Federal Ministry of Health & Social Welfare
Federal Republic of Nigeria

NCDC
NIGERIA CENTRE FOR DISEASE CONTROL AND PREVENTION

# NATIONAL GENOMICS SURVEILLANCE STRATEGY

FMAFS
FEDERAL MINISTRY OF AGRICULTURE AND FOOD SECURITY

FEDERAL MINISTRY OF ENVIRONMENT

# TABLE OF CONTENTS

# FOREWORD

## FOREWORD

With great pride and anticipation, I present the National Genomics Surveillance Strategy (NGSS) for Nigeria. This document marks a critical milestone in our commitment to fortifying public health, veterinary health, and environmental health systems by integrating advanced genomic technologies.

Nigeria like many countries in sub-Saharan Africa faces intricate health challenges that require innovative and collaborative solutions. The persistence of infectious diseases coupled with the emergence of new health threats necessitates a comprehensive approach that transcends traditional boundaries. The interconnectedness of human animal and environmental health is at the core of the one health concept which promotes cross sectoral collaboration to achieve optimal health outcomes for all.

The NGSS is not merely a technological enhancement but a strategic shift towards a scientific approach to addressing health security challenges. Genomic sequencing provides unparalleled insights into the genetic characteristics of pathogens enabling precise identification, tracking, and response to disease outbreaks. By harnessing these powerful tools, we can significantly enhance our disease surveillance capabilities respond more swiftly and effectively to health drugs and build a resilient health system that can withstand future challenges.

The NGSS outlines a clear vision and roadmap for integrating genomics into our health strategy. It includes detailed plans for capacity building, data management, ethical governance, and stakeholder engagement. It also emphasizes the importance of coordination mechanisms and policy frameworks that are essential for the successful implementation of the strategy.

This strategy aligns with President Bola Ahmed Tinubu's Renewed Hope Agenda for the health sector and emphasizes innovation resilience and sustainability in healthcare delivery it also integrates seamlessly with the sector wide approach swap that we are advancing providing a holistic framework for health system strengthening furthermore the NGSS serves as a strategic catalyst for the presidential initiative for unlocking the healthcare value chain aiming to stimulate growth in innovation research investment opportunities enterprise development and other areas that will generate economic value through health for Nigeria and the African region.

I extend my heartfelt gratitude to all stakeholders including government agencies academic institutions international partners and the private sector particularly the NCDC team who led and have contributed to the development of this strategy your dedication and collaboration are vital to the to our success.

As we embark on this transformative journey, I am confident that the national genomic surveillance strategy will significantly enhance Nigeria's health security and set a benchmark for other nations in Africa and the global South together we will build a healthier safer and more prosperous future for our nation and the African continent.

Thank you.

Professor Ali Pate
Coordinating Minister for Health and Social Welfare
Nigeria

# ACKNOWLEDGMENT

The development of the National Genomics Surveillance Strategy has been a collaborative effort, bringing together expertise from a wide array of stakeholders. We express our deepest gratitude to all those who have played a vital role in this process.

Firstly, we thank the Federal Ministry of Health and Social Welfare, Federal Ministry of Agriculture and Food Security and the Federal Ministry of Environment for their unwavering support and guidance their leadership has been instrumental in shaping this strategy. We thank our global and international partners for their technical assistance, funding and strategic advice including the World Health Organization (WHO), Global Fund (GF), Africa Centre for Disease Control and Prevention (Africa CDC), United Kingdom Health Security Agency (UKHSA), United States Centres for Disease Control and Prevention (US-CDC), Resolve to Save Lives (RTSL), Clinton Health Access Initiative (CHAI), Africa Society for Laboratory Medicine (ASLM), Johns Hopkins Program for International Education in Gynaecology and Obstetrics (JHPIEGO).

Our national partners have provided essential support and collaboration including the National Primary Health Care Development Agency (NPHCDA), University of Ibadan, Irrua Specialist Teaching Hospital (ISTH), National Institute for Pharmaceutical Research and Development (NIPRD), University of Lagos, Nigeria Institute of Medical Research (NIMR), Usmanu DanFodiyo University Sokoto, African Centre for Excellence for Genomics of Infectious Diseases (ACEGID), Edo State University (EDSU), University of Maiduguri, National Tuberculosis and Leprosy Control Program (NTBLCP), Medical Laboratory Science Council of Nigeria (MLSCN), Turne Wright Biosciences Limited, ISN Medicals, Insight Health Consulting Limited.

We also acknowledge the invaluable contribution of non-governmental organizations (NGOs) and Civil Society Organizations (CSOs) in ensuring the strategy is inclusive and community focused. Your efforts in advocacy and community engagement have enriched this document.

We particularly recognize the dedicated effort of the Nigeria Centre for Disease Control and Prevention (NCDC) team. Special thanks to the Public Health Laboratory Service Department, Project Management Unit, Surveillance Department, Legal Unit, Health Emergency Preparedness and Response Unit, Sub-national department and the Department of Planning Research and Statistics and other professionals for their outstanding coordination and facilitation. Your dedication and professionalism have been exemplary.

Together we have created a roadmap that will enhance Nigeria's health security, stimulate economic growth and contribute to the well-being of our nation and the African continent.

We look forward to continued collaboration as we implement this strategy and work towards a healthier, safer and more prosperous future.

Thank you.

Dr. Jide Idris
Director-General
Nigeria Centre for Disease Control and Prevention

# ABBREVIATIONS

| | |
|---|---|
| ACEGID | African Centre of Excellence for Genomics of Infectious Diseases |
| AI | Artificial Intelligence |
| AIDS | Advanced Immunodeficiency Syndrome |
| APIN | AIDS Prevention Initiative |
| AMR | Antimicrobial Resistance |
| ASLM | African Society for Laboratory Medicine |
| BCVL | Biorepository Clinical Virology Laboratory |
| BGI | Beijing Genomics Institute |
| BioRTC | Biomedical Research and Training Centre |
| CAMRET | Centre for Advanced Medical Research and Training |
| CD | Communicable Diseases |
| CDC | Centre for Disease Control and Prevention |
| CERID | Centre for Emerging and Reemerging Infectious Diseases |
| CGNPH | Centre for Genomics of Non-communicable Diseases and Personalized Health Care |
| CHAI | Clinton Health Access Initiative |
| CHAZVY | Centre for Human and Zoonotic Virology |
| CIF | Case Investigation Form |
| COVID-19 | Coronavirus Disease |
| CPHL | Central Public Health Laboratory |
| EHRs | Electronic Health Records |
| EMR | Electronic Medical Records |
| FAIR | Findable, Accessible, Interoperable, and Reusable |
| FMAFS | Federal Ministry of Agriculture and Food Security |
| FMEnv | Federal Ministry of Environment |
| FMOH&SW | Federal Ministry of Health and Social Welfare |
| GEAP | Genomic Epidemiology of Antimicrobial Pathogen |
| GISAID | The Global Initiative on Sharing All Influenza Data |
| HIV | Human Immunodeficiency Virus |
| HPC | High-Performance Computing |
| HRH-CERID | Humboldt Research Hub-Centre for Emerging and Reemerging Infectious Diseases |
| IATA | The International Air Transport Association |
| IHVN | Institute for Human Virology, Nigeria |
| IITA | International Institute for Tropical Agriculture |
| ISO | International Organization for Standardization |
| IVEPCR | Institute of Viral and Emergent Pathogens Control and Research |
| JHPIEGO | Johns Hopkins Program on International Education in Gynecology and Obstetrics |

| | |
|---|---|
| LAUTECH | Ladoke Akintola University of Technology |
| LIMS | Laboratory Information Management System |
| LSB | Lagos State Biobank |
| M&E | Monitoring and Evaluation |
| MGI | MGI Tech Co., Limited |
| MLSCN | Medical Laboratory Science Council of Nigeria |
| NAFDAC | National Agency for Food and Drug Administration and Control |
| NCBI | National Center for Biotechnology Information |
| NCDC | Nigerian Centre for Disease Control and Prevention |
| NCD | Non-Communicable Disease |
| NGO | Non-governmental Organisation |
| NGS | Next-generation Sequencing |
| NGSC | Nigeria Genomics Surveillance Consortium |
| NGSS | Nigeria Genomics Surveillance Strategy |
| NHREC | National Health Research Ethical Committee |
| NIMR | Nigeria Institute for Medical Research |
| NIPRD | National Institute for Pharmaceutical Research and Development |
| NITDA | National Information Technology Development Agency |
| NPHCDA | National Primary Health Care Development Agency |
| NRL | National Reference Laboratory |
| NVRI | National Veterinary Research Institute |
| PacBio | Pacific Biosciences |
| PCR | Polymerase Chain Reaction |
| QC | Quality Control |
| SDGs | Sustainable Development Goals |
| SOPs | Standard Operating Procedures |
| SORMAS | Surveillance, Outbreak Response Management and Analysis System |
| SWOT | Strengths, Weaknesses, Opportunities and Threats |
| TB | Tuberculosis |
| ToR | Terms of Reference |
| TWG | Technical Working Group |
| UI | University of Ibadan |
| UK | United Kingdom |
| UKHSA | UK Health Security Agency |
| UNILAG | University of Lagos |
| US | United States of America |
| WHO | World Health Organisation |

# EXECUTIVE SUMMARY

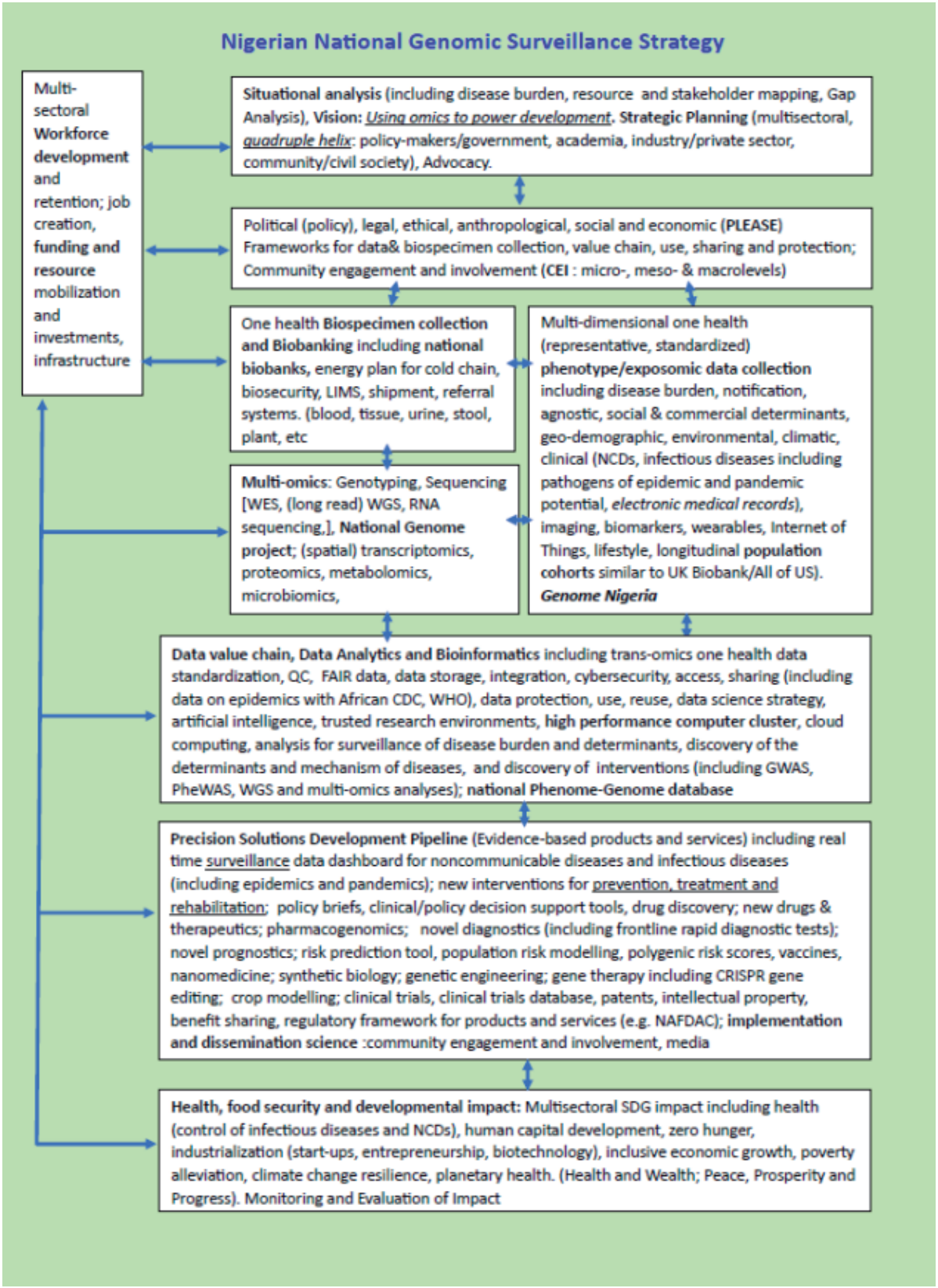
To develop the National Genomic Surveillance Strategy (NGSS), a series of workshops were conducted, including a stakeholder engagement workshop, a five-day strategy development workshop, and a three-day review and validation workshop. These workshops were held in a hybrid format to accommodate a wide range of contributors. The process was driven by two consultants, with coordination from the Nigeria Centre for Disease Control and Prevention (NCDC) and support from partners.

The development of the NGSS began with planning meetings involving NCDC technical staff and partners, such as CHAI, GU, GF/NACA, WHO, and JHPIEGO, to design the roadmap. The stakeholder engagement workshop, held on May 30, 2024, included participants from relevant ministries and agencies, academia, private sector, as well as, policy makers and research experts. This workshop had 79 attendees (49 in-person and 25 online). The objective was to align the approach for genomic sequencing activities, establish the National Genomic Surveillance Consortium (NGSC), and agree on the NGSS's development and implementation.

Following the engagement workshop, two consultants were engaged with support from CHAI. They were tasked with producing an initial draft of the strategy, which was then reviewed during a one-week strategy development workshop from June 10 to 14, 2024. The workshop had 115 participants (50 in-person and 65 online) and focused on creating a draft documentrepresenting the public sector, academia, research institutions, private companies, and suppliers of omics products. The workshop concluded with the production of a draft NGSS, followed by further online consultations with technical teams and partners to incorporate feedback.

The review and validation workshop, held from July 2 to 4, 2024, brought together 65 participants (45 in-person and 20 online), including members of the National Genomic Surveillance Consortium, sequencing laboratory representatives, One Health stakeholders, and other partners. The purpose was to review and validate the NGSS draft.

The NGSS is, therefore, the product of a collaborative effort involving diverse stakeholders and will play a crucial role in integrating genomics into Nigeria's One Health systems, significantly improving disease surveillance across the country.


Nigerian National Genomic Surveillance Strategy
Multi-sectoral Workforce development and retention; job creation, funding and resource mobilization and investments, infrastructure
Situational analysis (including disease burden, resource and stakeholder mapping, Gap Analysis), Vision: Using omics to power development. Strategic Planning (multisectoral, quadruple helix: policy-makers/government, academia, industry/private sector, community/civil society), Advocacy.
Political (policy), legal, ethical, anthropological, social and economic (PLEASE) Frameworks for data& biospecimen collection, value chain, use, sharing and protection; Community engagement and involvement (CEI : micro-, meso- & macrolevels)
One health Biospecimen collection and Biobanking including national biobanks, energy plan for cold chain, biosecurity, LIMS, shipment, referral systems. (blood, tissue, urine, stool, plant, etc
Multi-dimensional one health (representative, standardized) phenotype/exposomic data collection including disease burden, notification, agnostic, social & commercial determinants, geo-demographic, environmental, climatic, clinical (NCDs, infectious diseases including pathogens of epidemic and pandemic potential, electronic medical records), imaging, biomarkers, wearables, Internet of Things, lifestyle, longitudinal population cohorts similar to UK Biobank/All of US). Genome Nigeria
Multi-omics: Genotyping, Sequencing [WES, (long read) WGS, RNA sequencing,], National Genome project; (spatial) transcriptomics, proteomics, metabolomics, microbiomics,
Data value chain, Data Analytics and Bioinformatics including trans-omics one health data standardization, QC, FAIR data, data storage, integration, cybersecurity, access, sharing (including data on epidemics with African CDC, WHO), data protection, use, reuse, data science strategy, artificial intelligence, trusted research environments, high performance computer cluster, cloud computing, analysis for surveillance of disease burden and determinants, discovery of the determinants and mechanism of diseases, and discovery of interventions (including GWAS, PheWAS, WGS and multi-omics analyses); national Phenome-Genome database
Precision Solutions Development Pipeline (Evidence-based products and services) including real time surveillance data dashboard for noncommunicable diseases and infectious diseases (including epidemics and pandemics); new interventions for prevention, treatment and rehabilitation; policy briefs, clinical/policy decision support tools, drug discovery; new drugs & therapeutics; pharmacogenomics; novel diagnostics (including frontline rapid diagnostic tests); novel prognostics; risk prediction tool, population risk modelling, polygenic risk scores, vaccines, nanomedicine; synthetic biology; genetic engineering; gene therapy including CRISPR gene editing; crop modelling; clinical trials, clinical trials database, patents, intellectual property, benefit sharing, regulatory framework for products and services (e.g. NAFDAC); implementation and dissemination science :community engagement and involvement, media
Health, food security and developmental impact: Multisectoral SDG impact including health (control of infectious diseases and NCDs), human capital development, zero hunger, industrialization (start-ups, entrepreneurship, biotechnology), inclusive economic growth, poverty alleviation, climate change resilience, planetary health. (Health and Wealth; Peace, Prosperity and Progress). Monitoring and Evaluation of Impact

# ROADMAP FOR THE DEVELOPMENT OF THE NGSS

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# CHAPTER ONE

## INTRODUCTION AND SITUATIONAL ANALYSIS

Africa, recognized as the genetic birthplace of humanity, accounts for over 20% of the global population. Yet its contribution to the global genomic and multi-omics databases remains under 2%. This vast underrepresentation highlights a significant opportunity. Africa's diverse genetic makeup holds immense potential for breakthroughs in the genomic revolution, which can drive the development of new preventive health measures and tailor precision medicine. These advancements will foster innovatins, creating novel tools for risk prediction, diagnostics, prognostics, therapeutics, vaccines, and other healthcare solutions, andpositioning Africa as a key player in the knowledge-driven economy of the future.

With a One-Health approach, genomic surveillance can can enhance public health by offering precision tools such as biomarkers, polygenic risk scores for non-communicable diseases, and insights into pathogen evolution, antimicrobial resistance (AMR), and transmission. As Africa's most populous nation, Nigeria plays a key role in this effort, with one in five Africans being Nigerian. A national genomic surveillance strategy will create vast population data and biospecimen resources for research, training, and disease monitoring.

Building a resilient genomic network will improve health outcomes and contribute to achieving the Sustainable Development Goals (SDGs) through needs-driven science. Collaboration between academia, industry, policymakers, and the public (quadruple helix model) is crucial for success[1]. Empowering Nigerian researchers ensures locally relevant health solutions and reduces dependence on external expertise[2]. By leveraging the genomic revolution, Nigeria can advance Africa's Agenda 2063 for improved global quality-of-life measures through inclusive growth[3].

In Nigeria, Centers of Excellence have employed specialized laboratory techniques, including genomic sequencing, to investigate and manage diseases of public health importance such as Lassa fever, cholera, Mpox, influenza, Ebola virus disease, bacterial meningitis, COVID-19, and polio. Genomic sequencing is vital for seasonal surveillance, informed recommendations, and monitoring susceptibility to antimicrobial treatments. Genomic surveillance integrates clinical, epidemiological, genomic, environmental, and phenotypic data to track changes in pathogen transmission, virulence, and the effectiveness of medical countermeasures. This holistic approach also generates actionable information for the development of vaccines, therapeutics, diagnostic assays, and public health decision-making.

The COVID-19 pandemic revealed critical gaps in Nigeria's public health surveillance system, highlighting the need to strengthen early warning systems to efficiently detect emerging or re-emerging pathogens. Nigeria is facing a rising burden of non-

communicable diseases (NCDs). However, there are considerable gaps in the country's capacity for genomic sequencing, bioinformatics, and the development of precision medicine tools for NCDs. These gaps are largely due to the high costs and complexities involved in building the necessary infrastructure and resources.
There is an urgent need for a comprehensive national strategy on genomic surveillance that addresses both non-communicable and communicable diseases, including those with epidemic and pandemic potential. Such a strategy will strengthen Nigeria's ability to utilize advanced genomic tools for improved disease prevention, diagnosis, and treatment.

## RATIONALE FOR THE STRATEGY

This One-Health inspire genomic surveillance aims to leverage the specialized capabilities of genomics and bioinformatics as a core, adaptable capacity within the broader health system. Through a One-Health approach, the strategy unifies efforts to deploy genomics as a tool to address diverse public health challenges, including pandemic and epidemic preparedness and response.

This strategy seeks to integrate genomic surveillance into the wider public health frameworks by building on existing initiatives and capacities. It emphasizes collaboration, coordination, and community engagement in the development and implementation of genomic surveillance systems, while adhering to established standards. Recognizing that genomic surveillance extends beyond pandemics, the strategy also creates links with other programs targeting disease and pathogen control. This is vital for strengthening essential public health laboratory functions, including genomics, data analytics, and bioinformatics.

The NGSS outlines clear goals, objectives, and strategic actions, and highlights the need for commitments from the Nigerian government and stakeholders at the the national and international level to ensure successful implementation.

**Table 1:** In-country Genomic sequencing Capacity, June 2024 (more details in annex 1)

| Institution / Organization | Laboratory Name | Contact Person | Organisation | Sequencing Platforms |
|---|---|---|---|---|
| Irrua Specialist Teaching Hospital, Irrua, Edo State, Nigeria | Institute of Viral and Emergent Pathogens Control and Research (IVEPCR) | Director | Oxford Nanopore Technologies | Oxford Nanopore Technologies |
| Institute of Human Virology Nigeria (IHVN), Abuja, Nigeria | IHVN / International Research Centre of Excellence (IRCE), Genomics Laboratory | Executive Director | Illumina; Thermofisher 3500xl and 3130 Genetic Analyzers | Illumina; Thermofisher 3500xl and 3130 Genetic Analyzers |
| Ladoke Akintola University of Technology | Humboldt Research Hub-Centre for Emerging and Reemerging Infectious Diseases (HRH-CERID) | Head | Oxford Nanopore Technologies | Oxford Nanopore Technologies |
| Ministry of Health, Lagos State, Nigeria | Lagos State Biobank | Director | Illumina; MGI DNBSEQ400 | Illumina; MGI DNBSEQ400 |
| National Institute for Pharmaceutical Research and Development | NIPRD | Director General | BioBase | BioBase |
| National Veterinary Research Institute | Regional Laboratory for Animal Influenza & Transboundary Diseases | Principal Research Officer | Oxford Nanopore Technologies | Oxford Nanopore Technologies |
| Nigeria Centre for Disease Control and Prevention | National Reference Laboratory | Head, Genomics Sequencing | Oxford Nanopore Technologie; Illumina; Thermofisher 3500xL, SeqStudio | Oxford Nanopore Technologies; Illumina; Thermofisher 3500xL, SeqStudio |
| Nigerian Institute of Medical Research | Centre for Human Virology and Genomics and NIMR Central Research Laboratory | Chief Research Fellow | Oxford Nanopore Technologies; BGI; Thermofisher 3500xL, SeqStudio | Oxford Nanopore Technologies; BGI; Thermofisher 3500xL, SeqStudio |
| Redeemer's University, Ede, Osun State | African Centre of Excellence for Genomics of Infectious Diseases (ACEGID) | Director | Pacific Biosciences (PacBio); Oxford Nanopore Technologies; BGI; Ilumina | Pacific Biosciences (PacBio); Oxford Nanopore Technologies; BGI; Ilumina |
| University of Ibadan, Ibadan, Oyo State, Nigeria | Biorepository and Clinical Virology Laboratory, College of Medicine | Consultant Virologist | Oxford Nanopore Technologies | Oxford Nanopore Technologies |
| University of Ibadan, Ibadan, Oyo State, Nigeria | Damien Foundation Genomics and Mycobacteria Research and Training Centre | Team Lead | Oxford Nanopore Technologies | Oxford Nanopore Technologies |
| University of Ibadan, Ibadan, Oyo State, Nigeria | Global Health Research Unit for Genomic Surveillance of Antimicrobial Resistance | Lead Principal Investigator | Oxford Nanopore Technologies; Illumina | Oxford Nanopore Technologies; Illumina |
| University of Lagos, Lagos, Lagos State, Nigeria | Centre for Genomics of Non-communicable Diseases and Personalized Health Care (CGNPH) | Director | Illumina | Illumina |
| University of Lagos, Lagos, Lagos State, Nigeria | Centre for Human and Zoonotic Virology (CHAZVY), College of Medicine | Director | None yet | None yet |

**Table 1:** In-country Genomic sequencing Capacity, June 2024 (more details in annex 1)

| Institution / Organization | Laboratory Name | Contact Person | Contact Email | Sequencing Platforms |
|---|---|---|---|---|
| University of Lagos, Lagos, Lagos State, Nigeria | Genomic Epidemiology of Antimicrobial Pathogen (GEAP) Research Laboratory | Director | Oxford Nanopore Technologies | Oxford Nanopore Technologies |
| University of Maiduguri, Maiduguri, Borno State, Nigeria | WHO National Polio Laboratory | Director | Oxford Nanopore Technologies Sanger | Oxford Nanopore Technologies Sanger |
| Usmanu Danfodiyo University, Sokoto, Sokoto State, Nigeria | Centre for Advanced Medical Research and Training (CAMRET) | Director | Oxford Nanopore Technologies; Illumina | Oxford Nanopore Technologies; Illumina |

## DISEASE BURDEN

Nigeria's disease burden is dominated by non-communicable, communicable, maternal, neonatal, and nutritional deficiencies and those caused by injuries, self-harm, and violence[1],[2]. Some of these diseases are specific to certain age groups and genders, while others are prevalent irrespective of age and sex[3]. Of note, malaria has Nigeria's highest age-standardised mortality rate[4],[5]. Non-communicable diseases account for high age-standardised deaths, and have overtaken communicable, maternal, neonatal, and nutritional diseases as the leading contributor to mortality in Nigeria from 1990 to 2019[6]. Abubakar et al., reported cardiovascular diseases as the next leading cause of death after communicable and neonatal diseases[7].

| Category | Disease/Condition | Communicable | Non-Communicable | Reference |
|---|---|---|---|---|
| Human | Malaria | ✓ | | NCDC |
| | HIV/AIDS | ✓ | | NCDC |
| | Tuberculosis | ✓ | | NCDC TB |
| | Hypertension | ✓ | ✓ | Nigerian Heart Foundation |
| | Diabetes | | ✓ | International Diabetes Federation |
| Environment | Cholera | ✓ | | NCDC |
| | Lassa Fever | ✓ | | NCDC |
| | Air Pollution-Related conditions | | ✓ | WHO |
| Animals | Rabies | ✓ | | NCDC |
| | Avian Influenza (Bird Flu) | ✓ | | NCDC |
| | Brucellosis | ✓ | | NCDC |

*Obtain further documents related to the burden of diseases in Nigeria from the NCDC website (https://ncdc.gov.ng/)

Annex 2 highlights the risk factors driving disease burden in Nigeria

[1] Iwuchukwu and Vincent. 2021. doi: 10.17352/2455-5479.000156

[2] GBD 2019 Diseases and Injuries Collaborators. 2023. doi:10.1016/S0140-6736(20)30925-9

[3] Patwardhan, et al. doi:10.1016/S2468-2667(24)00053-7

[4] Ambe, et al. 2020. doi:10.1155/2020/9372457

[5] Awosolu, et al. 2021. doi:10.2147/IDR.S312519

[6] Shu and Jin. 2023. doi:10.1038/s41598-023-40595-7

[7] Abubakar, et al. 2022. doi:10.1016/S0140-6736(21)02488-0

## SUMMARY OF SITUATIONAL ANALYSIS

Analysis of the strengths, weaknesses, opportunities, and threats (SWOT) for the National Genomic Surveillace Consortium, the in-country facilities and laboratories involved in genomic research, focuses on nine key areas. The key areas were identified through a combination of self-assessment and a review of similar documents from national and international organizations. (see annex 3).

### Genomic Sequencing Platforms And Supply Chain

Nigeria has several sequencing platforms but only a few have in-country support system for human resources, maintenance, and consumables supply chain. Critical opportunities include joint negotiations and bulk purchasing power to ensure these commodities are affordable, well-maintained, and utilised.

### Sample Storage, Shipment, and Referral Systems

Existing networks provide minimal support and resources. Functional third-party logistics is available for public health diseases and the National Integrated Sample Referral Networks for HIV/TB across laboratories in the 36+1 states. However, these resources lack dedicated funds from the government. More importantly, there is a severe lack of biorepositories, and there is little coordination among the disease programmes. Efforts to leverage increased government and private sector health participation will advance the sector. However, poor power supply is a significant limitation.

### Bioinformatics and Data Structures

Existing national surveillance programmes have data infrastructure that can provide sample metadata. However, they may not be compatible with genomic data or sufficient for all facilities and purposes. Few facilities have dedicated and skilled data personnel, and the existing staff is insufficient. The NGSC can leverage technological advancements like high performance computing clusters, cloud computing, AI, and machine learning, to provide productive support to surveillance programmes, while countering brain drain and the challenges of equipment obsolescence.

### Workforce Development and Retention

The health sector has a well-developed cadre of staff with ongoing training opportunities. However, the number of skilled personnel is insufficient to meet the needs of a population of over 200 million. Moreover, there is a shortage of skilled individuals and retention is a challenge. Several tertiary institutions can train the upcoming workforce. Systemic improvements in the workplace and remuneration will help retain the workforce and possibly stem brain drain.

## Community Engagement: Ethical and Legal Issues

Several national policies are available to support research, such as the National Health Research Ethical Committee (NHREC) as well as various state and institutional ethical committees. However, these committees often operate without the capacity to provide continuing oversight of approved studies, which makes it difficult to detect protocol violations and unethical activities. Community and stakeholder involvement is lacking in the initial development and design of scientific projects and programmes. This needs to be addressed to establish ownership and sustainability.

The diversity of Nigeria's population remains attractive, and digital media could be used for education and advocacy. These new media avenues, especially social media consumed by all generations, could be used to counter misinformation, stigma, taboos, and cultural and religious misconceptions, which are still threats to community engagement.

# CHAPTER TWO

## STRATEGIC OBJECTIVES AND COMMITMENTS

This strategy outlines the overall direction for the integration of genomics, multiomics, and precision medicine into the national disease surveillance and control systems, focusing on both communicable and non-communicable diseases, including emerging pathogens – establishing a system to respond timely and adequately to public health emergencies.

### Vision

To become a national asset with the most inclusive multiomics One-Health biospecimen and data value chain for discovering, developing, and implementing evidence-based solutions to monitor and reduce the burden of disease while propelling economic growth and overall development in Nigeria.

### Mission

To create a national asset with multisectoral multiomics One-Health data and biospecimen resources aimed at discovering, developing, and implementing evidence-based innovative solutions for the prevention, diagnosis, and treatment of diseases and other public health threats.

### Strategic Pillars

A SWOT analysis informed the development of a roadmap with three technical and three cross-cutting objectives modelled after Genome England and similar initiatives[8, 9]

[8] GENOME UK The future of healthcare. https://www.gov.uk/government/publications/genome-uk-the-future-of-healthcare/genome-uk-the-future-of-healthcare

[9] 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

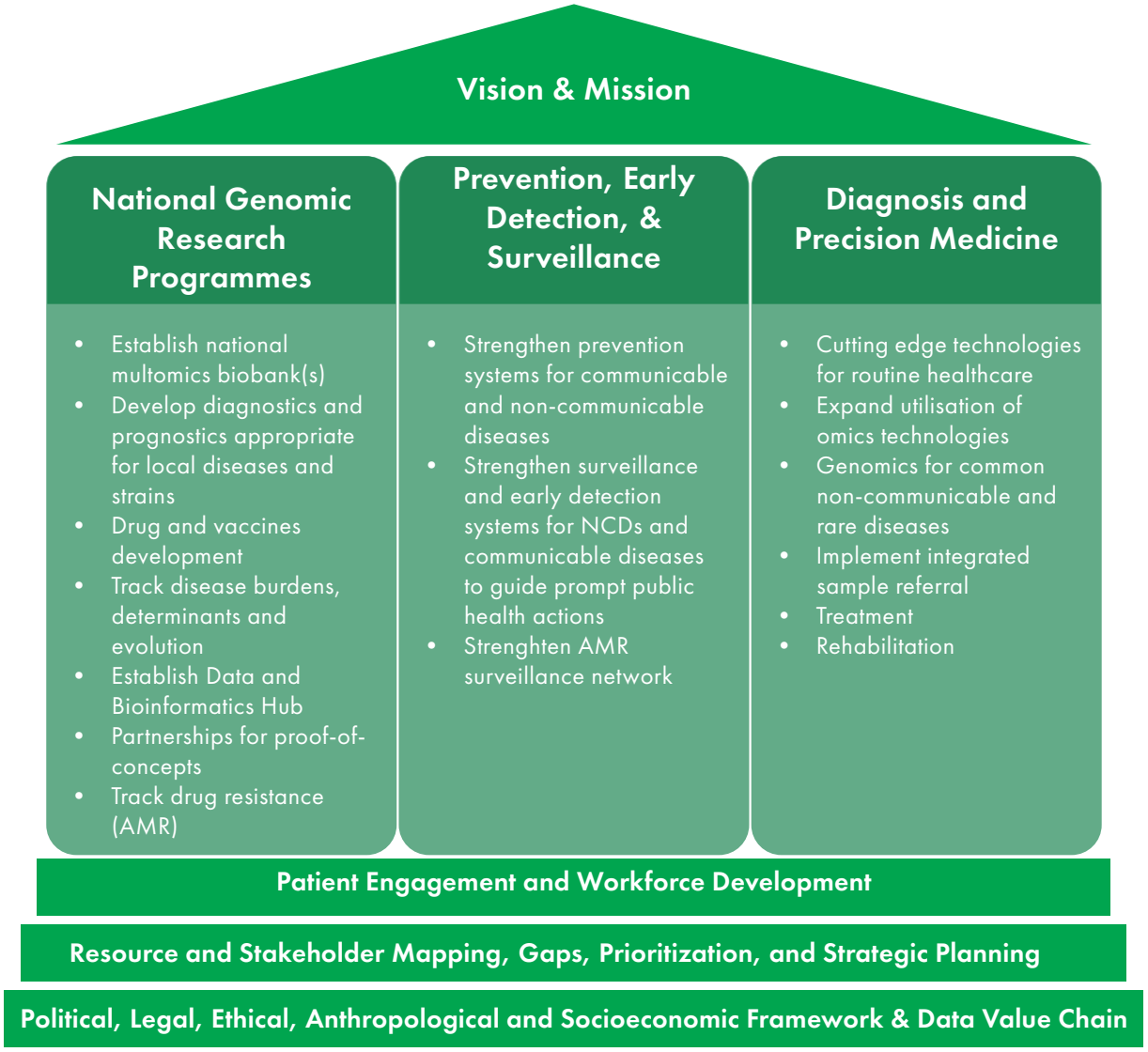


*Figure 2 NGSS Framework*

**Patient Engagement and Workforce Development**

- Engagements to improve trust in genomics
- Develop skilled workforce for omics and precision medicine
- Use of omics to drive growth in the health industry
- Co-develop an equitable and dynamic governance structure to maximize productivity and impact

**Resource and Stakeholder Mapping, Gaps, Prioritization, and Strategic Planning**

- Establish a national database of resources (personnel, institutions and organizations) involved in multiomics and precision medicine.
- Conduct a gap analysis of evidence, resource and solution gaps
- Co-create a national priority list and strategic plan to fund and harness multiomics and precision medicine research.

**Political, Legal, Ethical, Anthropological & Socioeconomic (PLEASE) framework & Data Value Chain**

- Strengthen data systems
- Strengthen ethical and legal frameworks
- Adapt frameworks for genomics

*Figure 3 Cross-Cutting Pillars in detail*

## Pillar 1: National Genomics Research Priority Programmes

| Pillar | Objectives | Actions/deliverables | Timeline |
|---|---|---|---|
| Establish national genomics research priority programmes. | Establish a national multiomics biobank and genome project | • Sign MoUs for political commitment and stakeholder engagement.<br>• Develop NGSS sustainability plan.<br>• Identify gaps in current Infrastructure<br>• Develop Political (Policy), legal, ethical, anthropological, social and economic (PLEASE) Framework.<br>• Implement Nigeria Genome Project (One Health) and longitudinal population cohort with biobank. | ST<br>ST<br>ST<br>ST<br>ST, CT |
| | Develop partnerships for proof-of-concept programmes | • Run a pilot programme led by NGSS consortium, integrating multiple data sources to support genomic testing.<br>• Establish partnerships with communities, health facilities, and pharmaceutical companies to build trust, understand, and address concerns. | ST<br>ST |
| | Develop diagnostics appropriate for local diseases and circulating pathogen strains | • Disseminate genomic surveillance strategy progress report.<br>• Scoping review, stakeholders' interviews/surveys.<br>• Disseminate progress report on tool development, validation and comparative effectiveness research.<br>• Enhance translational research.<br>• Develop new technologies and systems (diagnostics, prognostics, and biomarkers) using One Health approach to track emerging infections and offer early outbreak warnings to expedite control. | CT<br>ST<br>CT<br>CT<br>CT |
| | Design and develop drugs and vaccines | • Implement standardization of reporting protocols.<br>• Integrate data collection on communicable and non-communicable diseases from healthcare establishments with standard metadata.<br>• Promote pharmacogenomics, drug discovery and vaccine development. | ST<br>CT<br>MT, LT |
| | Track disease burdens, determinants and evolution | • Use omics to track disease burdens, determinants and evolution.<br>• Build infrastructures (sequencing technologies, bioinformatics and reference databases) to elucidate the dynamics and interplay determining health or disease.<br>• Establish collaborative network and partnerships.<br>• Develop feedback mechanism to communicate surveillance data to policymakers, public, and health care providers.<br>• Acquire relevant certification and accreditation of competence. | CT<br>ST, CT<br>ST, CT<br>CT<br>CT |
| | Establish data and bioinformatics hub | • Develop computational infrastructure (including high performance computing clusters, data storage solutions, cloud-based solutions and hardware).<br>• Develop and standardize bioinformatics workflow.<br>• Maintain database of bioinformaticians and data scientists.<br>• Build capacity in relevant fields. | ST, CT<br>ST, CT<br>ST, CT<br>ST, CT |

**ST=Short-term (Immediate to One year); MT= Medium-term (2-4 years); LT=Long-term (>4 years); CT=Continuous*

## Pillar 2: Prevention, Early Detection and Surveillance

| Pillar | Objectives | Actions/deliverables | Timeline |
|---|---|---|---|
| Prevention, Early Detection and Surveillance | Strengthen prevention systems for communicable and non-communicable diseases | • Develop policy briefs as advocacy and awareness creation tools for policymakers to prioritize genomics surveillance in national health agenda. | ST, CT |
| | | • Conduct a national mapping of existing capacities (staff, space, and systems) to maximise efficiencies, availability and geographic and multi-sectoral representativeness. | ST, CT |
| | | • Leverage on existing networks to support and facilitate data, specimens, and information sharing for public health action. | ST, CT |
| | | • Establish a One Health genomic surveillance system to promote inclusive data integration for public health actions. | ST, CT |
| | | • Integrate a One health genomic surveillance system into National One health surveillance programme. | ST |
| | | • Institutionlise joint projects Define required tools and develop innovative solutions to enhance access and information sharing. | MT, CT |
| | Strengthen surveillance and early detection systems for NCDs and communicable diseases to guide prompt public health actions | • Conduct annual simulation exercises to test the ability of genomic surveillance systems to stretch during an emergency (Simulation of epidemics) | MT, CT |
| | | • Implement continuous improvement processes, including after-action reviews, and utilize real-time information to strengthen practices. | MT, CT |
| | | • Expand the National Integrated Sample Referral Network to include samples from Humans, Animals and the Environment. | ST, CT |
| | | • Establish Zonal biobanks. | MT, CT |
| | | • Develop and enhance training programs for sample management service providers. | ST, CT |
| | | • Enhance automated sample storage and management to ensure quality, biosafety and biosecurity. | MT, LT |

**ST=Short-term (Immediate to One year); MT= Medium-term (2-4 years); LT=Long-term (>4 years); CT=Continuous*

## Pillar 3: Diagnosis and Precision Medicine

| Pillar | Objectives | Actions/deliverables | Timeline |
|---|---|---|---|
| Diagnosis and precision medicine | Deploy validated cutting-edge technologies for routine healthcare | • Develop evidence base for novel genomic and other molecular tools, technologies and biomarkers that improve disease risk prediction, diagnosis and treatment | ST, CT |
| | | • Incorporate validated advances in genomics into routine healthcare to improve disease diagnosis and treatment. | ST, CT |
| | | • Strengthen clinical care, diagnosis, and public health reporting triangulation to reinforce local capacity. | MT, CT |
| | | • Develop a responsive and prompt regulatory framework for adopting new products for routine healthcare. | MT, CT |
| | Expand utilisation of omics technologies for diagnosis of communicable diseases and precision medicine | • Integrate pathogen genomic data with existing epidemiological and laboratory data. | ST, CT |
| | | • Expand genome sequencing and analysis capacity to establish a world-leading pathogen genomics system. | ST, CT |
| | | • Develop genome sequencing to identify new variants and track genomic changes. | ST, CT |
| | | • Deliver and analyse genomes to inform diagnostics, vaccines, prevention, and containment strategies in response to public health threats. | ST, CT |
| | Omics for common non-communicable and rare diseases | • Create novel diagnostics, prognostics, therapeutics, prophylactics, vaccines, and polygenic risk scores. | MT, CT |
| | | • Build capacity for whole genome sequencing and research analytical environments | MT, CT |
| | | • Develop an array of precision medicine and synthetic biology products for diagnosis, prognosis, prevention and treatment of and rehabilitative interventions | MT, CT |
| | | • Progress consortium's long-term plan commitment to offer extensive genomic testing for diseases of concern. | MT, CT |
| | | • Provide molecular diagnosis framework for rare disorders. | MT, CT |
| | Implement an integrated sampling and referral system. | • Improve access to resources/tools for better geographical sampling and data outputs with a one-health approach. | MT, CT |
| | | • Establish a referral system for genetic diagnosis to support prognostic data that informs patient management. | MT, CT |
| | | • An integrated referral mechanism for human, animal and environmental samples. | MT, CT |

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## Cross-cutting Pillar 4: Patient Engagement and Workforce Development

| Pillar | Objectives | Actions/deliverables | Timeline |
|---|---|---|---|
| Stakeholder Engagement and Workforce Development | To engage stakeholders to improve trust in genomics and precision medicine in Nigeria | • Promote engagement between the health workforce and communities.<br>• Develop information and communication tools to enhance knowledge of omics and precision medicine.<br>• Enhance ethical standards, data security, and infrastructure supported by appropriate regulations to build and maintain patient and community trust. | CT<br>CT<br>CT |
| | To develop a skilled workforce for omics and precision medicine | • Strengthen the workforce for genomic surveillance, multiomics, data science and precision medicine to deliver at speed, scale, and quality<br>• Develop and implement omics and precision products competency-based training across relevant sectors.<br>• Design interventions to enhance retention of workforce for omics and precision products<br>• Establish systems for talent development and global partnerships. | ST&CT<br>ST&CT<br>MT&CT<br>CT |
| | Use of omics to drive industrialisation and job creation | • Create an enabling environment that facilitates the use of high-quality bio-samples into valuable data for genomics and precision products for industrialisation<br>• Collaborate with local and global industries to convert data from the bio-samples into drugs, biomarkers, vaccines, diagnostics, and predictive tools to more accessible and affordable products | MT, CT<br>MT, CT |
| | To establish an equitable dynamic governance structure to maximize developmental impact | • Co-develop an inclusive, diverse, and equitable dynamic governance structure for the National Genomics assets to maximize productivity, value, beneficence, impact | ST&CT |

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## Cross-cutting Pillar 5: Resource & Stakeholder Mapping, Gaps, Prioritization, & Strategic Planning

| Pillar | Objectives | Actions/deliverables | Timeline |
|---|---|---|---|
| esource and stakeholder mapping, gap analysis, prioritization and strategic planning | Develop a dynamic national database of resources involved in multiomics and precision medicine | • Create a national database of human, agricultural, and environmental health data, including climate data and biospecimens.<br>• Map existing genomic and multi-omics infrastructure, facilities, and expertise across the country.<br>• Identify and assess existing resources for precision medicine, such as drug discovery, gene therapy, and agricultural genomics.<br>• Disseminate stakeholder mapping document | MT, CT<br>MT, CT<br>MT, CT<br>MT, CT |
| | Conduct a gap analysis of evidence, resource and solution gaps. | • Conduct a gap analysis on the current capabilities of multi-sectoral healthcare workforce in terms of infrastructure, workforce, and expertise for implementing multiomics and precision medicine initiatives. | ST, CT |
| | Co-create a national priority list and strategic plan to fund and harness multiomics and precision medicine research | • Co-develop a national priority list with targets and timelines to address the data, resource, infrastructure, equipment, and human resource gaps in phases, based on the current and projected burden of diseases in line with national health and developmental priorities.<br>• Establish the Nigeria Genome Project and longitudinal population cohort with biobank.<br>• Implement sustainable funding and resource allocation models to support the National Genomic Surveillance Strategy.<br>• Develop a multisectoral strategy for driving One Health precision medicine products and services pipeline.<br>• Develop a monitoring and evaluation framework and program coordination plan for the National Genomics Surveillance Strategy<br>• Develop a multisectoral capacity building program for human resource development and infrastructure.<br>• Maximize partnerships and resources to promote value-add in the broader surveillance and precision medicine architecture.<br>• Create an enabling environment that facilitates the conversion of high-quality bio-samples into valuable data and products for genomics and precision medicine for industrialisation.<br>• Collaborate with local and global industries to convert data from the bio-samples into drugs, biomarkers, vaccines, diagnostics, and predictive tools to more accessible and affordable products. | ST, CT<br>ST, CT<br>ST&CT<br>ST&CT<br>ST&CT<br>ST&CT<br>ST&CT<br>ST&CT<br>ST&CT |

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## Cross-cutting Pillar 6: PLEASE Framework and Data Value Chain

| Pillar | Objectives | Actions/deliverables | Timeline |
|---|---|---|---|
| Political (policy), legal, ethical, anthropological, social and economic (PLEASE) Framework and Data Value Chain | To strengthen PLEASE framework. | • Establish PLEASE framework to govern data and biospecimen collection, storage, access, biosecurity, cybersecurity, sharing, intellectual property protection, and benefit sharing | ST&CT |
| | | • Strengthen the operations of the National Health Research Ethics Committee, State Recs and Institutional Health Research Ethics Committees, including genomics research, post-ethical approval monitoring, and patient welfare. | ST&CT |
| | | • Develop feedback mechanisms between researchers and communities and other stakeholders. | ST&CT |
| | Strengthen data ecosystems | • Build human resources and infrastructure required to curate, use, query, analyse and share genomic data. | ST&CT |
| | | • Establish a national genomic data science strategy, including cybersecurity, and data protection policy covering data sharing, storage, analysis, visualization, interpretation, and dissemination. | ST&CT |
| | | • Develop strategie to promote and manage artificial intelligence and machine learning (algorithms) for bioinformatics and data analysis. | ST&CT |
| | | • Establish coordination mechanisms for omics data management | ST&CT |
| | | • Set up regional genomic sequencing laboratories with state-of-the-art technology supported by AI for real-time data analysis. | ST&CT |
| | | • Build Infrastructure to support data management. | |

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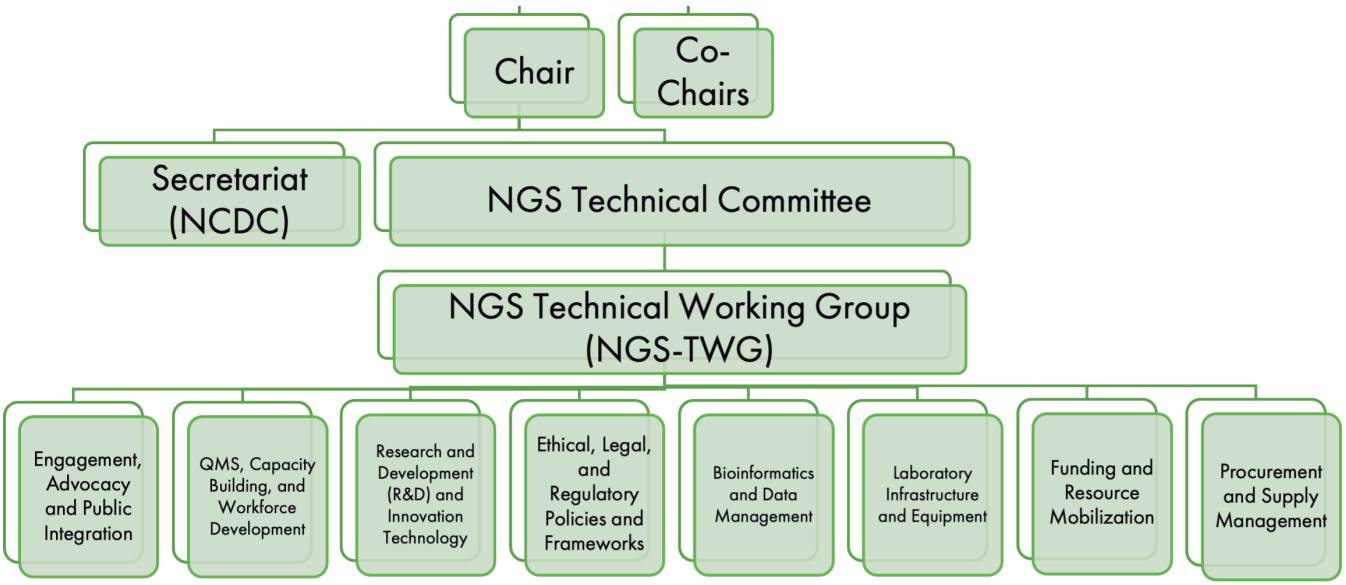
# CHAPTER THREE

## GOVERNANCE AND IMPLEMENTATION APPROACH

### Governance and Scientific Leadership

Nigeria has established the Nigeria Genomics Surveillance Consortium (NGSC) to support the development and integration of genomic technology in disease surveillance programmes. The consortium will facilitate nationwide genomics surveillance to enhance the identification, monitoring, and prevention of public health threats. The consortium includes all laboratories and facilities in the country with sequencing capacity, computational infrastructure, data analyses, and other relevant technologies (see annex 4).




### Roles and Responsibilities

The roles and responsibilities of stakeholders on the NGSC are listed below:

### Chair and Co-chairs

- Manage quarterly consortium meetings.
- Set the strategic vision and goals for the consortium.
- Ensure alignment of consortium activities with national genomic surveillance objectives and public health priorities.
- Provide leadership, national oversight, and support resource mobilization.

### Secretariat

- Develop the meeting schedule for each calendar year.
- Provide regular, comprehensive reports on implementation processes to the NGSC quarterly.
- Send meeting invites at least two weeks ahead of a scheduled meeting.
- Document meeting proceedings and send out meeting notes no later than five working days after the meeting is held.

## NATIONAL TECHNICAL COMMITTEE

### TWG 1: Engagement, Advocacy and Public Integration

- Provide technical advice to the government on the implementation of national policies for genomic sequencing.
- Identify and engage with key stakeholders, including government agencies, research institutions, healthcare providers, and industry partners.
- Stakeholder engagement to convey back information generated from the samples received.

### TWG 2: QMS, Capacity Building, and Workforce Development

- Implement quality management systems (QMS) across all sequencing laboratories.
- Provide external quality assessments (EQAs) to evaluate and enhance laboratory performance.
- Regularly report on performance metrics and quality indicators to stakeholders.
- Ensure compliance with and conduct of testing according to ISO 15189 or 17025 quality standards to genomic sequencing or other quality standards as applicable.

### TWG 3: Research and Development (R&D) and Innovation Technology

- Support implementation of operational research for diagnostics, vaccines and therapeutic development, and surveillance.
- Review research outputs and findings to inform public health policy and practice.
- Establish local capacity for production of reagents and consumables for genomic surveillance by incentivizing local suppliers/manufacturers.

### TWG 4: Ethical, Legal, and Regulatory Policies and Frameworks

- Coordinate .the ethical frameworks and legal issues regarding the implementation of the strategy

### TWG 5: Bioinformatics and Data Management

- Develop and maintain bioinformatics tools, systems and pipelines for genomic data analysis.
- Provide oversight for genomic data analysis.
- Monitor genomic data trends and report findings.
- 
- Create frameworks for data sharing, integration, and security to facilitate research while protecting individual privacy.

### TWG 6: Laboratory Infrastructure and Equipment

- Standardise laboratory equipment, including preferred models.
- Establish appropriate maintenance culture and system.

### TWG 7: Funding and Resource Mobilization

- Lead advocacy and resource mobilization to support national genomic sequencing efforts.

### TWG 8: Procurement and Supply Management

- Provide technical assistance on issues relating to selection, evaluation, and procurement of consumables and reagents.
- Coordinate all functions of genomic sequencing supply chain to ensure effective resource utilization.
- Lead advocacy and resource mobilization efforts for genomic sequencing supply chain.
- Develop and review of genomic sequencing supply chain SOPs.

## Molecular Testing and Sero-surveillance

Surveillance networks shall be established to:

- Incorporate the use of RDT at the primary health care laboratories for the diagnosis of infectious diseases.
- Positive RDT cases shall be referred to the secondary health care facilities for molecular testing and eventually upscaled to consortium labs for sequencing.
- Establish a link between laboratory facilities conducting genomic sequencing and facilities for case management of both communicable and non-communicable diseases.

## Strengthen Triangulation of Clinical Care, Diagnosis, and Public Health Reporting for Local Capacity

- Strengthen the integration of clinical care, diagnostics, and public health reporting by incorporating routine clinical data into the national surveillance system (SORMAS).
- Enhance healthcare infrastructure with essential medical equipment and current diagnostic tools.
- Establish a robust, interoperable health information system for seamless data exchange.
- Expand genome sequencing and analysis capacity and establish a cutting edge pathogen genomics system to detect and monitor local, regional, and national infectious disease threats.
- Develop a robust bioinformatics infrastructure for data storage, processing, and analysis and.
- Implement cloud-based solutions for scalable and secure data management.
- Train a cadre of bioinformaticians, laboratory professionals and researchers in genomic sequencing and data analysis.
- Foster collaborations with international genomic research centres and public health organisations and establish exchange programs and joint research initiatives to build local expertise.
- Establish a strong referral system for genetic diagnosis, allowing diagnostic and prognostic information to inform patient management.
- Develop a strategic plan with clear objectives, timelines, and responsibilities for establishing a referral system in line with the national health policies and international best practices.
- Enhance existing laboratories and healthcare facilities to support genetic testing and diagnostics to meet international quality standards.
- Develop and implement training programs for healthcare providers, including laboratory professionals, doctors and nurses, on genetic testing and patient referral processes.
- Develop and implement SOPs for genetic testing protocols, including referral criteria,
- , documentation requirements, and follow-up procedures.
- Establish a network of primary, secondary, and tertiary healthcare providers who can refer patients for genetic testing and follow-up care, and clear pathways and communication channels within the network to ensure efficient patient management.

## Establish an Integrated One Health Genomic Surveillance System

- Evaluate the current state of genomic surveillance capabilities across human, animal, and environmental health sectors.
- Establish and equip genomic sequencing laboratories with advanced technology for disease detection across humans, animal, and environmental samples.

- Conduct training for healthcare providers, veterinarians, environmental scientists, and laboratory professionals on genomic surveillance techniques and data analysis.
- Establish comprehensive surveillance programs that monitor CD and NCD threats across human, animal, and environmental health.
- Establish quality control protocols for genomic sequencing and data analysis to ensure accuracy and reliability.

## National Genomic and Research Programmes

- Establish national multiomics biobanks.
- Develop diagnostics and prognostics at primary, secondary and tertiary levels for both CDs and NCDs.
- Develop therapeutics and vaccines.
- Establish systems to track disease burden, and pathogy evolution

## Standardisation of Laboratory Protocols and Logistics

- Standardize laboratory protocols and logistics, especially consumables and equipment.

## Laboratory Metadata Collection Processes

- Develop and disseminate standardised protocols for metadata collection to ensure consistency across all laboratories.
- Ensure that all data collection instruments (e.g., questionnaires, electronic health records) are harmonised to capture essential metadata.

## Laboratory Quality Control Measures

- Implement regular QC checks to validate the accuracy and reliability of genomic data.
- Use centralized databases and QC software to flag inconsistencies and perform routine audits.
- Train staff on best practices for data entry, management, and error correction.
- Equipment that is defective or has outside specified requirements, shall be taken out of service, clearly labelled or marked as being out of service, until it has been verified to perform correctly. Laboratory shall examine the effect of the defect or deviation from specified requirements and initiate actions when non-conforming work occurs.
- Implement a preventive maintenance plan for equipment in all laboratories.

## Sample Handling, Storage, Transfer and Shipment

- Develop of SOP for metabolites as well as logistics and supply chain management system.
- Develop and deploy LIMS to laboratory network within the consortium to ensure uniform information sharing
- Ensure triple packaging for all samples and attach unique identifier according to IATA regulations.

### Sample Management

- Relevant ethical clearance will be obtained where applicable prior to sample collection and appropriate techniques used for specified sample
- Document all relevant metadata and store all samples accordingly.
- Patient samples and materials used in examination processes shall be stored in a manner that prevents cross contamination and deterioration.
- Dispose all biological waste according to regulatory requirements
- Laboratory Data collection plan
- Define standards of measurement with inclusion and exclusion criteria
- Standardization of instruments and tools specific for sample collection of CDs and NCDs
- Development of standardised general laboratory SOP for sample collection specific for CDs and NCDs. This also includes standardised logistics and supply chain management system.
- Processing and Preparation
- Develop standardised protocols for the extraction and purification of DNA, RNA, and protein.
- Implement automation and robotics systems during outbreaks and emergency situations to improve sample turnover.

## Laboratory Quality Control (QC) and Quality Assurance (QA)

- Implement procedures for the identification of compromised samples in all workflows for genomic sequencing other omics analyses.
- Conduct regular QC checks on sample integrity and documentation.
- Develop clear and accessible SOPs for genomic sequencing methods and other omics techniques
- Implement robust QC protocols at each step of the sequencing and analysis workflows to ensure data accuracy and reproducibility.
- Use control samples and benchmarks to validate sequencing runs and genotyping assaysThis might need to be a new section heading?

## Data Integration and Harmonization (including raw omics data)

- Create cloud-based platforms for hosting and sharing bioinformatics tools. Use centralized bioinformatics pipelines for data processing, analysis and sharing (following FAIR principle of data sharing). Plan for expert users to develop new pipelines or use command-line protocols (see annex 7).

## Training, Retraining, and Certification

- Develop regular training and retraining programs for both new, covering all aspects of genomics. Including Competence Certification and Personnel will be required to obtain all relevant competency-based certifications (See annex 5).
- Develop a certification process for laboratories and facilities (see annex 5)
- Logistics for Reagents and Consumables Shipping and Clearing
- Standardise shipping procedures. (see annex 6 for details
- Work with regulatory authorities (NAFDAC, Customs, MLSCN, etc.) to streamline the process for obtaining necessary waivers and permits.
- Develop unified waiver request template and submission schedule.
- Engage selected network of clearing and forwarding vendors with experience with biological materials.
- Ensure all shipments comply with international and local regulations to avoid delays and losses.

## Warehousing and Storage

- In-Country Logistics
- Intra-Network Reagents and Equipment Sharing
- Centralized Inventory System, Sharing Agreements and Logistics Coordination
- Procurement and Inventory Management

## Data Management and Visualisation

- The laboratory data from the wet-laboratory activities need processing. Valid and reliable epidemiologic data will also be required. This includes electronic health records from hospital-based data about the burden of diseases from patients presenting and requesting hospital services (See annex 7 for details).

## Risk Assessment and Mitigation

Risks along the entire workflow and pipeline have been identified and mitigation recommended for each risk identified. The areas evaluated for risks include governance and policy, laboratory data collection and integration, infrastructure and technology, workforce development, surveillance and monitoring, integrated laboratory and metadata sharing and collaboration, evaluation and feedback, and multiple and high taxation. (See annex 8 for details).

# CHAPTER FOUR

## NATIONAL AGENDA DASHBOARD AND HEALTH PRIORITIES

### Review of international best practices

Genomic sequences using metadata can significantly enhance the utility of genomic data for swift scientific discovery during disease emergencies. This is important for early mutation detection and tracking pathogen evolution and spread. Nigeria needs to urgently boost its sequencing and bioinformatics capabilities to meet international best practices, ensure timely data sharing, standardize metafiles, and upload genomic datato relevant biorepositories for equitable access and timely disease reporting and management. The following agenda is recommended for Nigeria's context.[10,11,12,13.]

### 1. Ensure equitable access to genomic surveillance infrastructure

- Advocacy and awareness to policymakers on the value of integrating genomics surveillance into national disease control strategies.
- Map and monitor capability and capacity landscape to maximize efficiencies, availability, and geographical and sectoral representation.
- Develop tailored, decentralized, sustainable tools and solutions that enhance access, optimize workflows, and drive information sharing.
- Stimulate innovation and research to address the development of solutions to local and global public health challenges.
- Provide an enabling environment for a quality-driven market that fosters equitable access, adoption, utilization of genomic surveillance and precision medicine product pipelines.

### 2. Strengthen and increase the workforce for Genomic Surveillance

- Develop and roll out training packages in genomics and bioinformatics for improved competencies and to facilitate evidence-driven decision-making.
- Establish and promote communities of practice and knowledge exchange programmes.
- Implement external quality assessment programmes for genomics and analytics and provide support to comprehensive quality management systems to ensure the accuracy of data and trust in the system.
- Strengthen programmes for workforce development and retention with clearly defined career pathways through the formalization of genomics-related functions and roles.

10 Chen, et al. 2022. doi:10.1038/s41588-022-01033-y

11 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

12 Genome UK: 2021 to 2022 implementation plan. https://www.gov.uk/government/publications/genome-uk-2021-to-2022-implementation-plan/genome-uk-2021-to-2022-implementation-plan

13 The Pandemic Institute. Tackling emerging infections and pandemic threats. https://www.thepandemicinstitute.org/app/uploads/2023/12/The-Pandemic-Institute-Brochure-2023.pdf.

### 3. Enhance data sharing and utilization for decision-making

- Develop a national guideline on genomic data and metadata standards, which balances data privacy with national sovereignty, while balancing the importance of contextual information.
- Develop data-sharing agreements in advance of acute events to promote timely collaboration and coordination.
- Create interoperable platforms and dashboards to support the utilization of genomics data in routine surveillance practice and disease prevention, preparedness, and response.

### 4. Maximize multi-sectoral partnerships and collaborations across institutions

- Leverage existing networks to support and facilitate data, specimen, and information sharing for effective, rapid collaboration to drive public health action.
- Increase network linkages to minimize information silos and maximize impact through sharing of resources, protocols, and bioinformatics tools.
- Foster targeted collaboration with One Health stakeholders for comprehensive, integrated surveillance.

### 5. Maintain preparedness posture for emergencies

- Provide frameworks to test the responsiveness of genomic surveillance systems in preparation for public health events or emergencies.
- Establish and sustain joint projects to maintain capacities and prime systems, including the onboarding of new technologies and tools needed in an emergency.
- Implement continuous improvement processes and utilize resulting information in real-time to strengthen practices.

## Ethics and Confidentiality

- Institute an ethics framework for genomic data privacy, and data sharing to ensure stakeholder trust and engagement.
- Establish a communication interface among researchers, stakeholders, and communities.
- Encourage platforms to improve study participants' literacy on rights and privileges from related research processes and outcomes.
- Establish processes and frameworks to address ethical, legal, and social implications of genomic research.

## Genomic Surveillance System Integration to One Health

Integrating Genomic Surveillance Systems into the One Health approach is crucial for advancing our ability to monitor and respond to emerging communicable and non-communicable diseases that affect humans, animals, plants, and the environment. Nigeria has launched its One Health strategic plan offers a collaborative, multi-sectoral, and transdisciplinary approach to zoonotic diseases. Integrating genomic surveillance systems into the One Health approach will improve the accuracy and effectiveness of disease surveillance, outbreak investigation, and transmission dynamics that promote a holistic and collaborative approach to global health security and sustainability. The genomic surveillance strategy will be integrated into the existing One Health plan through:

### Advocacy and Strategic Engagement of Relevant Existing National One Health structures

- Ensure integrated protocols and methodologies
- Joint training and capacity-building programs
- Coordinated policy and decision-making frameworks
- Public engagement and awareness initiatives
- Develop a framework for open data sharing and collaboration
- Develop a framework for Early Warning Systems based on integrated one-surveillance data

### Integrating One Health Genomic Surveillance Data

- Scaling up the utilization of omics in one health is crucial for early detection, rapid response, and effective control of communicable and non-communicable diseases, bioterrorism events, natural disasters, and other public health emergencies. The activities will encompass human health, animal health, and environmental health as follows:
- Source Mapping to identify all One Health data that are available from hospitals, clinics, laboratories, public health agencies, electronic health records (EHRs), health surveys, wearable devices, social media, and other relevant sources to the dashboard
- Ensure compliance with standards for data collection to ensure consistency, uniformity, and compatibility across different sources. This may involve the use of standardized forms such as CIF and other format
- Develop mechanisms for integrating data from diverse sources into a single, centralized platform or database. This could involve data interoperability standards and data integration technologies (Dashboard)
- Implement data visualisation techniques such as charts, graphs, and maps, data validation, cleaning processes, and data quality assurance. Utilize statistical and analytical methods to analyse integrated surveillance data and extract meaningful insights that impact public health emergencies.
- Interdisciplinary Collaboration among public health professionals, epidemiologists,

statisticians, data scientists, clinicians, and other relevant stakeholders to leverage their data analysis and interpretation expertise.
- Privacy and Security measures to protect sensitive health data
- Real-time monitoring of health indicators and early detection of disease outbreaks or health emergencies. Perform an Annual Impact Assessment to evaluate changes in genomic data annually.
- Stakeholder Engagement: Leverage on the already existing multisectoral structures One Health, National Environmental Sanitation inter-ministerial Committees etch to discuss findings and implications
- Biosecurity and Disease Control: Use integrated surveillance data to inform biosecurity measures and disease control strategies to prevent and mitigate zoonotic diseases.
- Regulatory Compliance: Ensure compliance with relevant regulations governing animal health data, such as veterinary confidentiality laws and animal disease reporting requirements.
- Assess climate Impacts on ecosystems and Infectious Disease considering Environmental Changes, Temperature, weather, Floods -Effect of these Impacts, including the intersection for Zoonotic Infectious diseases. See annex 9 for more details and breakdown.

## Animals, wildlife and plants (food crops)

Scaling up the utilization of omics in Animal and Plant Sectors

- Identification and selection of economically important animals and crops in Nigeria
    - Animals: cattle, poultry, fish, wildlife and others
    - Crops: cassava, yam, maize, cocoa, oil palm, rice etc.
- Identification of genetic markers associated with desirable traits through genomic sequencing
    - Animals: high milk and leather yield, faster growth rate, selection of parent
    - Plants: drought tolerance, disease resistance, high crop yield
- Conduct sequencing the genomes of pathogens that affect key animals and crops to reveal vulnerabilities and inform the development of resistant varieties
    - Animals: Avian influenza, African Swine fever, Anthrax, Mpox
    - Plants: Cassava mosaic virus, Rice blast fungus and other fungal diseases.
- Integrate genomic data with existing agriculture practices
    - Plants: optimization of planting schedules, fertilization, and pest control, thereby increasing overall crop productivity.
    - Animals: Optimization of breeding programmes accelerating the development of superior breeds that combine high productivity with disease resistance.
- Development of genetically modified organism (GMO) for animals and crops with enhanced traits such as faster growth rates, higher nutritional value, and improved resistance to environmental stresses
- Identification and conservation of unique genetic variants within animal and plant

populations through genomic sequencing to enhance biodiversity.

Linkage of Plants and Animals Specimen to Genomic Sequencing Facilities

- Enhance Collaboration with relevant MDAs and other institutions conducting sequencing activities.
- Identify existing genomic sequencing laboratories for animal and plant, and map sites for referrals.
- Expand existing biorepository to include animals and plants samples.

Reducing the Risk of transmission of Zoonotic Diseases

- Implement routine genomic surveillance in livestock, wildlife, and humans to detect zoonotic pathogens early.
- Conduct sequencing to detect novel or mutated strains that might pose a higher risk of transmission or virulence.
- Develop predictive models using genomic data to forecast outbreaks and guide preventive measures.

## Environmental monitoring

- Incorporate environmental epigenetics into the integrated National Environmental Health Surveillance System Guidelines.
- Impact Evaluation
- Data Integration and Analysis
- Conduct a continuous monitoring of the various environmental factors influencing genomic health.
- Evaluate the impact of environmental changes of genomics on human health and animal health.
- Regulate the discharge and distribution of pollutants into the environment.
- Create awareness on the impact of environmental pollution on genomics with respect to human and animal health.

## AMR surveillance and monitoring (Annex 10 details recommendations)

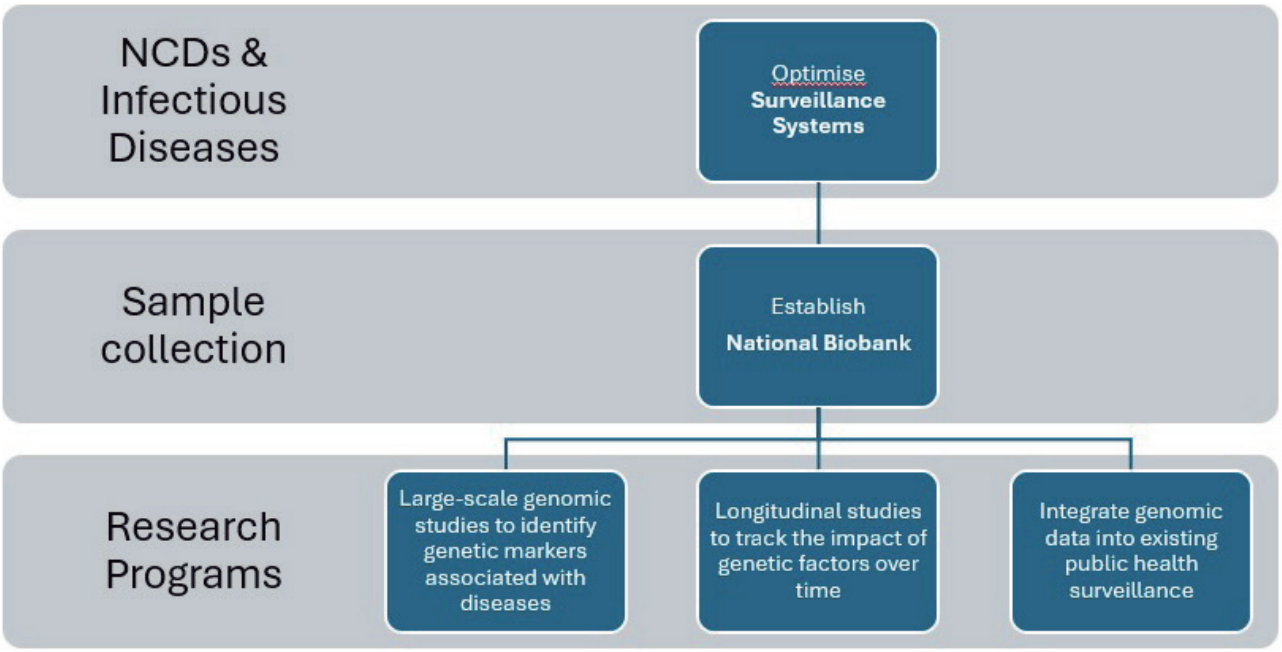
- Develop national guidelines and protocols for implementing WGS for AMR surveillance
- Expand sequencing of AMR pathogens
- Conduct large surveys across one-health sectors
- Integrate data collection and reporting platforms to integrate genomic and phenotypic data for proper interpretation
- Establish a feedback mechanism at different levels of data generation to inform decision making both at the clinical level as well as on a national level

## Precision medicine products pipeline

- Foster the precision medicine and products value chain for prompt, effective and pragmatic solutions to health problems and to propel economic growth in Nigeria. Fit for purpose, for Research and Development, Intellectual Property protection, drug discovery, vaccine, tests, clinical trials, entrepreneurship. Annex 11 details the recommended actions and priorities.

## National surveillance programmes

Establish Surveillance and research programs for NCDs, including large-scale genomic studies to identify genetic markers associated with diseases. Develop a nationwide network of collection sites including hospitals, research institutes, PHCs and the communities and link to the National Biobank. Collect and store samples (blood, stool, urine, saliva) representation of the population and perform deep phenotyping and monitoring. Implement longitudinal studies to track the impact of genetic factors over time and integrate genomic data into existing public health surveillance.




Existing surveillance and research programs include:

- HIV
- Tuberculosis
- Malaria
- Cholera
- CSM
- Measles/Rubella
- Yellow fever virus
- Diphtheria
- COVID-19

- AMR surveillance
- Environmental surveillance

## NCDs recommended for Genomic Research and Surveillance

- Cardiovascular diseases, including stroke
- Cancers (cervical, breast, prostate, colon, leukaemia, lymphoma etc)
- Diabetes
- Obesity
- Kidney disease
- Liver disorders, blood diseases, including anaemia

## National priority pathogens for surveillance

These selected priority pathogens cut across diverse health priorities

- Zoonotic Disease Prevention and Control
- Antimicrobial Resistance (AMR)
- Food Safety and Security
- Neglected Tropical Disease
- Environmental Health and Climate Change
- Research and Innovation
- Disease surveillance and early detection

## Priority pathogens for genomic surveillance programs under one-health approach

- Lassa fever virus
- Mpox
- HIV
- Tuberculosis (MDR/XDR)
- Cholera
- Malaria
- Diphtheria/Pertussis
- Poliomyelitis
- Yellow fever virus
- Meningitis
- COVID-19
- Measles/Rubella
- Dengue
- Influenza
- Rabies
- Ebola
- Marburg
- Avian Influenza
- Rabies
- African swine fever
- Bovine TB
- Anthrax
- Food and mouth disease
- Newcastle disease
- ESKAPE pathogens, ESBL-Ec [AMR surveillance]

## Precision medicine products pipeline

Foster the precision medicine and products value chain for prompt, effective and pragmatic solutions to health problems and to propel economic growth in Nigeria. Fit for purpose, for Research and Development, Intellectual Property protection, drug discovery, vaccine, tests, clinical trials, entrepreneurship. Annex 10 details the recommended actions and priorities.

## Potential Sources of Funding

Securing sustainable funding is necessary for effective implementation. A diversified source of funding through a range of stakeholders, both domestic and international, can strengthen implementation of the NGSS. Domestic sources include the government and the private sector. International development partners include multilateral development partners and global health security partners.

**Domestic Sources**

Governmental Sources

- National Budget: Ministries of Health, Education, Environment, Finance, Agriculture and the Basic Healthcare Provision Fund.
- National Council of Health
- Central Bank of Nigeria
- Sin Taxes: Taxes on tobacco, alcohol, and unhealthy food can generate revenue for health programs.

Private Sector

- Corporate Social Responsibility (CSR) from biotech, pharmaceutical, and medical equipment companies.
- Pandemic Preparedness Funds (e.g., COVAX) and Climate Change Resilience Funds

**International Development Partners**

Multilateral Development Banks

- World Bank
- African Development Bank
- African Union Agenda 2063 funding and SDG funders

Global Health Initiatives

- World Health Organization (WHO)
- African Centre for Disease Control & Prevention (ACDC)
- Global Fund (GF)
- European and Developing Countries Clinical Trials Partnership (EDCTP)

Philanthropic Organizations

- -Bill and Melinda Gates Foundation
- -Other NGOs and Foundations (e.g., Clinton Health Access Initiative)

# CHAPTER FIVE

## INTEGRATED GENOMIC DATA, BENEFITS AND PUBLIC HEALTH DECISION-MAKING

The application of the One Health approach is vital for all-inclusive genomic surveillance and the use of genomic data for national public health security. This approach uses data management systems to ensure effective monitoring, prevention, and control of diseases. The consortium will disseminate findings from sequence data analysis to relevant health stakeholders before public disseminations. Relevant information will be shared in bulletins, circulars or situation reports as fits the need or recipient. NCDC will ensure that the modalities of data sharing would be in line with national, WHO and African CDC policy statements on data sharing in the context of public health emergencies.

### Integrated Genomic Data

Integrated genomic data combines various data types, including laboratory data, metadata, and phenotype data. Integrating these datasets will provide deeper understanding of biological systems and diseases. Unlike traditional approaches that analyze each dataset separately, integrated genomic data analysis pulls together several data sources for a more extensive and synergistic view. The objectives of integrating genomic data include:

- To enhance data interoperability by facilitating the exchange and analysis of genomic data across different disciplines, sectors, and institutions for holistic analysis and response to health threats.
- To strengthen data security and privacy by implementing robust security measures to protect sensitive genomic data, adhering to data privacy regulations and guidelines, and ensuring informed consent and data anonymization.
- To establish ethical data use by promoting the responsible use of genomic data to advance public health while safeguarding individual privacy.
- To build capacity and infrastructure development by investing in infrastructure, training, and resources to support effective data management and analysis.
- To accelerate research and innovation using integrated genomic data to drive scientific discovery and develop innovative health interventions.

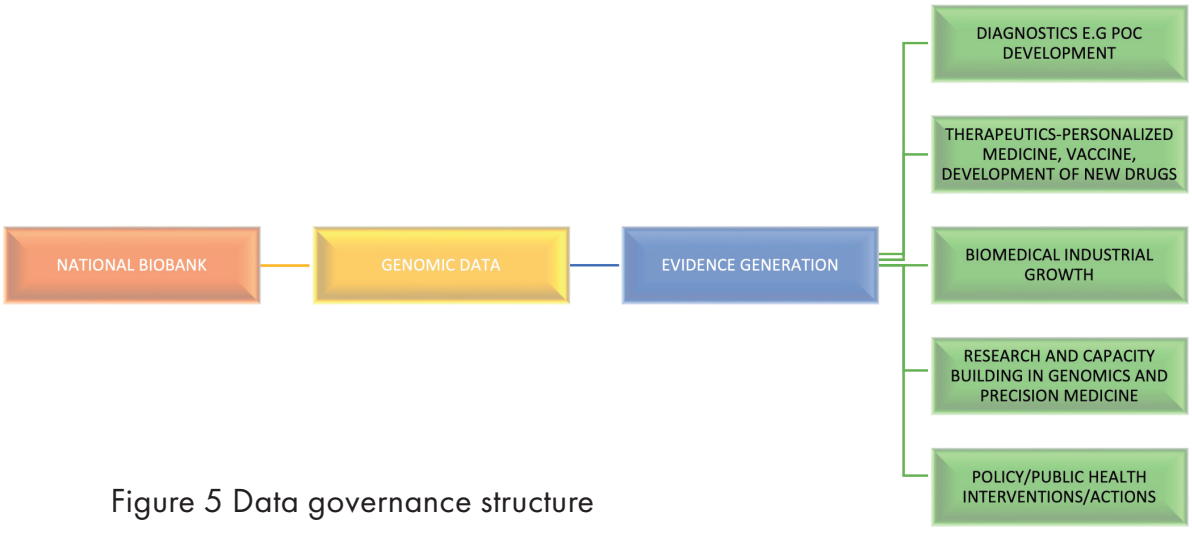



Figure 5 Data governance structure

## Data governance

To ensure the ethical and legal use of genomic sequencing data, the consortium will disseminate relevant policy documents, enforce data access rules, and raise awareness of potential consequences for non-compliance.

- Constitute and commission a genomic sequencing data governance TWG to develop data governance policy and ensure its implementation across all cascades of data management.
- Constitute and commission a genomic sequencing data governance TWG to develop data governance policy and ensure its implementation across all cascades of data management
- Conduct a periodic data governance TWG meeting to address issues regarding genomics surveillance data, conduct analysis and review data quality assessment reports for informed decision making.
- Conduct periodic audits and continuous monitoring to detect and address vulnerabilities.
- Establish a Digital One Health framework for leveraging technology to create a shared data resource for OH decision-making.

## Data collection

Identify Data Sources: Develop mechanisms for integrating data from diverse sources into a single, centralized platform or database. This includes hospitals, clinics, laboratories, public health agencies, electronic health records (EHRs), health surveys, wearable devices, social media, and other relevant sources to the dashboard.

- Adopt standardised protocols by implementing rigorous quality control measures to ensure the accuracy, reliability, and integrity of genomic data collected for consistency and comparability across different sectors (Humans, Animals, and Environment) and regions.
- Obtain informed consent from individuals and communities before collecting genomic data, ensuring transparency about how the data will be used and protected.
- Establish the use of uniform data capturing tools across all facilities and surveillance systems to improve completeness of meta-data.

## Data Validation and Quality Assurance

Define and implement rigorous data quality standards for genomic sequencing data to ensure accuracy, consistency, and reliability.

- Develop and execute data validation protocols to verify the integrity and correctness of genomic data throughout the data lifecycle.
- Perform regular audits to assess data quality and compliance with established standard protocols such as orthogonal methods (technical e.g., Sanger sequencing, digital PCR) to confirm NGS results, and Analytical Validation for sensitivity and Specificity by Comparing NGS results with known reference standards.
- Develop a scoring system that will enable the researchers to quality-assure every generated data.

- Regularly update protocols based on validation outcomes and new research.
- Provide ongoing training for laboratory personnel on updated procedures and technologies.

## Data Storage and Archiving

To establish the relevance of data storage and archiving for effective data capturing, computing, data storage capacity and cyber-security to handle multiomics data using a one health approach.

- Develop a central genomic storage system that will unify and house data from across the nation including deposition of raw reads (fast qc files) from the sequencer to the national data repository.
- Strengthen monthly collection of genetic sequencing data across the genomic sequencing surveillance network.
- Establish long-term archiving solutions to preserve genomic data, allowing for future research and retrospective analysis.

## Data Utilization

- Conduct market research to identify potential applications of genomic data in developing new products and establish partnerships with biotechnology and pharmaceutical companies to leverage genomic data in product development.
- Establish stringent quality control protocols to ensure the reliability and accuracy of genomic data used in product development.
- Create a comprehensive commercialization strategy, including marketing and distribution plans, for products developed using genomic data.
- Implement systems to monitor the performance and impact of products in the market, utilizing feedback for continuous improvement.

## Data Sharing, Access and Protection

Data sharing interventions are based on best global practices to ensure ownership and protection of meta-data.

- Adopt and adapt the 13 WHO guiding principles for pathogen genomic data sharing, incorporate cybersecurity, encryption and access protocols to facilitate responsible and equitable data sharing while protecting private information.
- Establish harmonised protocols, norms, standards and reference materials for metadata standards, and templates for data sharing agreements, data use, data visualisation.
- Develop frameworks for informed consent, data/sample sharing and governance of population health data in line with global ethical guidelines (such as WHO, H3Africa, DS-I Africa, Africa CDC).
- Establish a national scientific community to conduct large scale data analysis following good and ethical practices. This will permit answers to critical public health questions such as epidemiological characteristics, transmission dynamics, emergence

of variants, drug or vaccine resistance and the effectiveness of diagnostics.
- Expand the strategy to cover data sharing for NCDs leveraging data sharing resources[14].

Key considerations for data access include processing of personal data, data ownership, benefits to contributors and participants, data repository, data protection and retention policy, and training

- Establish a Data Science Strategy (DSS) that addresses specific standards and use cases in consultation with the relevant stakeholders.
- Develop guidelines for data processing in line with Data Protection Regulations (Nigerian Data Protection Act[15]; intellectual property laws).
- Adopt the Nagoya protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation[16].
- Incorporate cybersecurity, encryption and access protocols to facilitate responsible and equitable data sharing while protecting private information.
- Develop clear data-sharing agreements that outline the terms and conditions for data access and use, balancing openness with security and privacy concerns.

## Capacity building

- Conduct a holistic assessment of the laboratory and surveillance network to determine capacity development needs that can establish and sustain data generation, processing, and submission, as well as reliable curation and bioinformatics and computational biology.
- Establish adequate sequencing capacity, including long read sequencing as well as capacity for multiomics including spatial transcriptomics, proteomics, microbiomics, pharmacogenomics, epigenetics and metabolomics.
- Train bioinformaticians to interpret genomic data to promote decision making, development of new drugs and vaccines and improve diagnostics etc.
- Foster entrepreneurial training, first and second-degree programs, postdoctoral training and programs in relevant disciplines (genetics, veterinary science, bioinformatics, medical laboratory sciences, microbiology, virology, data science, etc) in tertiary institutions in Nigeria.

14 Genomic Data Sharing Policy. https://sharing.nih.gov/genomic-data-sharing-policy.

15 Nigeria Data Protection Act, 2023. https://ndpc.gov.ng/Files/Nigeria_Data_Protection_Act_2023.pdf.

16 Nagoya Protocol. 2010. https://treaties.un.org/doc/Treaties/2010/11/20101127%2002-08%20PM/XXVII-8-b-Corr-Original.pdf

### Procurement and maintenance of data tools:

- Procure data tool - high processing computer gadgets, genomic sequencing equipment, internet connectivity, licensure, and other data management tools for efficient generation, storage infrastructure, processing and analysis of data.
- Distribute equipment, and other data tools to sequencing laboratories and PCR labs in the network
- Deploy experts to install, validate and certify data tools including genomic sequencing equipment
- Conduct end-user training for new and existing equipment to ensure adequate usage and maintenance
- Conduct routine maintenance, timely repair and software upgrading of all data tools and equipment.

## Monitoring and Evaluation (M&E) for Genomic Surveillance

| Activity | Responsible | Timeline | Verifiers |
|---|---|---|---|
| Develop/Finalize the national action plan for genomic surveillance | NGS consortium | Q3 2024 | Approved version of the national action plan |
| Establish an M&E working group | NGS consortium | Q4 2024 | M&E working group inaugurated ToR developed |
| Identify and adapt relevant data collection tools for use across One Health sectors | NGS consortium TWG | Q1 2025 | Scoping report |
| Conduct workshops to develop the M&E framework | NGS consortium/ TWG | Q4 2024 | Workshop report |
| Develop national genomic surveillance M&E guidelines | NGS Consortium TWG | Q1 2025 | Final version of the guidelines |
| Conduct training for M&E officers across One Health sectors | NGS consortium/ TWG | Q2 2025 | Training report |
| Pilot the developed tools across sectors and review based on findings | TWG M&E officers | Q2 2025 | Pilot report |
| Conduct annual supportive supervision to surveillance sites | TWG M&E officers | Q4 every year | Supervisory visit report |
| Conduct annual M&E working group review meeting | M&E TWG | Q4 every year | Annual review meeting report |

## POLITICAL, LEGAL, ETHICAL, ANTHROPOLOGICAL, SOCIAL AND ECONOMIC (PLEASE) FRAMEWORK (DETAILS IN ANNEX 8)


### POLITICAL

To establish a government-wide policy framework to promote sustainable investment in and development of national genomics, multiomics, precision medicine, and One Health initiatives.

### LEGAL

To develop a legal framework that ensures the ethical, legal, and equitable governance of genomic data and biospecimens, promoting the responsible use of these resources for the advancement of public health and scientific research.

### ETHICS

To develop an ethical framework that governs the responsible conduct of genomic research, including informed consent, data privacy, and benefit-sharing.
In collaboration with NHREC, the framework should align with international ethical standards and promote the equitable use of genomic data..

### ANTHROPOLOGICAL

To cultivate a scientific culture that promotes multiomics, precision medicine, One Health, and data science research, with the goal of accelerating healthcare advancements and contributing to national development..

### SOCIAL

To consider the social impact of genomic research through public engagement, awareness, and assessment.

ECONOMIC

To use the multiomics and precision medicine ecosystem to power industrial and inclusive economic growth in Nigeria.

## Data Access and Benefits

Key considerations for data access include processing of personal data, data ownership, benefits to contributors and participants, stakeholders buy-in on unified data repository, data protection policy, document retention policy and training. These will be considered under the following pillars:

**Monetary and non-Monetary Benefits**

Monetary benefits may include, but not be limited to: Access fees/fee per sample collected or otherwise acquired, Up-front payments, milestone payments, payment of royalties, licence fees in case of commercialization, special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity, salaries and preferential terms where mutually agreed, research funding, joint ventures and joint ownership of relevant intellectual property rights.

Non-monetary benefits may include, but not be limited to: sharing of research and development results, collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources and incentives for presentation of cases.

## Genomic Data and Public Health Decision-making

The national data dashboard features should include:

- Interactive filters to allow users to filter data by date, source, or type of error.
- Drill-Down Capabilities to enable users drill down into specific metrics for detailed analysis.
- Automated alerts for when certain thresholds are breached, e.g., error rate exceeds a defined limit.
- Export options with access control allowing users export data and visualizations for offline analysis.
- Monthly collection of genetic sequencing data across the nation
- Inculcate the use of electronic medical record system into the disease surveillance system.
- Deposit of raw fast files from the sequencer to National data repository.
- Utilize genomic data to create prototypes of new products, such as diagnostic tests, personalized medicine solutions, and gene therapies.
- Engage with regulatory bodies to obtain necessary approvals for new products developed using genomic data.
- Ensure that the development and use of genomic data for products adhere to ethical standards and guidelines.

# ANNEXES

## ANNEX 1: Summary of the 2024 Genomic sequencing Capacity Survey

| Institution / Organisation | Lab Name | Contact Person | Contact email | Sequencing Platforms | TAT (Days) | LIMS available? | Shipment services? | # Wet-Lab Staff | # Dry-Lab Staff | # Biobanking Staff | Data Sharing? | QC Measures? | Lab QMS? | ISO standard? |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Irrua Specialist Teaching Hospital, Irrua, Edo State, Nigeria | Institute of Viral and Emergent Pathogens Control and Research (IVEPCR) | Dr Joseph Okoeguale | okoegualejoseph85@gmail.com | Oxford Nanopore Technologies | 14 | Yes | Yes | 6 | 6 | 20 | Yes | Yes | Yes | Not yet |
| Institute of Human Virology Nigeria (IHVN), Abuja, Nigeria | IHVN / International Research Centre of Excellence (IRCE), Genomics Laboratory | Dr Ezenwa James Onyemata | eonyemata@ihvnigeria.org | Illumina; Thermofisher 3500xl and 3130 Genetic Analyzers | 5 | Yes | Yes | 4 | 4 | 6 | Yes | Yes | Yes | Yes |
| Ladoke Akintola University of Technology | Humboldt Research Hub-Centre for Emerging and Reemerging Infectious Diseases (HRH-CERID) | Prof Olusola Ojurongbe | oojurongbe@lautech.edu.ng | Oxford Nanopore Technologies | 2 | No | No | 6 | 2 | 0 | Yes | Yes | No | Not yet |
| Ministry of Health, Lagos State, Nigeria | Lagos State Biobank | Dr Bamidele Mutiu | bamidele.mutiu@lasucom.edu.ng | Illumina; MGI DNBSEQ400 | 3 | NS | NS | 2 | NS | NS | Yes | Yes | No | Not yet |
| National Institute for Pharmaceutical Research and Development | NIPRD | Dr Peters Oladosu | petyem2001@yahoo.co.uk; petersoladosu@gmail.com | BioBase | NA | No | No | 3 | 0 | 1 | No | No | Yes | 17025 |
| National Veterinary Research Institute | Regional Laboratory for Animal Influenza & Transboundary Diseases | Dr Clement Meseko | cameseko@yahoo.com | Oxford Nanopore Technologies | 2 | Yes | Yes | 10 | 20 | 10 | Yes | Yes | Yes | 17260 |
| Nigeria Centre for Disease Control and Prevention | National Reference Laboratory | Dr Olusola Akanbi | olusola.akanbi@ncdc.gov.ng | Oxford Nanopore Technologies; Illumina; Thermofisher 3500xL, SeqStudio | 5 | No | Yes | 7 | 3 | 2 | Yes | Yes | Yes | Not yet |
| Nigerian Institute of Medical Research | Centre for Human Virology and Genomics and NIMR Central Research Laboratory | Dr CK Onwuamah | chikaonwuamah@yahoo.com ck.onwuamah@nimr.gov.ng | Oxford Nanopore Technologies; BGI; Thermofisher 3500xL, SeqStudio | 5 | Yes | Yes | 8 | 8 | 4 | Yes | Yes | Yes | 15189 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Redeemer's University, Ede, Osun State | African Centre of Excellence for Genomics of Infectious Diseases (ACEGID) | Prof Christian Happi | happic@run.edu.ng | Pacific Biosciences (PacBio); Oxford Nanopore Technologies; BGI; Illumina | 3 | Yes | Yes | 12 | 8 | 3 | Yes | Yes | Yes | Not yet |
| University of Ibadan, Ibadan, Oyo State, Nigeria | Biorepository and Clinical Virology Laboratory, College of Medicine | Olatunji Akande | tunjifishi@yahoo.com | Oxford Nanopore Technologies | 7 | NS | NS | 2 | NS | NS | Yes | Yes | Yes | 15189 |
| University of Ibadan, Ibadan, Oyo State, Nigeria | Damien Foundation Genomics and Mycobacteria Research and Training Centre | Prof Simeon I.B. Cadmus | simeonc5@gmail.com | Oxford Nanopore Technologies | 4 | NS | NS | 3 | NS | NS | Yes | Yes | Yes | Not yet |
| University of Ibadan, Ibadan, Oyo State, Nigeria | Centre for Genomic and Precision Medicine (with biorepository and bioinformatic facilities) | Prof. Mayowa Owolabi | mayowaowolabi@yahoo.com | None yet | NS | NS | NS | NS | NS | NS | NS | NS | NS | Not yet |
| University of Ibadan, Ibadan, Oyo State, Nigeria | Global Health Research Unit for Genomic Surveillance of Antimicrobial Resistance | Mariam Odebode | mariam.a.odebode@gmail.com | Oxford Nanopore Technologies; Illumina | Varies | NS | NS | 8 | NS | NS | Yes | Yes | No | Not yet |
| University of Lagos, Lagos, Lagos State, Nigeria | Centre for Genomics of Non-communicable Diseases and Personalized Health Care (CGNPH) | Prof O. Akinloye | oakinloye@unilag.edu.ng | Illumina | NA | No | No | 6 | 8 | 2 | No | Yes | Yes | Not yet |
| University of Lagos, Lagos, Lagos State, Nigeria | Centre for Human and Zoonotic Virology (CHAZVY), College of Medicine | Prof SA Omilabu | omilabusa@yahoo.com | None yet | NA | Yes | Yes | 3 | 2 | 2 | Yes | Yes | Yes | 15189 |
| University of Lagos, Lagos, Lagos State, Nigeria | Genomic Epidemiology of Antimicrobial Pathogen (GEAP) Research Laboratory | Dr Adesola Olalekan | adesolaolalekan@unilag.edu.ng | Oxford Nanopore Technologies | 4 | No | No | 2 | 2 | 1 | No | Yes | No | Not yet |
| University of Maiduguri, Maiduguri, Borno State, Nigeria | WHO National Polio Laboratory | Prof Marycelin Baba | marycelinb@yahoo.com | Oxford Nanopore Technologies Sanger | 3 | NS | NS | 4 | NS | NS | Yes | Yes | Yes | Not yet |
| Usmanu Danfodiyo University, Sokoto, Sokoto State, Nigeria | Centre for Advanced Medical Research and Training (CAMRET) | Abdurrahman Hassan Jibril | Jibril.hassan@udusok.edu.ng | Oxford Nanopore Technologies; Illumina | 5 | No | No | 2 | 2 | 3 | Yes | Yes | Yes | Not yet |

*NS= Not specified*

## ANNEX 2: Tabular representation of the key risk factors driving disease in Nigeria

| RISKS | SOURCES | DISEASE BURDEN | ESTIMATE as at 2021 (DALYs) | ESTIMATE as at 2021 (Death) |
|---|---|---|---|---|
| Environmental | Unsafe water, poor sanitation Air pollution, Ozone pollution, Nitrogen dioxide pollution. Non-optimal temperature, residential radon, lead exposure. | Respiratory Infection, Enteric Infection, Cardiovascular infection, Musculoskeletal Infection. | 10,840.97 per 100,000 | 158.42 per 100,000 |
| Occupational | Exposure to carcinogens Occupational asthmagens Occupational gas fumes Occupational noise Occupational injuries Occupational ergonomic | Transport Injuries, Respiratory diseases, personal violence. | 10,840.97 per 100,000 | 158.42 per 100,000 |
| Behavioural | Malnutrition Poor diet Intimate partner violence Tobacco smoking, alcohol and drug use. | Maternal and neonatal infection, HIV and AIDS, Respiratory Infection, Enteric Infection, Neglected tropical disease and malaria, Mental disorder, Neoplasm | 20,340.95 per 100,000 | 256.8 per 100,000 |
| Metabolic | High fasting plasma glucose High LDL cholesterol High body-mass index Low bone mineral density | Cardiovascular, diabetes and kidney diseases. | 2,588.95 per 100,000 | 88.74 per 100,000 |

# ANNEX 3: SWOT Analysis
## Genomic sequencing platforms and supply chain

| Strengths | Weaknesses |
|---|---|
| • Sequencing technologies: Oxford nanopore – MinION; Illumina - Miseq, Hiseq, Nextseq 500, 2000, Nova seq 6000, Nova seq X Plus, I-SCAN; Thermofisher – ABI 3500xL, ION torrent, GeneXus, GeneTitan Microarray; MGI – G50, G200; 10X Single cell sequencer.<br>• Reagents, consumables and supply chain: In-country channel partners or representatives available for some platforms.<br>• Local production of reagents and supply: Local primers production as oligosynthesizer available in-country. | • Maintenance: In-country engineers not available for all the platforms; most facilities lack maintenance contracts for their equipment; Extensive Instrument downtime as critical spare parts not available in-country for replacement.<br>• Reagents, consumables and supply chain: limited local production; expensive reagents; cold-chain transport and storage challenges; multiple channels for supply besides channel partners; tedious customs clearing procedures; little institutional support for supply chain systems.<br>• Local production of reagents and supply: mostly closed systems; erratic power supply; lack of funding; no access to license patented technology; local source of quality raw materials for production. |
| **Opportunities** | **Threats** |
| • Sequencing platforms: Interlaboratory collaboration for quality control, proficiency testing, peer mentoring and data sharing; In-country capacity development, especially for pandemic preparedness; Establish Nigerian reference genomes project to include more African genomic diversity being the most populous country in Africa; Deepen local health industry with products (diagnostics, drugs, vaccines); Revenue generation from products.<br>• Maintenance: More affordable group maintenance contracts<br>• Reagents, consumables and Supply Chain: Increasing supply channels of supply; cheaper bulk procurement as a group.<br>• Local production of reagents and supply: New biorepository for samples storage and support further research; Build on diagnostics production to improve local production of health products. | • Sequencing platforms: Denial of Nigerian visas for resource persons and bioengineers; Brain drain targeting limited highly technical personnel.<br>• Maintenance: Very expensive maintenance contracts; equipment underutilized and functions in silos; long idle time predispose them to malfunction; Obsolescence of equipment.<br>• Reagents, consumables and supply chain: Currency fluctuations and inflation; Short shelf life; Power fluctuations and no fund for multi-layer power backup systems; Multiple charges for shipping; Inconsistent government policy for goods clearance.<br>• Local production of reagents and supply: Patented technologies difficult to license. |

## Sample Referral Systems

| Strengths | Weaknesses |
|---|---|
| • National structures exist for sample referral and transportation in human health<br>• NISRN for HIV/TB and 3PL sample referral for epidemic prone diseases from state capitals to national reference laboratories (NCDC).<br>• Availability of trained health workers, including IATA certified staff, for sample collection, packaging and transport.<br>• Compliance with International Standards<br>• Strategic partnership and collaborations with agencies, research institutions, international partners and private sectors. | • Fragmentation and limited coordination of sample referral and shipment networks across diverse diseases and programmes.<br>• Logistical inefficiencies, mostly in rural areas.<br>• Few successful biorepositories for sample storage, especially at the national level.<br>• Lack of dedicated government funding for sample referral, transport and storage at all levels, leading to non-optimal maintenance of facilities and capacities.<br>• Insufficient skilled health workforce<br>• Inadequate metadata for samples |
| **Opportunities** | **Threats** |
| • Leverage lessons learnt from the NIPOST trial for sustainable sample referral<br>• Expand infrastructure at storage facilities, including provision of alternative power supply e.g. solar, wind.<br>• Develop and scale-up training programs for sample referral and storage nationwide.<br>• Increase political interest in health security, epidemic preparedness and response.<br>• Leverage and adopt digital sample tracking system<br>• Establish and maintain biorepositories to preserve positive samples for rare pathogens as a valuable resource for future research, and products Research and development.<br>• Increased public-private sector collaborations and participation in the health industry. | • Erratic Power supply<br>• Dwindling funding from development partners<br>• Increasing insecurity and inaccessibility to remote areas affect sample transportation<br>• Political and economic instability<br>• Biosecurity and biosafety threats<br>• Vulnerable sample transport network |

## Bioinformatics and Data Infrastructure

| Strengths | Weaknesses |
|---|---|
| • Improved facilities and infrastructure, with Lab capacity to collect sequencing data.<br>• Genomic data acquired in-country is shared in databases like GISAID (EpiPox, EpiFlu, EpiCov) and NCBI.<br>• Functional national disease surveillance systems (e.g. COVID-19, V. cholera, measles and rubella, yellow fever, Lassa fever)<br>• Collaboration with international labs, UKHSA, CDC, and national AMR surveillance system in human health<br>• Growing talent pool, including expertise and innovation especially in the National TB, HIV programmes | • Insufficient sequencing and bioinformatics capacity<br>• Knowledge, equipment and technology gap<br>• Lack of national EQA programme for sequencingdata<br>• Poor internet infrastructure, power supply, expertise, and equipment maintenance<br>• Limited training opportunities, shortage of skilled workforce and brain drain<br>• Lack of national data storage resources e.g cloud, servers, backup.<br>• Poor data reporting, data integration, data privacy, and data quality |
| **Opportunities** | **Threats** |
| • Global collaboration, virtual trainings and networking<br>• Technology advancement, Internet infrastructure, cloud computing<br>• Government support and Private sector engagement to engender better data and analytics to support policy, interventions and investment.<br>• All-inclusive database, including bacterial, parasite and fungi genomes. | • Cybersecurity risks<br>• Funding variability and lack of sustainability<br>• Political and economic instability<br>• Technological obsolescence and rapid technology changes.<br>• Brain drains - sustainability issue.<br>• Poor regulatory and policy frameworks. |

## Workforce Development and Retention

| Strengths | Weaknesses |
|---|---|
| • Availability of different categories of workforce.<br>• Multiple genomic sequencing labs.<br>• Evolving national commitment | • Inadequate skilled professionals, especially bioinformaticians, geneticists and virologists.<br>• Lack of an established national training package on genomics.<br>• High attrition and low retention of trained workforce |
| **Opportunities** | **Threats** |
| • Leveraging onpolio HIV and COVID-19 infrastructure for other diseases.<br>• Rising global and regional interest in surveillance<br>• Collaborations with international partners on pandemic preparedness and combating Disease X.<br>• Availability of several academic institutions amenable for genomic trainings | • Economic instability<br>• Inconsistency in policies and changes in priorities<br>• Brain drain syndrome |

## Patients, communities and stakeholder engagement, ethical and legal issues

| Strengths | Weaknesses |
|---|---|
| • Availability of relevant policies e.g. National Health Research Policies, Medical Laboratory Services (includes laboratory ethics).<br>• Government Commitment: The Nigerian government, through initiatives like the National Genomic Sequencing Consortium, shows strong commitment to advancing genomic research by engaging various stakeholders to support this goal.<br>• Existing advocacy mechanisms and frameworks for the healthcare systems like RCCE and community informant mechanisms.<br>• The existence of national and state ethics committees and institutional review boards | • Insufficient ethical and legal frameworks for genomic data privacy, consent, and data sharing, .<br>• Lack of community and stakeholder involvement in the design of scientific studies and programs.<br>• Communication challenges between researchers, stakeholders and communities.<br>• Low literacy levels in some communities<br>• Little synergy between programmes, exhibiting siloed programme implementation.<br>• Suboptimal monitoring of research projects after ethical approval, to ensure they are being implemented as approved. |
| **Opportunities** | **Threats** |
| • Existing opportunities and resources within the private sector.<br>• A large and diverse population provides a rich resource for genomic research.<br>• Utilizing digital platforms for information dissemination and engagement with stakeholders.<br>• Policy development and advocacy to address the ethical, legal, and social implications of genomic research and encourage public trust and participation. | • Public perceptions around health research<br>• Legal and ethical issues around incentivization (non-universality of what constitutes coercion, issues around patients' safety)<br>• Misinformation, stigma, cultural and religious issues-<br>• High cost of implementing genomic research |

## ANNEX 4: Members of the Consortium, Technical Committee and Technical Working Groups

### National Genomics Surveillance Consortium (NGSC) membership will include:

- DG NCDC—Chairman of the Consortium
- Representatives from Ministries:
    - Ministry of Health (Division of Non-Communicable Diseases and control)
    - Ministry of Agriculture and Food Security
    - Ministry of Environment
- Representatives from Institutions
    - NCDC, NIMR, NIPRD, ACEGID, BCVL, CERID, CAMRET, CHAZVY, IVEPCR, CGNPH, NVRI, IHVN, IITA, ACEPHAP, BioRTC, MOGID ATBU, BRML Bauchi, Polio Laboratory, Lagos State Biobank (LSB), GEAP, University of Maiduguri, University of Ibadan etc.
- Representatives from Academia
- Industry experts and partners
    - Funding Agencies and partners
    - Original Equipment Manufacturers (OEMs)

### National Genomics Surveillance Technical Committee

Membership of the technical committee will include:

- DG NCDC
- One representative from FMoH, Division of Non-Communicable Diseases and Control
- Chief Veterinary Officer
- Director of Environment
- Five (5) representatives from NCDC::
    - Director of Surveillance and Epidemiology
    - Director of Planning, Research, and Statistics
    - Director of Health Emergency Preparedness and Response
    - Director of Public Health Laboratory Service
    - Director of Health Promotion and Disease Prevention
- National Health Research and Ethical Committee
- National Institute for Cancer Research and Treatment (NICRAT)
- Federal Ministry of Agriculture and Food Security
- Federal Ministry of Environment
- Office of the National Security Adviser (ONSA)
- Nigerian Customs
- Agencies and Health councils (NVRI, NIMR, NAFDAC, NACA, NPHCDA, NITDA, NIPRD, NHIA, NOTAP, NABDA, MDCN, NMCN, MLSCN, PCN, VCN)
- National Emergency Management Agency (NEMA) and Ambulance system
- National Environmental Standards and Regulations Enforcement Agency (NESREA)
- National Universities Commission (NUC)
- Private Associations (ANPMP, NBGN, Genomics Africa, GMLD, AMLSN)
- Partners: WHO, FAO, WTO, CDC, AFENET, Africa CDC, CHAI, JHPIEGO, GU,

RTSL, UKHSA etc
- Information and Media Partners, for public engagement and dissemination

## National Genomics Surveillance Technical Working Group (NGS-TWG)

Membership of this technical working group shall include the following institutions:
- National Reference Laboratory (NRL)
- Central Public Health Laboratory (CPHL)
- Nigeria Institute for Medical Research (NIMR)
- National Veterinary Research Institute (NVRI)
- National Institute for Pharmaceutical Research and Development (NIPRD)
- State Ministries of Health and relevant agencies
- Centre for Genomics and Precision Medicine, University of Ibadan, Ibadan, Nigeria
- Africa Centre for Excellence for Genomics of Infectious Diseases (ACEGID), Redeemer's University, Ede
- WHO Polio Laboratory, University of Maiduguri
- Centre for Human and Zoonotic Virology (CHAZVY), University of Lagos Teaching Hospital
- Global Health Research Unit for Genomic Surveillance of Antimicrobial Resistance (GHRU-GSA), University of Ibadan
- Biorepository Clinical Virology Laboratory (BCVL), College of Medicine, University of Ibadan
- Centre for Emerging and Reemerging Infectious Diseases (CERID), LAUTECH
- Lagos State Biobank (LSB)
- Centre for Advanced Medical Research and Training (CAMRET), UDUTH, Sokoto
- Genomic Epidemiology of Antimicrobial Resistant Pathogen (GEAP) CMUL, UNILAG
- Institute of Viral and Emergent Pathogen Control and Research (IVEPCR), Irrua
- Centre for Genomics of NCDs and Personalized Healthcare (CGNPH), UNILAG
- International Institute for Tropical Agriculture (IITA)
- Representatives of Specific Disease Programs
- National Implementing Partners e.g. IHVN, APIN
- Humboldt Research Hub for Zoonotic Arboviral Diseases (HRH-ZAD), University of Ibadan
- Genomics Africa, Nigeria
- Biomedical Research and Training Centre (BioRTC)

## ANNEX 5: Personnel and Facilities Competence Certification and Samples Handling Protocols

### Personnel Training certificate

- Capacity building for the personnel (laboratory, Data, support staff etc)
- Quality Management System-
- ISO-Accreditation training
- Biosafety and bio risk management
- Equipment maintenance and use by the end users
- SOP design
- Bioinformatics and Data Science
- Digital epidemiology

### Facility Service Certification

- Quality Management System, as a minimum standard
- Requisite ISO Accreditation (ISO 15189:2022, ISO 17025:2017)
- National Regulatory Requirement

## Sample Management

### Sampling and Sample Size Estimation

Representative sampling and sequencing from routine surveillance and outbreaks will be used to identify and track emerging variants. This approach focuses on sequencing of genomes in proportion to the number of cases of the respective pathogens per time complemented by interventions to increase genomic sampling density and diversity.

Although driven by a phylodynamic approach to nationwide genomics surveillance, the following sampling frames will be considered:

- Outbreaks and Clusters: Representative sampling with a minimum of five specimens per event should be collected from each outbreak or cluster to investigate transmission dynamics, identify novel variants, and support public health interventions.
- Unusual Pathogens: Any number of specimens can be collected for unusual outbreaks in healthcare facilities to track transmission and implement infection control measures.
- Confirmed Cases with Travel-Related Cases: To mitigate the risk of variant introduction and transmission, comprehensive genomic sequencing of all individuals with travel histories to outbreak-affected areas is strongly recommended.
- Unusual Events: For unusual clinical presentations or super-spreading events, comprehensive sampling is recommended to investigate transmission dynamics and identify potential new variants.

Sampling size and strategy will vary per time and will be updated in response to changes in the epidemiological situation.

### Sample Referral and Transport

To ensure seamless operation of the genomic surveillance system, it is necessary to establish efficient sample referral and transportation processes. NCDC will coordinate with the Nigeria Consortium for Genomic Surveillance (NGCS) to facilitate sample transfer and transportation, leveraging existing infrastructure. Using third-party logistics, the NCDC will carry out the following:

- - Sample collection from testing laboratories and transporting them to sequencing laboratories.
- Provision of necessary cold chain logistics and equipment, such as transport media and cool boxes, to maintain sample integrity.
- Sample tracking by implementing a system to monitor the movement of samples and provide daily/weekly updates.

## Sample Collection:

- Follow standardized procedures for collecting samples to minimize variability and ensure consistency.
- Use appropriate techniques for different sample types (e.g., swab, blood, tissues, stool, soil, water etc.) and for obtaining measurements for environmental surveillance and/or toxicological analysis.
- Sites to work with the Consortium to specify how isolates are obtained, purified, and quality assured prior to shipment to the sequencing labs. And also, whether source specimen is retained or also forwarded.
- Document relevant metadata, such as demography, clinical information, GPS coordinates, environmental conditions, and any observed anomalies.
- Storage space, with conditions that ensure continuing integrity of samples, equipment, reagents, consumables, documents and records shall be provided.
- Patient samples and materials used in examination processes shall be stored in a manner that prevents cross contamination and deterioration.
- Storage and disposal facilities for hazardous materials and biological waste shall be appropriate to the classification of materials in the context of any statutory or regulatory requirements.

## Data collection plan for Samples

- Adopt standards for the metadata such as the PHA4GE. Looking at other standards of measurement such as inclusion and exclusion criteria.
- Instrument and tools needed for collection- hardcopies, electronics standardized devices, software
- Content of CIF (Case Investigation Form) should be specific to the pathogen being considered, where known. There should be standardized CIF for each group or family of pathogen, e.g. for VHFs, and that for non-communicable diseases. This will vary when pathogens are isolated during routine surveillance.
- For unknown aetiologies, include as much information as possible, including environmental confounders as not all occurrences will be caused by pathogens.
- Standardization of modalities for sample collection methods, specific to the pathogen

of interest and parameters of interest

- Development of SOP- this includes General Laboratory SOP for sample collection and Specifics for the pathogen of interest as well as other parameters, considering Non-Infectious diseases. This also includes SOPS for packaging, Transportation, reception, Storage of samples as well as shipment.

## Samples Storage, Transfer and Shipment

### Storage

- Standardize storage conditions (e.g., temperature, humidity) for different sample types.
- Implement a centralized inventory system for tracking sample storage locations and conditions.

### Transfer and Shipment

- Package samples securely to prevent leakage, breakage, or contamination during transport.
- Label each sample container clearly with unique identifiers, sampling information, and any required handling instructions.
- Ensure compliance with transportation regulations and shipping guidelines for hazardous or perishable materials.

## ANNEX 6: Logistics for Shipping, Clearing and Inventory management of Reagents and Consumables

### Shipping Procedures

Develop standardised procedures for the shipping of samples, including appropriate packaging, labelling, and documentation.
Use courier services with expertise in biological sample transport to ensure compliance with regulatory requirements.
Sample should be transported at the appropriate temperatures and tracked real time to the last mile distribution pathway.

### Warehousing and Storage

- Provide an adequate storage system for all commodities with the relevant temperature monitoring standard.
- Provide storage facilities, ensuring proper handling, storage, and security measures are in place.

### In-Country Logistics

- Develop network of internal last-mile delivery services
- Determine the logistics requirements including transportation modes, routes, timelines, and budget constraints.
- Identify potential risks such as delays, damages, or security threats and develop contingency plans to mitigate them.

### Intra-Network Reagents and Equipment Sharing

Implement a centralized inventory system, sharing agreements and logistics coordination

- Develop site-agnostic inventory system
- Deploy system and conduct relevant trainings across partner laboratories
- Conduct periodic audits to ensure compliance of sites with input and updating of assets and consumables

### Sharing Agreements

- Develop templates for reagent and equipment sharing across sites

### Logistics Coordination

- Develop SOPs for asset packaging, shipment and receipt
- Ensure the SOPs include the detailed instructions for preservation of cold chain throughout the transport process, as necessary
- Develop verified network of delivery/courier services
- Develop checklist to ensure delivery services can comply with our transport SOPs

**Procurement and Inventory Management (Product Selection, Quantification, Procurement, and Inventory Management)**

- Evaluate equipment footprint in the country
- Evaluate available local and international vendors on basis of cost, availability of supply, lead time for orders and quality of products
- Ensure availability of technical support

**Quantification and Procurement**

- Develop centralized procurement SOPs
- Use consortium-wise procurement strategies for effective negotiation, when applicable
- Estimate volume of commodities needed per time and place supply orders Establish necessary warranties and service agreements.

**Inventory Management**

- Implement centralized inventory system as explained above
- Adjust future orders based on usage to prevent instance of stockout or oversupply (operate system on a regular feedback loop)

## ANNEX 7: Data Management and Visualisation (mostly wet-lab data, including raw data)

A few data systems exist for selected infectious diseases such as COVID, etc

- GISAID (EpiPox, EpiFlu, EpiCov) and NCBI.
- Functional national disease surveillance systems (e.g. COVID-19, V. cholera, measles and rubella, yellow fever, Lassa fever) driving evident-based decisions.
- Collaboration with international labs, UKHSA, CDC, and national AMR surveillance system in human health

The data sets being collection of related set of information that can be analysed is sourced usually from health facility, situation reports, line list and SORMAS (eIDSR) with set of variables that are usually in tabular form from these data sources or when extracted, organised and cleaned. The data systems in use now are but not limited to: SORMAS, mSERS, DHIS2, LIMS, LMIS, SITAWARE etc and DAVS solely for analytics. SITREP. National Diseases Outbreaks dashboard.[17].

### Identifying existing data policies and legal framework in Nigeria

### Identify data protection and regulatory bodies/polices

- National Data Protection Commission
- Nigeria Data Protection Act 2023

### Review current data policies

- Understand how genomic data can be managed in accordance with the frameworks
- Addition of policies and review to fit genomic data e.g. Emerging Technology Act
    - Develop and implement consensus on data and meta data standards
    - Establish data sharing and access principles
    - Ensure data sharing agreements
    - Harmonize norms, standards, benchmarks and reference materials

### Data management strategy and visualization

- Develop strategy on data management, collection, transmission, analysis, access and storage
- Engage and Disseminate strategies to key stakeholders and end-users
- Develop advanced data visualization tools that allow intuitive exploration and interpretation
- Train key stakeholders and users on the data management tools to enable effective use
- Standardize tools to provide quality data for informed decision and policy making, research, industries etc

[17] https://ncdc.gov.ng/data

## National big-data storage and computing network

- Create a indigenous cloud storage solution capable of storing large volume of data- e.g. collaboration with galaxy backbone. Raw data will be stored here.
- Create a shared data centre for the consortium with a bigger bandwidth and high-performance computing network. Members can access the platform from anywhere.
- Development of Data computing network that allows for effective resource sharing, centralized management, enhanced security. Configured as standardised pipelines to facilitate analysis.
- Maintain an expert team to develop new pipelines and analysis and maintains and updates the existing pipelines.
- Implement pathways for expert analysts to develop and use Command Line protocols on the computing platform. This gives room for when standard pipelines cannot handle the data etc and can be standardised in SOPs. It could ultimately lead to the development of new pipelines or command-line protocols for analysis.
- Firewall the metadata according to global standards[18].

## Data usage and stakeholders' engagement

- Developing guidelines that will ensure trusted research environment that will span across data management chain.
- Coordinating access to genomic data including patent and copyrights (intellectual property).
- Developing framework for commercialization of genomic data
- Guideline for integration of artificial intelligence in data analysis and usage with emphasis on quality indigenous data.

[18] https://osf.io/preprints/osf/s6wkt

## ANNEX 8: Risk assessment and mitigation

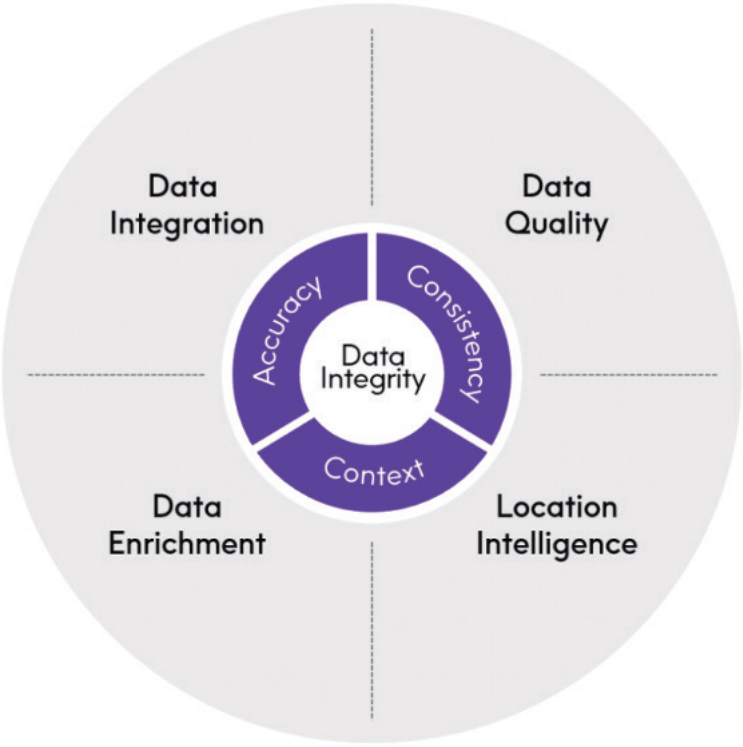

### Governance and Policy Risks

- Fragmented governance efforts.
    - Mitigation: Establish a national governance body to oversee and coordinate all genomic sequencing activities across sectors.
- Insufficient ethical and legal frameworks as well as Poor Adherence to ethical guidelines
    - Mitigation: Improve the current ethical and legal guidelines for genomic data use, ensuring privacy, consent, and data security.
- Standardization of policy and procedure
    - Mitigation: Develop a multi-sectoral SOPs and policy to drive genomic surveillance and associated
- Budget and Financing
    - Mitigation: Develop a robust policy that will enhance adequate budgeting, financing and timely release of funds for the implementation projects: industry, facilities
- Lack of sustained commitments across the 3-tiers of Government
    - Mitigation: Develop a data-driven advocacy strategy, policy briefs that can be used to engage across the three government levels
- Poor stakeholder consensus:
    - Mitigation: Strengthen existing coordination mechanisms e.g. TWGs

### Data Collection and Integration Risks

- Inconsistent data collection protocols.
    - Mitigation: Implement standardized protocols for data collection across human, animal, and environmental health sectors.
- Data silos and lack of interoperability.
    - Mitigation: Develop interoperable data systems and promote multisectoral data sharing using standardized formats and APIs.
- Incomplete or inaccurate data collection.
    - Mitigation 1: Train personnel in accurate data collection methods and regularly audit data quality.

    - Mitigation 2: Develop a SOPs that will guide the activities of data quality personnel and ensure compliance.
- Data integrity and quality
    - Mitigation: Develop minimum data quality standard that will ensure the quality and integrity of data across sectors
- Data protection
    - Mitigation: Develop a robust data protection policy that will be widely disseminated across health and other health-related sectors




## Infrastructure and Technology Risks

- Insufficient computing and storage infrastructure: Biorepository, industry, facilities
    - Mitigation: Commit resources to high-performance computing (HPC) and cloud storage solutions to handle large-scale genomic data.
- Rapid obsolescence of technology and infrastructure
    - Mitigation: Encourage regular update programs and skills
- Cybersecurity threats.
    - Mitigation: leverage on NITDA cybersecurity platforms to strengthen cybersecurity measures, including encryption, firewalls, and regular security audits.

## Workforce Development Associated Risks

- Limited bioinformatics expertise.
    - Mitigation: Develop training programs and hire skilled bioinformaticians to build local expertise.
- Training and competence.

    - Mitigation: Access and availability to training and exposure
- Perceived poor remuneration package
    - Establish special salary scale for crucial desired professionals

### Surveillance and Monitoring Risks

- Delayed detection of health threats.
    - Mitigation: Implement real-time data monitoring systems supported by AI for rapid threat detection.
- Ineffective outbreak response.
    - Mitigation: Develop and regularly update outbreak response protocols, ensuring readiness for rapid genomic sequencing and analysis during health crises.
    - Mitigation 2: Develop a multi-sectoral monitoring and response system that will also include non-orthodox health systems (traditional and alternative medicine practition-ers) and the communities.
    - Nonorthodox: traditional healers for notification
- Inadequate epidemiological surveillance.
- Mitigation: Integrate genomic data with traditional epidemiological surveillance to enhance disease monitoring and control.

### Data Sharing and Collaboration Risks

- Restricted data access due to privacy concerns.
    - Mitigation: Implement data anonymization techniques and establish clear data-sharing agreements that respect privacy while facilitating collaboration.
- Non-alignment of organizational philosophy, target and goals of key players
    - Mitigation: Foster collaborative networks and partnerships between academic institutions, research centres, and international organizations.
- Incomplete data sharing leading to knowledge gaps.
    - Mitigation: Promote open data initiatives and incentivize comprehensive data sharing across sectors.
- Lack of collaboration between sectors.
    - Mitigation: Special interagency advocacy team to promote collaboration

### Evaluation and Feedback Risks

- Ineffective framework evaluation.
    - Mitigation: Conduct regular audits and evaluations of the genomic sequencing framework, using both internal and external reviewers.
- Lack of actionable feedback.
    - Mitigation: Establish mechanisms for continuous stakeholder feedback and use AI to analyse feedback for actionable insights.
- Unclear impact assessment.
    - Mitigation: Develop clear metrics and indicators for impact assessment, ensuring regular reporting and transparency.


**Multiple and high Tax Risks**

- Ineffective framework evaluation.
    - Mitigation: Conduct regular audits and evaluations of the genomic sequencing framework, using both internal and external reviewers.

## ANNEX 9: Integrated Surveillance Data

### General

- Interdisciplinary Collaboration: Foster collaboration between environmental scientists, ecologists, geographers, climatologists, statisticians, data scientists, policymakers, and other relevant stakeholders to leverage their expertise in environmental data analysis and interpretation.
- Environmental Monitoring Networks: Expand and strengthen environmental monitoring networks to increase data coverage and resolution across different spatial and temporal scales.
- Early Warning Systems: Develop early warning systems based on integrated environmental surveillance data to detect and respond to environmental hazards, such as pollution events, natural disasters, and climate change impacts. Implement automated alert mechanisms and risk assessment tools to facilitate timely interventions.
- Sustainability and Resilience: Use integrated surveillance data to inform sustainable resource management practices and enhance ecosystem resilience to environmental stressors. Identify priority areas for conservation, restoration, and adaptive management based on environmental monitoring results.
- Resource Allocation and Utilization: Personnel training, Infrastructure funding, Interdisciplinary research, Combined surveillance systems and Integration interventions
- Health Outcomes and Impact: Effective prevention and control of diseases, Positive health outcomes for populations and ecosystems and Minimal risk
- Policy and Regulatory Updates: Genomics has the potential to improve the health of all Nigerians by aiding in disease prevention, diagnosis, treatment, and monitoring

.

The National Health Genomics Surveillance Strategy is a blueprint to embed genomics in the Nigerian one- health system approach. The purpose of the framework is to:

- Establish a high-level policy document to guide government activity across public genomics policy
- Help mainstream genomic services to deliver better health outcomes
- Raise ethical, legal and social issues to do with genomics
- Ensure policymakers consider ethical, legal and social issues when developing or implementing public policy and research
- Provide national leadership for embedding genomics in the Nigerian one health system approach.

The National Framework aims to help people live longer and better lives through harnessing the benefits of human genomics in a cost-effective, equitable, and ethical way in the Australian health system. It sets the direction for a nationally coordinated approach to genomics that avoids duplication of effort and leverages current activities. The framework outlines strategic priorities and identifies priority action areas for each.

### Shared data and resources

- Standardized protocols and methodologies
- Joint training and capacity-building programs

- Coordinated policy and decision-making frameworks
- Public engagement and awareness initiatives
- Support for global health initiatives and frameworks
- Encouragement of open data sharing and collaboration
- Bio-genomes and Biodiversity integration

### Human Health

- Identify Data Sources: Bring all the sources of health data that are available. Which include hospitals, clinics, laboratories, public health agencies, electronic health records (EHRs), health surveys, wearable devices, social media, and other relevant sources to the dashboard
- To ensure compliance to standards for data collection to ensure consistency, uniformity and compatibility across different sources. This may involve CIF and other format
- Develop mechanisms for integrating data from diverse sources into a single, centralized platform or database. This could involve data interoperability standards, and data integration technologies (Dashboard)
- Data quality assurance and analysis: This may include data validation, error detection, and data cleaning processes. Utilize statistical and analytical methods to analyse integrated surveillance data and extract meaningful insights.
- Visualization and reporting through data visualization techniques such as charts, graphs, and maps.
- Interdisciplinary Collaboration: Foster collaboration between public health professionals, epidemiologists, statisticians, data scientists, clinicians, and other relevant stakeholders to leverage their expertise in data analysis and interpretation.
- Privacy and Security: Implement robust privacy and security measures to protect sensitive health data
- Real-Time Monitoring: Establish mechanisms for real-time monitoring of health indicators and early detection of disease outbreaks or health emergencies

### Animal Health

Following the same step as in human health with the following additional activities

- Biosecurity and Disease Control: Use integrated surveillance data to inform biosecurity measures and disease control strategies aimed at preventing and mitigating animal diseases.
- One Health Approach: Embrace a One Health approach that recognizes the interconnectedness of human, animal, and environmental health.
- Regulatory Compliance: Ensure compliance with relevant regulations governing animal health data, such as veterinary confidentiality laws and animal disease reporting requirements.

### Environmental Health

Follow up the steps specified above with the additional activities

- Climate Impacts on ecosystems and Infectious Disease considering Environmental Changes, Temperature, weather, Floods
- Effect of these Impacts including the intersection for Zoonotic Infectious diseases

- Tools for bio-surveillance and discovery, Molecular detection and metagenomic sequencing

Several environmental factors affect genomic health, including:

- Air Quality (Particulate Matter, NO2, So2, volatile organic compounds, heavy metals etc)
- Water Quality: Heavy Metals (Lead, Mercury, Cadmium), Pesticides and Herbicides, Industrial Chemicals (PCBs, Dioxins), Pathogens (Bacteria, Viruses, Parasites), Nutrient Levels (Nitrates, Phosphates), pH Levels, Dissolved Oxygen and Salinity
- Soil Quality: Heavy Metals (Lead, Arsenic, Cadmium), Pesticide Residues, Organic Pollutants, Soil pH, Soil Nutrient Levels (Nitrogen, Phosphorus, Potassium) and Microbial Diversity.
- Radiation: Ultraviolet (UV) Radiation, Ionizing Radiation (Radon, Gamma Rays) and Electromagnetic Fields (EMFs)
- Lifestyle and Behavioural Factors: Diet and Nutrition, Physical Activity Levels, Tobacco and Alcohol Use, and Stress and Mental Health
- Chemical Exposures: Industrial Chemicals (Benzene, Formaldehyde), Household Chemicals (Cleaning Agents, Paints), and Pharmaceuticals and Personal Care Products (PPCPs)
- Biological Factors: Microbial Communities (Bacteria, Fungi), Plant and Animal Diversity, and Pathogen Prevalence (Viruses, Bacteria)
- Socioeconomic Factors: Income Levels, Education and Awareness, Occupational Exposures and Access to Healthcare
- Climate Factors: Temperature Variability, Humidity Levels, Extreme Weather Events (Floods, Droughts) and Seasonal Changes
- Light Pollution: Exposure to Artificial Light at Night and Circadian Rhythm Disruption

## Monitoring framework

| Activity | Description |
|---|---|
| Baseline Data Collection | |
| Site Selection | Identify and select representative sites for monitoring. |
| Data Collection | Collect baseline data on air, water, soil, food samples. |
| Data Analysis | Analyse collected data to establish baseline environmental conditions. |
| **Continuous Monitoring** | |
| Quarterly Monitoring | Prepare and submit quarterly reports of findings to Governance Structure for action. |
| Data Analysis | Continuous analysis of monitoring data to detect changes. |
| Impact Assessment | |
| Annual Impact Assessment | Evaluate the impact of environmental changes on genomic data annually. |
| Stakeholder Engagement | Leverage on the already existing National Environmental sanitation interministerial Committees to discuss findings and implications. |
| Policy Development | Develop policies based on findings from impact assessments. |

## Evaluation Metrics

| | |
|---|---|
| 1 | Number of Sites Selected: Reflects the comprehensiveness of baseline data. |
| 2 | Number of Samples Collected: Indicates the robustness of the baseline data collection process. |
| 3 | Baseline Data Reports: Timeliness, Accuracy and completeness of baseline data. |
| 4 | Number of Monitoring Events: Frequency and consistency of monitoring efforts. |
| 5 | Quarterly Monitoring Reports: Insight into environmental changes over time. |
| 6 | Annual Impact Assessment Reports: Effectiveness of assessments in identifying impacts. |
| 7 | Number of Stakeholder Meetings: Level of stakeholder engagement. |
| 8 | Number of Policies Developed: Responsiveness to assessment findings. |
| 9 | Number of Intervention Programs: Effectiveness of mitigation efforts. |
| 10 | Number of Campaigns Conducted: Public awareness and engagement levels. |

## Proposed Interventions

- Incorporate environmental epigenetics into the integrated National Environmental Health Surveillance System Guidelines.
- Impact Evaluation
- Assessment of specific genomic changes (mutations, epigenetic modifications, gene expression alterations) associated with environmental factors)
- Identification of patterns and clusters of genomic alterations in response to environmental stressors
- Establish comprehensive baseline data on environmental factors affecting genomic health as well identify genomic markers that are specific for different

environmental-related diseases.

- Data Integration and Analysis
    - Build the capacity of Environmental Health Officers at all tiers of Government in the areas of advanced bioinformatics and statistical tools to analyse relationships between environmental factors and genomic changes.
    - Development of predictive models to forecast potential genomic impacts based on environmental trends
- Conduct a continuous monitoring of the various environmental factors influencing genomic health.
- Evaluate the impact of environmental changes of genomics on human health and animal health.
- Regulate the discharge and distribution of pollutants into the environment.
- Create awareness on the impact of environmental pollution on genomics with respect to human and animal health.

## ANNEX 10: AMR GENOMICS SURVEILLANCE

### Aim

To implement a national genomic surveillance system that rapidly detects and monitors antimicrobial resistance, informing public health interventions and guiding clinical treatments to reduce the spread and impact of AMR.

### Goals

1. Develop an integrated national network for genomic surveillance of AMR.
2. Strengthen Sentinel laboratories genomics and bioinformatics capacities for AMR detection and monitoring at the NRLs.
3. Promote local, national and international data sharing to track AMR patterns and trends.
4. Leverage AMR genomic data to inform clinical and public health decisions.
5. Ensure sustainable funding, governance, and policy support for long-term genomic AMR surveillance.

### Approach

**A. National Coordination and Governance**

1. **Establishment of a National AMR Genomic Surveillance Committee as a sub-committee under the existing AMR Laboratory Surveillance Sub-TWG:** A multi-sectoral body to oversee the design, implementation, and evaluation of genomic surveillance activities. (add the point at which this is going to fit into the existing national AMR surveillance structure).
2. **Stakeholder Engagement:** Include representatives from public health agencies, clinical laboratories, hospitals, academia, industry, and international partners across the One-Health (OH) sector.
3. **Legal and Regulatory Framework:** Develop a policy framework that addresses data security, ethical use of genomic data, and intellectual property issues, aligned with national and international regulations.

**B. Infrastructure and Capacity Building**

4. **Laboratory Capacity:** Establish a network of sequencing laboratories and provide support with high-throughput sequencing technologies and bioinformatics tools. Identify centralized and regional hubs for sequencing and data management.
5. **Workforce Development:** Build a skilled workforce capable of conducting genomic surveillance. This includes training healthcare workers, laboratory personnel, bioinformaticians, and epidemiologists in sequencing technologies and data interpretation.
6. **Digital Infrastructure:** Create a robust, secure IT infrastructure for data collection, storage, and analysis, ensuring compliance with the National Data Protection Laws.

## C. Genomic Sequencing for AMR Surveillance

7. **Standardized Protocols:** Develop and implement national guidelines for sample management, genomic sequencing, and data analysis, ensuring consistency across all facilities.
8. **Target Pathogens:** Focus genomic surveillance on National priority AMR pathogens, in line with the quadripartite AMR pathogens.
9. **Data Collection:** Collect samples and relevant information from clinical and non-clinical settings for comprehensive AMR monitoring.

## D. Bioinformatics and Data Analysis

10. **Data Pipelines:** Align AMR genomics with the National bioinformatics pipelines for the analysis of genomic data.
11. **Real-Time Data Analysis:** Integrate real-time data analysis platforms to identify emerging resistance trends, gene mutations, and transmission clusters.
12. **Data Sharing:** Ensure secure, transparent sharing of genomic data with national, regional, and international databases, such as the National Center for Biotechnology Information (NCBI) or the European Nucleotide Archive (ENA).

## E. AMR genomic data for Public Health action

13. Harmonize genomic and phenotypic data to provide a comprehensive picture of resistance patterns and their clinical relevance.
14. Ensure that genomic AMR data is available to clinicians in a timely manner to inform decision making across the OH sectors.
15. Use genomic data generated across the OH sector to inform outbreak investigations, and transmissions develop infection control measures, and guide the use of antimicrobial agents.

## F. Data Management, Security, and Ethical Considerations

16. **Data Storage:** Establish secure, scalable cloud or on-site storage solutions for big data generated by genomic sequencing.
17. **Interoperability:** Ensure that data systems are interoperable, allowing seamless exchange of information between laboratories, healthcare providers, and public health authorities.
18. **Encryption and Access Control**: Implement stringent security measures, such as data encryption, to protect patient data and assign appropriate access to authorized personnel.
19. **Compliance:** Ensure compliance with national and international regulations on data security, privacy, and patient confidentiality (e.g., GDPR, HIPAA).
20. **Informed Consent:** Obtain necessary informed consent for genomic AMR surveillance in line with National Ethical Guidelines.
21. **Ethical Use of Data:** Ensure that the use of genomic data adheres to ethical standards, with considerations for privacy, data ownership, and potential misuse.

## ANNEX 11: Precision Medicine Products Pipeline

### Objective

Foster the precision medicine and products value chain for prompt, effective and pragmatic solutions to health problems and to propel economic growth in Nigeria. Fit for purpose, for Research and Development, Intellectual Property protection, drug discovery, vaccine, tests, clinical trials, entrepreneurship.

### Actions

1. Evaluate and prioritize existing precision medicine (PM) products and solutions for near term implementation in African population for national priorities based on disease burden.
2. Establish Equity, Diversity and Inclusiveness (EDI) product development policies that facilitate the discovery, translation, implementation and sustainability of African PM products.
3. Develop a prioritization process for precision medicine that addresses key unmet needs across the African continent based on key criteria i.e. increase quality of care, increase precision, increase cost effectiveness, decrease turnaround time, decrease burden to participants and users, increase innovation potential leveraging competitive advantage to African researchers.
4. Develop a framework and policies that enable transformative partnerships with key industries, academia, professional networks, health service, private investors and government organizations for sustainable product development.
5. Generate a list of potential precision medicine products, services and solutions including novel therapeutics (drugs), vaccines, synthetic biology, biomarkers, prediction tools, prognostics, novel diagnostics, point of care/frontline diagnostics, mobile app-based health solutions, targeted health policies, etc
6. Establish product development and testing pipeline including clinical trials cohorts, regulations, and registration database, like clinical trials.org.
7. Establish Nigeria precision medicine, biotechnology, genetic engineering, and synthetic biology industrial and manufacturing hub/city/ free trade zone
8. Engage health economics and the private sector to develop an economic case, a business case and business model, and assess the SDG impact for the innovative one health value cycle involving biobanks, genomics and the precision medicine value chain.
9. Prepare Case studies: a) synthetic biology and monoclonal antibodies for long-acting therapeutics and cures for hypertension, DM, etc; b) cure for sickle cell disease through CRISP technology c) spit test for prostate ..developed from polygenic risk score which could fetch billions of dollars annually. study calculated the polygenic risk score (PRS) of 6,142 European men recruited from their GP surgeries, aged 55-69 – an age at which risk of prostate cancer is increased. The score is based on 130 genetic variations in the DNA code that are linked to prostate cancer, and it was developed by studying the DNA of hundreds of thousands of men[19].

## Key priorities

### Establish

1. Nigeria Medical Research Council
2. Nigeria Genome project/ Nigerian Genome/ Multiomics Centre of Excellence (Biobank, Sequencing, Multiomics, Precision Medicine, Synthetic biology).
3. Nigeria epidemiologic digital health database for one health, NCDs, communicable disease, etc like CASALUD[20, 21, 22] recognised at the UN, dbGAP, EGA.
4. Nigeria longitudinal population study and biobank (similar to UK biobank, All of US, China Kadoorie biobank).
5. Nigeria precision medicine, biotechnology, genetic engineering, and synthetic biology industrial and manufacturing hub/city/ free trade zone.
6. Nigeria precision medicine industrial and manufacturing hub/city/ free trade zone.
7. Upgrade the NCDC dashboard to include real-time data on the burden of common noncommunicable diseases and outbreaks of infectious diseases.

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[19] Prostate cancer spit test better for men with high genetic risk than standard blood test. https://www.royalmarsden.nhs.uk/news-and-events/news/prostate-cancer-spit-test-better-men-high-genetic-risk-standard-blood-test#:~:text=A%20spit%20test%2C%20where%20a,test%2C%20a%20new%20study%20reports.&text=The%20BARCODE%201%20study%20calculated,called%20a%20polygenic%20risk%20score.

[20] Tapia-Conyer, et al. 2013. doi:10.1177/1757913913511423

[21] Tapia-Conyer, et al. 2016. doi.org/10.1186/s12961-016-0125-0

[22] https://fundacioncarlosslim.org/english/casalud-100-mexican-digital-health-model-recognized-united-nations-assembly/

## ANNEX 12: Political, Legal, Ethical, Anthropological, Social and Economic (PLEASE) framework

### POLITICAL

### Objective

To establish a whole-of-government policy framework for sustainable investment in and development of a national genomics and multiomics program and One Health resource as a catalyst for national development and prosperity.

### Actions Item

1. Iincrease budgetary allocation for health, education, science, technology and innovation at all levels of government to power development through innovation and increased productivity. .
2. Develop a policy framework to provide an enabling environment for the multi-sectoral development of One Health epidemiologic and multiomics database (like db GAP, EGA, clinical trials.org, REDCap), biospecimen resource, technology, infrastructure, workforce and longitudinal population-based studies and biobanks for surveillance and control of diseases, health promotion, food security and environmental protection. This will foster the development of precision medicine products and solutions, new drugs and vaccines, pandemic preparedness, to reduce the rising burden of non-communicable diseases, promote resilience to climate change, reduce hunger and accelerate the achievement of the SDGs in Nigeria as a leader in Africa.
3. Establish a national biobank and longitudinal epidemiological ecosystem similar to the UK Biobank, China Kadoorie Biobank, All of US, etc.
4. A national genomics database by whole genome sequencing hundreds of thousands of Nigerian genomes, with deep phenotype data covering infectious, and non-communicable diseases, and the health population, across sociopolitical and ethnic regions in Nigeria.
5. Adequate sequencing capacity, including long read sequencing as well as capacity for multiomics including spatial transcriptomics, proteomics, microbiomics, pharmacogenomics, epigenetics and metabolomics.
6. Establishment of trusted research environments and databases with adequate computing and data storage capacity and cyber-security to handle muti-omics data across disease and one health spectra.
7. Establishment of a national research council to be funded by a proportion of the national budget to enable need-driven and impactful research while attracting counterpart funding from development partners.
8. Utilize real-time reliable and valid data about health for interventions and government decisions and policies; and apply pragmatic evidence-based home-grown solutions to prevent and control diseases and improve food security and accelerate development.
9. Collaborate with academic institutions, the private sector (industry and NGOs) and the community (the public) for synergistic action and efficiency for sustainable and

accelerated impact.

10. Foster entrepreneurial training, first and second-degree programs, postdoctoral training and programs in relevant disciplines (genetics, bioinformatics, medical laboratory sciences, microbiology, virology, data science, etc) in tertiary institutions in Nigeria.
11. Provide an enabling environment for startups and indigenous companies to participate in the precision medicine products pipeline as well as the provision of technologies, equipment and facilities to build capacity for biobanking, multiomics.

## LEGAL

### Objective

To develop a legislative framework including acts, laws and regulations to ensure equitable, just, and fair ownership, processing, sharing, and utilization of the national genome one health ecosystem and value chain (including data, biospecimen,) to foster development while protecting the rights of study participants and intellectual property of investigators; and maximizing health and developmental benefits to Nigeria primarily and the world at large.

### Actions Items

1. Leverage the Nigerian data protection act (2023) and work with the Nigerian data protection Commission to achieve the objective
2. Leverage the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity to develop a legal framework for sharing the benefits arising from the utilization of genetic resources in a fair and equitable way.
3. Collaborate with National Health Research Ethics Committee of Nigeria (NHREC) to develop a legal framework to govern data and material use and transfers; towards maximizing benefits to the primary owners of the data and biospecimen in the first place; while also allowing maximal use of the resources for the benefit of humanity.
4. Collaborate with National Office for Technology Acquisition and Promotion to optimise patency and intellectual property laws and procedures to foster maximal benefit to Nigeria in line with the objective.
5. Provide a legal framework for the use of data and multiomics resources for dispute management, crime management and forensic interventions.
6. Provide a legal framework to protect the rights of study participants and biospecimen providers while mitigating against discrimination.

## ETHICS

### Objective

Collaborate with National Health Research Ethics Committee of Nigeria (NHREC) to develop an ethics framework to govern informed consenting, data and biospecimen collection, use, sharing and transfers; in line with international best practices, guided by the principles of non-maleficence, beneficence and feedbacks (disclosure of results) to study participants, confidentiality, equitable partnerships, equal respect – protection against discrimination and fairness; towards maximizing benefits to the primary owners

of the data and biospecimen in the first place; while also allowing maximal use of the resources for the benefit of humanity.

### Actions

1. Establish a national code of ethics to govern epidemiologic, genomics, multiomics, precision medicine, and One Health research in human health, agricultural , environmental and climate change research.
2. Establish policies to govern genomics, multiomics and precision medicine pipeline research in conjunction with NHREC, civil society, academic institutions and relevant government agencies. These should include:
    a. Ensuring that informed consent is comprehensive and obtained in a cordial atmosphere with full understanding by the study participants.
    b. Protecting and respecting the confidentiality and rights of as well as the consent type provided by study participants who contributed the data and biospecimens.
    c. Ensuring that study participants cannot be identified from the data and biospecimen provided.
    d. Protecting the intellectual property rights of the investigators/scientists who designed the study and collected the data and biospecimen.
    e. Allowing regulated access by scientists and investigators from Africa and across the globe to maximize the utility of the data and biospecimen for discovery science, and precision medicine pipeline.
    f. Ensuring that research benefits accrue to the study participants and communities who contributed the data and biospecimens.
    g. Defining the conditions to be fulfilled for commercial/ industry access to and use of the data and biospecimen including benefits to the study participants and original investigators.
    h. Ensuring fairness through procedural justice where all decision making is transparent, reasonable & inclusive of all parties involved.

3. In conjunction with NHREC and academic institutions, develop template informed consent form, material transfer agreement form, data use agreement form. This could leverage the Nagoya protocol, H3Africa Consortium Data and Biospecimen Access Committee guidelines and other relevant protocols.
4. Establish data sharing and access principles ensuring that ownership of the data and biospecimen is permanently retained by the original investigators who designed the studies and collected the samples and should be involved in any processes, products, publications or patents emanating from the use of the data and biospecimen.
5. Ensure that recipients of data or biospecimen cannot transfer directly to a third party and can only use the biospecimen or data for the purpose specified in their application for data or biospecimen transfer /use.
6. Define how data and biospecimen should be handled after use, e.g. return to the providers or destruction with evidence.
7. Request periodic progress reports by requestors for data and biospecimen use to monitor progress and observance of the terms of agreement.
8. Ensure feedback and return of results and benefits to the participants who contribute

data and biospecimen.

9. Ensure protection of confidentiality of the study participants throughout the process by de-identifying data and avoiding sharing of individual level data unless deemed inevitable for the research study in question.

## ANTHROPOLOGICAL

### Objective

To engender a national culture to foster multiomics, precision medicine, one health and data science research to fast-track health for all and national development.

### Actions

1. Engage the Federal Ministry of Information and National Orientation and utilize social media and home videos and the entertainment industry to engender a culture to support multiomics research and precision medicine pipeline for improving health outcomes and national development.
2. Improve genetic literacy- (public knowledge and understanding)

## SOCIAL

### Objective

To engage, involve and empower individuals, families and communities to participate in co-creating the national multiomics and precision medicine ecosystem to accelerate national development and reduce the burden of disease.

### Actions

1. To incorporate robust community engagement and involvement in the development, implementation and monitoring of the national multiomics and precision medicine ecosystem.

## ECONOMIC

### Objective

To use the multiomics and precision medicine ecosystem to power industrial and inclusive economic growth in Nigeria.

### Actions

Provide an enabling business environment for industry and private sector actors in the genomics, multiomics and precision medicine and synthetic biology equipment, facilities and product pipeline.

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