225	
	2.7.2: Provide monthly updates on genomic sequencing and surveillance to the National Genomics Committee		$42,854	$42,854	$42,854	$42,854	$42,854	$42,854	$42,854	$42,854	$0	$342,835	
	2.7.3 Provide updates on genomic sequencing at		$52,686	$52,686	$52,686	$52,686	$52,686	$52,686	$52,686	$52,686	$0	$421,485	**$1,121,853**

Inputs	Key Activities	Status	2023	2024	2025	2026	2027	2028	2029	2030	Available Funding	Funding Gap	Total cost per section
	quarterly technical working groups												
	2.7.4 Conduct public sensitization activities on genomic sequencing and surveillance		$38,979	$38,979	$38,979	$38,979	$38,979	$38,979	$38,979	$38,979	$0	$311,831	
	2.7.5 Develop genomic sequencing curricula for local universities			$13,851							$0	$13,851	
	2.7.6 Advocate for inclusion of basic information about genomic sequencing and surveillance in the primary and secondary school curricula				$7,813			$7,813			$0	$15,626	
Yearly Totals			**$2,405,790**	**$2,661,054**	**$2,294,151**	**$2,210,360**	**$2,677,117**	**$2,159,137**	**$2,270,824**	**$2,601,324**			
										Available Funds	**$0**		
										Funding Gap	**$19,279,759**		
										Total Funds Needed		**$19,279,759**	

Appendix 3: Monitoring and Evaluation Framework

Thematic Area	Strategies	Activities	Indicators	Baseline	Target	Responsible institution	Years							
							2023	2024	2025	2026	2027	2028	2029	2030
2.1 Research and Surveillance	Implement priority research on genomic sequencing	Extend membership of the National Genomics Committee to include more stakeholders	Number of stakeholders engaged in the National Genomics Committee											
		Identify research priorities that align with the national health agenda	Number of research publications produced from priority research areas Success rate of genomics research in improving health outcomes in the targeted areas											
		Establish a National Genomics Research Network	Number of institutions or organizations that are part of the network											
		Conduct joint regular meetings and workshops with partners	Number of regular joint meetings and workshops held											
	Strengthen timely detection of emerging variants	Establish new sequencing centres	Number of new sequencing centres established											
		Establish a cross-border working group	Number of joint meetings and investigations conducted with neighbouring countries Compliance rate with data sharing policies											
	Maintain preparedness and readiness for emergencies	Develop emergency plans	Frequency of emergency plan updates											
		Conduct regular risk assessments	Completion of regular risk assessments Implementation of tailored emergency plans based on risk assessments											

		Establish communication protocols	Effectiveness of communication protocols during emergencies, as measured by feedback from stakeholders											
		Train staff in emergency procedures and protocols	Percentage of staff members trained in emergency procedures and protocols											
	Test the ability of genomic surveillance systems to stretch during an emergency	Perform surge exercises to simulate an increase in the number of cases of a specific pathogen	Number of samples collected and sequenced during the surge exercise											
			Turnaround time for sequencing and analysis of samples during the surge exercise											
			Accuracy of sequencing and analysis results during the surge exercise											
			Weaknesses or bottlenecks identified											
			Reduction in the time and resources required to process and analyze samples during subsequent surge exercises											
	Make the use of genomics routine in surveillance	Conduct pilot studies to assess the feasibility and effectiveness of incorporating genomic sequencing into routine surveillance practices	Number of next-generation sequencing platforms procured and installed across the country Number of public health practitioners and laboratory personnel trained in the use of next-generation sequencing platforms and data analysis											
		Develop guidelines and standard operating procedures for the routine	Existence of guidelines and SOPs for the routine use genomic sequencing at PHIM											

		use of genomic sequencing	Training records on the guidelines and SOPs											
		Develop and implement a data-sharing platform	Percentage of outbreaks with a confirmed source identified using genomic sequencing data Number of targeted interventions developed and implemented based on genomic sequencing data											
	Promote ethical practices	Update guidelines on the ethical collection, storage, and use of genomic data	Availability and adoption of the updated guidelines											
2.2 Health Systems Strengthening	Improve the infrastructure and equipment for genomic sequencing	Conduct an annual needs assessment to determine the state of infrastructure and equipment	Number of annual needs assessments conducted											
		Collaborate with stakeholders to develop budgets and secure funding for the equipment and infrastructure	Amount of funding for equipment and infrastructure secured with collaborators											
		Construct and refurbish sequencing laboratories	Number of sequencing laboratories constructed and refurbished											
		Develop an equipment donation policy	Availability and adoption of the policy											
		Invest in dry and cold storage equipment, ICT infrastructure, power backup, and water supply at all the sequencing laboratories	Amount of investment made in dry and cold storage equipment, water and power supply backup and ICT infrastructure											
	Sustain the functionality of genomic sequencing infrastructure and equipment	1. Establish long-term service contract agreements with instrument manufacturers to guarantee equipment	Percentage of installed equipment that is functional Number of appropriate NextGen sequencing machines procured based on need											

		maintenance n local engineers on enance of next ation sequencing nent												
	Enhance collaboration with locally and nternational artners	Conduct joint meetings workshops with tners locally and oss-borders	Number of joint meetings and workshops conducted annually with collaborators											
	Strengthening supply chain system	Conduct regular nts to establish and volume of and consumables	Genomic sequencing ommodities forecasted and uantified											
		Identify suppliers of reagents and consumables	List of multiple suppliers of enomic sequencing and eagents											
		Procure and distribute enomic sequencing ommodities	Amount of genomic uencing commodities ilable in the testing lities											
		Orient staff on commodity nanagement, inventories nd reporting	Availability of well locumented tracking and nventories for commodities.											
		Develop a contingency n that will respond to uptions in reagents consumable supply	Contingency plan in place											
	Implement EQA rogrammes for enomic sequencing	Identify EQA providers	List of genomics EQA providers											
		Enrol genomic sequencing labs in EQA programmes	Number of facilities enrolled for genomics EQA											
		Monitor EQA results and participant feedback	Records of EQA results											

	Sample collection and transport	Coordinate to ensure that ıt samples are collected he right containers and kaged appropriately	Availability sample collection ınd packaging materials and ecords											
		Institute sample tracking systems	Functional sample tracking systems in place											
2.3 Capacity ding for nan ources	Establish knowledge exchange programs	Identify collaborators	Number of collaborators identified with mutual interest											
		Develop the structure of the program	Availability of the curriculum for the programme											
		Source funding for the program	Amount of funding secured											
		Evaluate the effectiveness of the program	M&E results											
	Staffing	Hire or assign additional taff to support in Gene equencing labs	Number of people hired or ıssigned conducting test at the ab											
		Hire or assign additional taff to support sample ollection and shipping to the testing sites	Number of people assigned for ample collection per that eporting period											
		Hire data clerks for data ntry and management in esting labs	Number of data clerks hired per reporting period											
	Training	Training staff in proper sample collection	Availability and number of trained sample collectors											
		Training technical staff on sequencing	Availability and number of trained testing staff at the lab											
		Training staff on Bioinformatics	Availability and number of trained bioinformaticians											
		Training for data clerks	Availability and number of trained data clerks											

	Certification	Coordinate to ensure that veryone who needs ertification is certified	Number of trained staff who re certified to work as per ecommendation												
	Equipment election and tandardization	Conduct a workshop with ey stakeholders to select quipment	Standardization manual development												
		Coordinate an equipment election and tandardization activities including development of standardization manual	Equipment for sequencing selected and endorsed												
	Reagent storage nd quality ssurance	Ensure proper storage of eagents and consumables	Reagents and consumables eing stored at an ambient emperature												
		Conduct validations and verifications of reagents	Reagents verification and validation being conducted.												
2.4 Data Management	Development of sequencing ion nent	Implement digital systems ure that data is tly captured, stored, sed and shared for	Availability of data in digital systems												
		Inclusion of genomic ncing workflows into g laboratory ation management ns (LIMS).	Sequencing data available in LIMS												
	Develop SOPs for enomic ng data mation nent	Conduct a workshop to levelop SOPs on data sage and management	SOPs developed and available.												
2.5 Resource Mobilization	Develop a guide on how resource	Mobilize and justify for unding allocation from MOH	Resource mobilization guide development												

	mobilization will be done	Quantify funding needs ınd present to the ɔartners and donors	Gaps and funding need quantified and documented											
		Leverage available funding ;et an allocation for omics including ning and procurement	Agreement and partnership leals sealed											
2.6 'ernance, ulation, and cy	Set up national ;enomics ommittee	Develop TORs for the ion genomic ımmittee including ;ulations, QMS, Biosecurity)	National genomics Committee in place											
		Define a policy to guide the committee	TORs and implementation roadmap developed											
		Develop and implementation roadmap												
2.7 Stakeholder Engagement	Formulation and scheduling ;enomics technical vorking group	Develop schedule for the TWG (Including research discussion, curricula rovals, update and v innovations :ussions	TWG schedule developed and approved.											