



Global genomic surveillance strategy

**for pathogens with pandemic
and epidemic potential**

2022–2032



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Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032

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FOREWORD FROM THE DIRECTOR-GENERAL

The COVID-19 pandemic has brought into sharp focus the devastation caused by infectious diseases, claiming millions of lives and disrupting societies and economies around the world. Progress towards many of the Sustainable Development Goals has stalled or regressed, and up to 100 million people have been pushed into extreme poverty.

The pandemic has been a watershed moment in the world's efforts to strengthen resilience to new and emerging pathogens. We have to learn the lessons of COVID-19, which both spurred rapid innovation and proliferation of health tools and technologies, and raised significant challenges in how they were used, particularly in the areas of equitable and timely access.

The emergence of SARS-CoV-2, including its variants of concern, crystalized the need for coherent country, regional and global genomic surveillance systems. From the outset, public health systems needed to detect, characterize, and assess the risks of this virus rapidly and routinely. This information was and remains critical to inform the design and maintenance of effective countermeasures including vaccines, therapeutics, diagnostics, and public health and social measures. We are grateful for countries and partners who stepped up their genomics capabilities, and openly and rapidly shared their data in this collective effort.

In 2021, the World Health Assembly called on Member States to strengthen genomic surveillance in emergency preparedness and response. But genomic surveillance presents challenges, in terms of the laboratory and surveillance infrastructure, capacities and capabilities needed, and the harmonization across systems and countries to be able to compare and use the data effectively. More than two-thirds of countries now have sequencing capability, but some need to stabilize and sustain this powerful technology, while others need to establish and strengthen their genomic surveillance capacities for SARS-CoV-2 and other pathogens with pandemic and epidemic potential.

This new global strategy document is designed to support countries in their efforts to expand their capacities and bring harmonized approaches to robust local-to-global genomic surveillance. The complexities of genomics and the challenges of sustaining capacities in different settings, including workforce needs, means that most countries cannot develop these capabilities on their own. Partners from the entire health ecosystem, along with those in other sectors, can contribute towards this common agenda to leverage what exists, address barriers and fill gaps. We will do best if we work together.

The global strategy helps keep our eyes on the horizon and provides a unifying framework for action. WHO looks forward to working with countries and partners in this important and highly dynamic field.



A handwritten signature in blue ink, which appears to read 'Tedros Adhanom Ghebreyesus'. The signature is fluid and cursive.

Dr Tedros Adhanom Ghebreyesus
WHO Director-General

ACKNOWLEDGEMENTS

In May 2021, during the course of the COVID-19 pandemic, the 74th World Health Assembly adopted Resolution 74.7 on Strengthening WHO preparedness for and response to health emergencies. The Resolution urged WHO Member States to increase their capacity to detect new threats, including through laboratory techniques, such as genomic sequencing.

To support Member States in this endeavor, WHO led a global multi-step consultative process in an inclusive and transparent spirit, to develop the Global genomic surveillance strategy for pathogens with pandemic and epidemic potential.

WHO would like to acknowledge the stakeholders who took the time to provide comments and support the development of this document.

This includes representatives from Member States, global disease networks, international organizations, civil society organizations, private sector, academia and research institutions, and staff of WHO headquarters, regional offices and country offices.

ABBREVIATIONS AND ACRONYMS

ACT Accelerator	Access to COVID-19 Tools Accelerator
COVID-19	Coronavirus disease 2019
EVD	Ebola virus disease
FAO	Food and Agriculture Organization of the United Nations
GISRS	Global influenza surveillance and response system
GOARN	Global Outbreak Alert and Response Network
GPLN	Global polio laboratory network
GSD	Genetic sequence data
IHR (2005)	International Health Regulations 2005
IPPPR	Independent Panel for Pandemic Preparedness and Response
IPSN	International Pathogen Surveillance Network
OIE	World Organisation for Animal Health (Office International des Epizooties)
R&D	Research and Development
SARS-CoV-2	Severe acute respiratory coronavirus 2
SPAR	State Party Self-Assessment Annual Reporting tool
UNEP	United Nations Environment Programme
WHA	World Health Assembly
WHO	World Health Organization

INTRODUCTION

Genomic surveillance is transforming public health action by providing a deeper understanding of pathogens, their evolution and circulation. Used with clinical, epidemiological and other multi-source data, genomic data for pathogens with pandemic and epidemic potential inform risk assessments, the development of vaccines, therapeutics, diagnostic assays, and decisions on public health and social measures. New technologies in sequencing and bioinformatics have emerged in recent years, and some countries have made major strides in establishing and strengthening their capacities and capabilities.

The need for a global strategy

The COVID-19 pandemic has exposed challenges for genomics in public health surveillance systems. Laboratories and networks dedicated to specific disease threats such as influenza, tuberculosis, measles/rubella and polio, were mobilized to support SARS-CoV-2 genomic surveillance efforts. In some contexts, repurposing capacities came at a cost to the disease programmes and their own surveillance and diagnostic needs. In addition, the scale, geographic representativeness, timeliness, quality, comparability and integration of genomic surveillance outputs with epidemiological and clinical surveillance findings remain weak.

We are now at an important nexus. Genomic surveillance has a clear role to play and there is growing global recognition among countries, partners and other stakeholders of the need to scale up in the context of COVID-19. In January, July and October 2021, the International Health Regulations (IHR) Emergency Committee for COVID-19 recommended increasing global sequencing capacities, encouraging the rapid sharing of data including meta data, and for WHO to actively support countries to strengthen systematic genomic surveillance (1). Further, in its report to the Seventy-fourth World Health Assembly in May 2021, the Independent Panel for Pandemic Preparedness and Response recommended regular funding for the delivery of specific global public goods including genomic sequencing as part of pandemic preparedness (2). This culminated in the 74th World Health Assembly (WHA) resolution 74.7 on strengthening WHO preparedness for and response to health emergencies (3). The Assembly urged Member States to increase their capacity to detect new threats, including through laboratory techniques, such as genomic sequencing.

“We are now at an important nexus. Genomic surveillance has a clear role to play and there is growing global recognition among countries, partners and other stakeholders of the need to scale up in the context of COVID-19.”

There is a clear need for a globally coherent, pathogen agnostic, global genomic surveillance strategy for pathogens with pandemic and epidemic potential.

The COVID-19 pandemic has accelerated integration of genomics into public health

Gains have been made in access to genomic sequencing globally. Between 1 March 2021 and 31 January 2022, there was a 14% increase in the proportion of WHO Member States with sequencing capability for SARS-CoV-2, 68% of Member States in total. These gains represent the great efforts of Member States and existing partnerships in strengthening capacities, including the Access to COVID-19 Tools (ACT) Accelerator (4). The ACT Accelerator brought a number of global partners together with the objective to increase equitable access to SARS-CoV-2 tests and sequencing. There is now the need to sustain the gains made and strengthen capacities further.

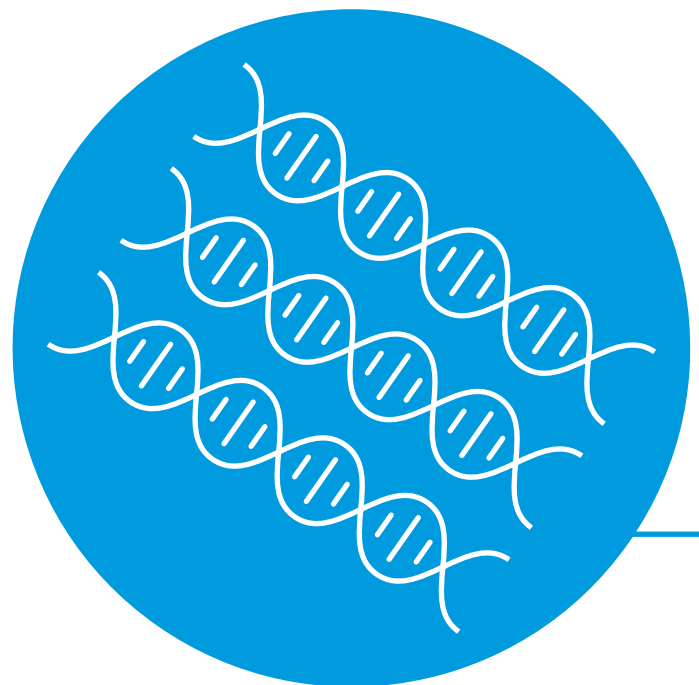
While recognizing its specialized contribution, genomic surveillance and its integration into national public health systems comes at a high cost technically and financially especially in resource-limited settings. The value-add of such an investment should be carefully considered, including in the broader surveillance and landscape of human, animal and environmental health to maintain a coherent One Health approach. In addition, there may be opportunities to strengthen relationships with non-traditional public health partners across private and academic sectors.

Genomic surveillance for other pandemic and epidemic threats

In the context of public health emergencies, there is further impetus to take cross-cutting approaches, develop and apply globally harmonized principles and approaches. Information on public health threats needs to be rapidly available to allow for country, regional and global risk assessments that can quickly trigger public health interventions. The IHR (2005) obligates State Parties to develop national capacity for the detection, investigation and reporting through WHO of potential public health emergencies of international concern (5). Reliable and accessible laboratory services that produce quality-assured results in a timely manner is critical for any country's surveillance capacity and early warning function.

Specialized laboratory techniques such as genomic sequencing are increasingly being used in the investigation and acute management of diseases that could constitute public health emergencies including cholera, influenza, Ebola virus disease, bacterial meningitis and polio. These programmes also have momentum to embed genomic sequencing capacities at country level and integrate with other disease surveillance systems to ensure genomic surveillance can become a part of national public health programming. For example, the Global Polio Eradication Strategy 2022–2026 recognizes that the Global Polio Laboratory Network (GPLN) serves as the gold-standard in poliovirus surveillance, and molecular epidemiology has been used throughout recent outbreaks of Ebola virus disease to assess transmission chains (6, 7).

For influenza, the Global Influenza Surveillance and Response System (GISRS) has been using the genomic sequencing as an integral part of



response to outbreaks of zoonotic influenza and pandemic preparedness as well as seasonal influenza surveillance to inform influenza vaccine virus recommendations and for monitoring of susceptibility to antivirals (8). GISRS was leveraged to integrate SARS-CoV-2 into sentinel systems for influenza-like illness, acute respiratory infection and severe acute respiratory infection to inform policy and the national response to the COVID-19 pandemic.

However, with the need to sustain genomic surveillance in perpetuity as a growing component of public health intelligence, work is underway to transform approaches and shift genomics from academic research into routine public health practice, while supporting countries to establish and take ownership of this function. COVID-19 has accelerated the development of in country capacity and regional networks, which should be leveraged as a foundation to sustainably build genomic surveillance capacity.

Surveillance needs and objectives differ over time including during and between acute public health events. The role and value-add of genomic surveillance should be clarified and embedded throughout the preparedness, readiness, response and recovery cycle. Opportunities to leverage genomics capacities in other communicable and non-communicable disease programmes, and across One Health sectors, should be explored as a means to build on, sustain and surge capacities for pandemics or epidemics. Additionally, innovation, research and development should be encouraged so that new genomic tools and technologies are developed for use in either universal or context-specific needs.

The global strategy

Building on the lessons of the past, the lessons from the COVID-19 pandemic and thinking ahead to future-proof and sustain investments, this strategy focuses on the specialized role of genomics as a cross-cutting capacity within the broader health system from a public health lens.

“It seeks to build on the strengths and capacities that exist through other initiatives, link and embed within the broader surveillance and public health architecture, and identify opportunities to establish capacities, partnerships and systems including norms and standards where needed.”



The strategy does not focus on one pathogen or a specific public health threat. Rather, it aims to provide a unifying vision for using genomics as a powerful addition to address public health needs for pandemic and epidemic preparedness and response broadly. It seeks to build on the strengths and capacities that exist through other initiatives, link and embed within the broader surveillance and public health architecture, and identify opportunities to establish capacities, partnerships and systems including norms and standards where needed. Ultimately, genomic surveillance is part of the broader surveillance and laboratory system, and its implementation should reinforce end-to-end capacities including sample collection, diagnostics, data sharing and analysis.

The strategy focuses on genomic surveillance for pathogens with pandemic and epidemic potential. It will anchor and complement initiatives that operationally strengthen global cooperation. As the genomic surveillance use cases extend beyond pandemic and epidemic preparedness and response, the strategy aims to facilitate the connectivity with other disease control programmes and surveillance networks. This interoperability will strengthen the cross-cutting essential public health laboratory functions underpinning genomics holistically.


The strategy articulates the overarching goal, objectives and strategic actions needed. These are dependent on commitments from countries, partners and WHO for their implementation. Annex 1 outlines the strategy development process.

TARGET AUDIENCE

The document is intended to be used at the **national, sub-national, regional** and **global levels**.

Target audiences include human, animal and environmental health authorities, partners, donors, public health officers, academia, private sector, laboratory specialists, and technical or non-technical experts seeking an overview on integrating genomic surveillance into the broader public health architecture for preparedness and response to pandemic- and epidemic- prone pathogens.

STRATEGY GOAL



The goal of the Strategy is that **genomic surveillance** for pathogens with pandemic and epidemic potential is **strengthened and scaled for quality, timely and appropriate public health actions** within local to global surveillance systems.

The strategy will equip public health agencies to incorporate genetic sequence data (GSD) that enable the connections within and across country, regional and global levels to prepare for and respond to pandemic- and epidemic-prone pathogens, including bacteria, viruses and parasites.

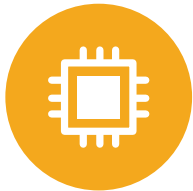
There are five objectives which will support the achievement of the strategy's goal (Figure 1). Each objective is underpinned by a set of strategic actions.

Collectively, these objectives outline the features of the ecosystem that will contribute to the enhanced integration of genomic sequencing within and across country, regional and global surveillance and response efforts.

Figure 1 Results hierarchy of objectives and strategic actions



OBJECTIVES



Objective 1:

Improve access to tools for better geographic representation

This objective focuses on ensuring appropriate and sustainable technology and infrastructure are accessible to countries. The aim is to not only expand access to **accurate and sensitive laboratory systems**, but also expand computational infrastructure and provide the right **analytics to interpret and contextualize the very rich and complex information** generated. Tools both for sequencing and bioinformatics should be **adapted to country needs** (infrastructure, human resources, decentralized support) and available at costs that are applicable for all countries. Without optimized, simple, interoperable and

affordable tools, genomic surveillance architecture will continue to be scaled in an inequitable and unsustainable manner, leading to gaps and impaired early warning and response systems. Market development for sustainability includes end to end procurement, purchasing and maintenance strategies. Each of these require detailed landscape mapping to understand context specific challenges. The five strategic actions recognize that genomic sequencing and bioinformatics infrastructure are essential but must be implemented across geographies to be right sized to ensure sustainability.

Strategic Actions



Advocate for and raise awareness of the value of genomic surveillance with policy makers to bring genomics into national disease control strategies.

Map and monitor capability and capacity landscape to maximize efficiencies, availability and geographic representativeness.

Define required tools and solutions in order **to deliver contextualized, decentralized and sustainable technology and innovation solutions** to ensure simple and optimized workflows to enhance access and information sharing.

Stimulate innovation and research to address local to global needs to promote the development of tools that are optimized to address global public health needs.

Shape a sustainable and quality market to maximize access to enable more equitable uptake and implementation of sequencing technology and associated bioinformatics and analytics.



Objective 2: Strengthen the workforce to deliver at speed, scale and quality

This objective focuses on the establishment of an **enhanced technical workforce that meets country needs and is country-owned** to detect, monitor and respond. In inter-pandemic or inter-epidemic periods, the workforce must deliver genomic surveillance information as part of routine activities and programmes for priority pathogens identified by country authorities based on risk assessments. At the time of an emergency, the workforce must be capacitated to surge, connect and deliver at speed. Country capacities should be strengthened through the **creation of enabling resources and systems that are adapted and optimized to country, regional and global priorities, while**

maximizing harmonization within and between networks. Without elevating the appropriate capabilities across geographies, efforts to engage policy makers, public health agencies and communities in prevention, control and response will be limited. As the landscape continues to evolve, there is clear need to adapt formal training programmes and recognized employment descriptions and professional roles with defined career pathways within public health structures to meet new demands. The four strategic actions included below aim to promote the exchange of technical information, while promoting use of standards and quality to ensure trust and confidence across the ecosystem.

Strategic Actions



Develop and roll-out training packages in genomics and bioinformatics for improved competencies and to facilitate evidence-driven decision making.

Promote communities of practice and knowledge exchange programmes to disseminate and share good practices that build capacity, address common challenges and strengthen cross-country engagement.

Implement external quality assessment programmes for genomics and analytics and provide support to comprehensive quality management systems to ensure accuracy of data and trust in the system.

Strengthen programmes for workforce development and retention with clearly defined pathways through formalization of the genomics-related functions and roles.



Objective 3: Enhance data sharing and utility for streamlined local to global public health decision-making and action

This objective focuses on promoting use of standards to **enable interoperability** of systems to generate data and information that can be used for timely decision making and action. Explicit, minimum, harmonized norms, policies, standards and principles are required to avoid fragmentation of information and lack of comparability that hamper **local to global situational awareness and surveillance efforts**. In addition, rigorous quality standards are needed to enable accurate data and confidence in information. Recognizing the benefits of genomic surveillance, it is imperative that data-related systems are easy to contribute to, access and utilize, each of which requires a foundation of quality and trust. WHO is working with Member States and stakeholders in developing

mechanisms for rapid data sharing in line with WHA Resolution 74.7 (3). The five strategic actions associated with this objective aim to articulate the **baseline architecture necessary to facilitate appropriate transparency, attribution, exchange and collaboration**. Genomic surveillance systems must apply standards to ensure that data are interpreted and shared effectively and that essential meta data are captured for maximal utility. Increased focus should be given to the development of global data standards, including standard vocabularies for meta data, along with data sharing mechanisms that facilitate sharing across borders, both equitably and with appropriate attribution and recognition.

Strategic Actions



Develop consensus on **data and meta data standards**, which recognize the importance of data privacy and national sovereignty, while balancing the importance of contextual information to accompany genomic sequencing data.

Establish data sharing and access principles that are widely agreed upon and explicit to foster transparency for rapid and equitable dissemination.

Ensure **data sharing agreements** are already in place in advance of acute events to promote timely collaboration and coordination.

Harmonize norms, standards, benchmarks, and reference materials to facilitate high quality information sharing.

Make the use of genomics routine in surveillance practice and disease prevention, preparedness, readiness and response.



Objective 4: Maximize connectivity for timely value-add in the broader surveillance architecture

This objective focuses on ensuring connections and flow of information within and across countries, disease areas and disciplines to maximize impact, alignment and efficiency, enabling more effective and timely preparedness and response actions. Genomic surveillance for pandemic and epidemic preparedness and response will be most successful **by encouraging linkages to build on existing strengths and capacities.** Partnerships and collaborations with multi-sectoral partnerships and participation of a broad coalition of stakeholders should be anchored to national public health agencies with the responsibility for public health surveillance. Connections and communications should be strengthened across individuals, networks and laboratories. The four strategic actions listed below serve to facilitate engagement across multiple levels.

“Genomic surveillance for pandemic and epidemic preparedness and response will be most successful by encouraging linkages to build on existing strengths and capacities.”

Strategic Actions



Leverage existing networks to support **and facilitate data, specimen and information sharing** to foster effective, rapid collaboration to drive public health action.

Increase network linkages at country, regional and global levels to minimize information siloes and maximize impact, through sharing of resources, protocols and bioinformatics tools.

Implement **targeted collaboration with One Health partners** for comprehensive, integrated surveillance.

Support and strengthen national, regional and global **networks in routine, epidemic and pandemic contexts.**



Objective 5: Maintain a readiness posture for emergencies

This objective focuses on building and sustaining country, regional and global readiness to use and surge genomic surveillance appropriately for emergencies. Genomic surveillance is anchored to the routine needs of disease control programmes, but there will periodically be a need to scale up capacity as part of emergencies – be this for known pathogens and public health priorities or for emerging threats. Readiness actions are critical to cope with the added pressure of an emergency. A number of strategic actions need to be applied to develop and maintain this readiness posture including having surge procedures for bolstering the emergency workforce, technical and material resources for increased sequencing and computational

throughput, exercising genomic surveillance surge within the end-to-end early warning alert response system, undertaking joint projects that foster cooperation, trust and functionality among stakeholders that would be involved during emergencies, and conducting periodic evaluations or after action reviews to identify ways that continuously improve the contribution of genomic surveillance within the public health surveillance architecture. Collectively, these actions provide confidence that the systems and procedures are functional and appropriately responsive when scaled up for an emergency. Ultimately, this serves the purpose of having the minimum core capacities needed for surveillance and response under the IHR.

Strategic Actions



Test the ability of genomic surveillance systems to stretch during an emergency using surge exercises and use findings to maintain right-sized capacity levels during routine and acute event periods.

Establish or sustain joint projects to maintain capacities and prime systems including the onboarding of new technologies and tools needed at the time of an emergency.

Implement continuous improvement processes including **inter- or after- action reviews** and utilize information in real-time to strengthen practices.

STRATEGY IMPLEMENTATION APPROACH

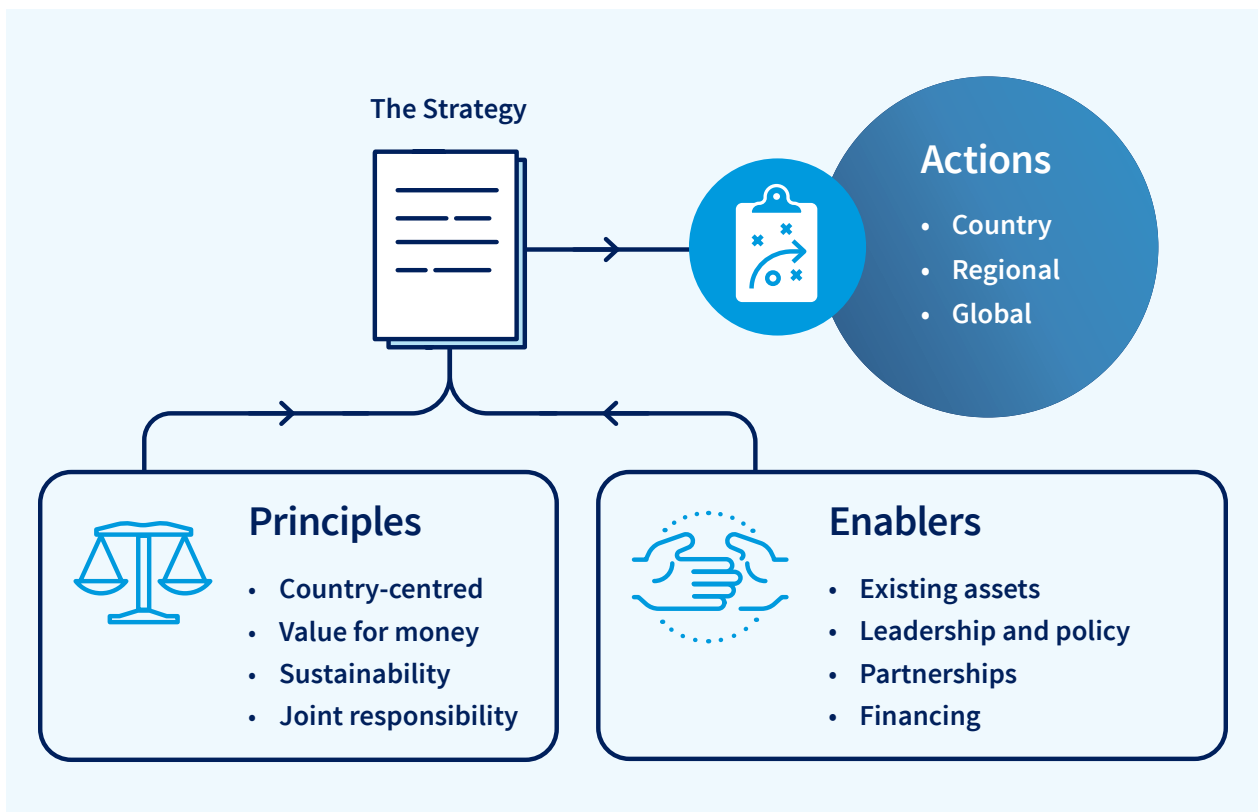
This strategy provides a landscape of global priorities and considerations for building global genomic surveillance capabilities, capacities and competencies for over the next 10 years.

There is a landscape of competing priorities for development and expansion of laboratory and surveillance systems, therefore implementation of this strategy will require a collaborative approach across governments, networks, programmes, and partners for maximal impact and contribution to public health.

Successful implementation of genomic surveillance requires strengthened end-to-end laboratory and surveillance systems alongside complementary interpretation of meta data and phenotypic, clinical and epidemiological characterization

for timely and appropriate public health action. Actions are expected at the country, regional and global levels, as shown in Figure 2. Additional frameworks and initiatives may be necessary to articulate and define implementation for different contexts or stakeholders including at regional or country levels. WHO encourages adaptation and adoption so that maximal coherence and harmonization are maintained locally to globally. The strategy is underpinned by a set of core principles and enablers which help set collective expectations and approaches for implementation (Figure 2).

Figure 2 The principles and enablers for delivering the strategic actions needed at country, regional and global level



Principles

There are five principles at the centre of this global strategy that will guide its implementation to ensure an effective and ethically grounded approach:

- 1 Countries at the centre of the strategy
- 2 Value for money
- 3 Sustainability
- 4 Joint responsibility
- 5 Local to global thinking

These core principles are cross cutting and equally applicable to all strategy objectives and are further described below.

1 Countries at the centre of the strategy

Strong and effective capacities at country level underpin regional and global public health. This places countries at the centre of the strategy, with a leadership role, so that a solid foundation is available and sustained for generating, analyzing, using and sharing GSD for public health action. To strengthen genomic surveillance for pathogens with pandemic and epidemic potential, country-focused activities, work plans and outputs are needed with strong commitment and ownership by government. Countries are encouraged to develop, refine and share their national plans and policies for integrating the use of genomics into laboratory and surveillance systems, strengthen their in-country linkages and connections with regional and international networks, and to advocate for national funding to be directed towards their specific requirements as part of pandemic preparedness and response.

2 Value for money

Value for money is fundamental to ensure that the information generated is used optimally while being cognizant of the resources and context at hand. Surveillance is a global investment and interconnected, where quality systems provide value for money returns in the reduction of outbreak severity and lives saved. In 2018, WHO launched a five-dimensional approach to guide value for money in public health practice which ensures that actions by stakeholders contribute to shared public health impact (9):

- **Economy:** keeping inputs (human and financial resources) as lean as possible;
- **Efficiency:** using those inputs to obtain or “buy” as much output as possible;

- **Effectiveness:** keeping the quality of output as high as possible to have the greatest possible impact;
- **Equity:** taking into consideration the extent to which outputs benefit and ensure coverage of the most vulnerable and hard-to-reach population; and
- **Ethics:** ensuring that inputs, outputs and outcomes uphold the fundamental ethical principles of respect, goodwill, justice and not causing harm.

As high-throughput sequencing and bioinformatics for pathogens with pandemic and epidemic potential are cost-intensive and remain out of reach for many, the value for money approach establishes a common understanding of the implementation approach needed for the strategy. As the technological landscape advances, maximizing and sustaining access are key requirements to inform global innovation. Similarly, programmes that strengthen workforce capacities, connectivity between networks and readiness for surge and stretch need to optimize delivery with value for money in mind.

3 Sustainability

Genomics is a growing frontier in the surveillance and response to pathogens with pandemic and epidemic potential, and a long-term vision is required so that sustainable programmes are built over time. The access to and availability of genomic sequencing capacities is recognized under the IHR (2005) laboratory core capacity, where IHR (2005) State Parties are expected to report on access to or availability of this capacity as part of the State Party Self-assessment annual reporting tool (SPAR) (10). The recognition of genomic sequencing as a core laboratory testing capacity modality provides impetus to build and sustain genomic sequencing as part of meeting IHR (2005) obligations. Defining the needs, optimizing implementation and aligning

with other in-country priorities for pandemic and epidemic prone pathogen surveillance is critical for the sustainability of genomics. This will require stepwise capacity building, continuous reassessment of needs and opportunities, and partnerships that invest and support these efforts. Programmes should be balanced considering the need for routine activities and demand for surge capacity. Sustainability can be cultivated by strengthening country, regional and global networks, as well as developing capabilities and capacities according to a needs-based approach.

4 Joint responsibility

Genomic surveillance for pathogens with pandemic and epidemic potential contributes to public health action within country, regional and global systems. While countries at the heart of the strategy, there are various stakeholders with critical responsibilities in advancing and supporting the implementation of the strategy including academia, the private sector,

philanthropy, inter-governmental agencies and civil society. WHO plays a central role in enabling and maximizing coherence globally so that the national and international ecosystem of stakeholders and their unique contribution is recognized and fostered into a joint responsibility for achieving the goal and objectives of this strategy (Box 1).

5 Local to global thinking

The range and impact of emerging and re-emerging pathogens in the past century demonstrate the importance of coherent local to global genomic surveillance systems. Regional and global action are inherently tied to actions at the national or subnational level, and strong commitment, governance and investments are needed to enable timely, appropriate and quality public health preparedness and response across the entire system. Countries are encouraged to develop their genomic surveillance capacities cognizant of the international interface since pathogens know no borders.

Enablers

In order for this strategy to be implemented in a cohesive manner according to the core principles, certain enabling factors must be in place. Four enabling factors will facilitate implementation of the strategy:

- 1 Building on and aligning with existing assets
- 2 Leadership
- 3 Partnership and networks for greatest gains
- 4 Financing

These enablers are further described below.

1 Building on and aligning with existing assets

Genomic surveillance requires a broad range of expertise and brings together cross cutting areas. To develop a robust strategy and support countries to build their capabilities and capacities, a wide network of partners must be aligned towards the common goal. Implementation of genomic surveillance will build on the work done by a wide network of partners and cross cutting WHO assets and strategies. Key WHO assets are described in Annex 2. Stakeholders at global, regional and country levels are invited through this strategy to indicate and 'catalogue' their assets and initiatives to facilitate information-sharing, maximize coherence and drive partnerships, avoiding siloed actions. Having a consolidated understanding of the landscape is key for genomic surveillance to be strengthened.

As implementation work plans are developed for each objective, the landscape of assets and existing strategies need to be leveraged so that country, regional and global level activities can optimize efficiency and sustainability. Importantly, the existing global workforce and infrastructure for genomic surveillance is a key resource that should be leveraged, strengthened, and appropriately positioned in order to attain maximum benefit and contribution to the objectives of this strategy.

2 Leadership

Country leadership drives public health prioritization and implementation including that for disease surveillance and laboratory systems. Even though genomic sequencing and surveillance capacities exist beyond public systems, such as in academia and the private sector, priorities established by public health officials will maximize

the utilization of genomic surveillance to inform public health assessments, decision-making and effective participation in cross-sectoral, regional, and global systems. The responsibility for driving the strategy lies with national authorities, which will also help ensure that end-to-end surveillance and laboratory systems are cohesively and coherently strengthened and sustained. Successful implementation of the strategy necessitates in-country, regional and global collaborations, such as with One Health stakeholders, academic and other partners. Those who drive the strategy must be empowered to advocate for capacity building and capability development to promote genomic surveillance in local to global public health practice.

WHO provides global leadership on public health emergencies including pandemic and epidemic preparedness and response. In the context of this strategy, key elements of WHO's Health Emergencies Programme leadership include defining the global use cases for genomic surveillance for pathogens with pandemic and epidemic potential, facilitating the work of the different global disease networks, developing standardized and coherent approaches for strengthening and supporting local to global capacities, and utilizing genomic surveillance data to inform global risk assessments and public health action. WHO also facilitates the sharing of data and information, including within the context of other international bodies and agreements, such as the Nagoya Protocol to the Convention on Biological Diversity. For this, WHO's Science Division leads the translation of the latest in science, evidence, innovation, and digital solutions to improve health and health equity for all. The Science Division holds a critical global role in coordinating science so that access to new therapies, diagnostics, and vaccines under development is equitable and that they are available to all who need them.

3 Partnerships and networks for greatest gains

Genomic surveillance requires international multi-sectoral engagement to leverage global resources effectively. The COVID-19 pandemic demonstrated the power of scientists and countries working together to detect, analyze and utilize genomic data to inform public health action. The large-scale need for sequencing and bioinformatics during the COVID-19 pandemic has introduced or reinforced collaborations with partners in academia, industry and the private sector. Looking ahead in the context of this strategy, partnerships and networks are critical to strengthen genomic surveillance capabilities and capacities globally. Successful implementation of the country, regional and global strategic actions described in the results hierarchy undoubtedly require the continued engagement from government, non-governmental and international organizations.

4 Financing

Surveillance is a costly yet essential public health function to underpin pandemic and epidemic preparedness and response. National, regional and global implementation plans in line with this strategy need to be costed so that genomic surveillance delivers the relevant quality and timely data needed. Those in leadership positions must advocate for direction of funds towards the implementation of genomic surveillance and identify and utilize pooled resources, across different programmes for example, to maximize cost efficiency. Dedicated budgets and national funding commitments should adhere to the principles described in the previous section, particularly in regard to country ownership and sustainability.

Box 1 WHO's role in implementation

The role of the WHO secretariat will be to facilitate and advance the strategy's goal. Overall, in its global leadership role, WHO will be the convener of the strategy. WHO will advocate for engagement, resourcing, and implementation, and will work with countries and partners to develop and implement plans and monitor progress. Partnerships are critical for achieving the results hierarchy outlined in this strategy. Through the regional and country offices, WHO will ensure that global implementation and advancement of the strategy centres around local needs and priorities. The specific roles of WHO under each objective are articulated further below.



Objective 1: **Improve access to tools for better geographic representation**

The WHO Secretariat will develop and facilitate consensus-driven plans, engage and convene funding and research partners and promote, review and synthesize the generation and sharing of evidence and new developments, with a specific link to the WHO Research and Development (R&D) Blueprint and vertical disease surveillance efforts. In addition, the WHO Secretariat, across its global, regional and country offices, will promote harmonization to ensure needs at each level of the value chain are addressed and advocate for dedicated and sustained country resourcing.



Objective 2: **Strengthen the workforce to deliver at speed, scale and quality**

The WHO Secretariat will provide technical assistance and standards, identify synergies and support integration across efforts, develop guidance to ensure the necessary investment in training to empower national agencies to have primary ownership and responsibility for genomic surveillance and coordinate support for additional expertise and surge capacity needs.



Objective 3: **Enhance data sharing and utility for streamlined local to global public health decision-making and action**

The WHO Secretariat will provide guidance, and support country-led approaches, harnessing the work and expertise internally including by the Science Division and from different organizations and expert networks. In this capacity, WHO will provide leadership regarding ethical sharing,

standardization and harmonization to promote high quality data generation and exchange, including convening advisory, technical and working groups to build consensus on protocols, norms, standards and principles. WHO will also support the generation of reference materials, where necessary, and develop or update guidance, including establishment of global targets linked to epidemiological context and monitoring frameworks to measure impact.



Objective 4: **Maximize connectivity for timely value-add in the broader surveillance architecture**

The WHO Secretariat will enable coordination and expand partnerships including with Food and Agriculture Organization (FAO), World Organisation for Animal Health (OIE) and the United Nations Environment Programme (UNEP) to facilitate transparency, openness and alignment across One Health sectors. In addition, the WHO secretariat will advocate to ensure adequate funding and investment is available to facilitate integrated genomic surveillance.



Objective 5: **Maintain a readiness posture for emergencies**

The WHO Secretariat will advocate to stakeholders the need for having and investing in a readiness posture, develop and disseminate technical guidance and tools to facilitate the objective, build the country-to-global level capacities needed including among inter-sectoral partners and stakeholders within the broader health ecosystem, and participate in the readiness actions either through the disease specific initiatives or cross-cutting upstream steps that are pathogen-agnostic.

MONITORING AND EVALUATION

Monitoring and evaluation are key to understand progress towards and drive the achievement of the strategy's results hierarchy. The Strategy's key measure of success is:

By 2032, all 194 WHO Member States have, or have access to, timely genomic sequencing for pathogens with pandemic and epidemic potential.¹

Strategy implementation will facilitate expansion of genomic surveillance capacities and access across all Member States through in-country capacity and referral networks. This approach recognizes that foundational laboratory and surveillance capacities need to be in place to successfully introduce, integrate and sustain genomic surveillance. Stepwise strengthening of systems is critical so that genomic surveillance has a solid governance foundation, quality management systems, clear surveillance objectives, sustained resourcing and pathways to inform public health decision-making and action.

For cross-cutting aspects of this strategy, a number of high-level measures should also be monitored to ensure that all countries have access to genomic surveillance. Measures including the following:

- Countries with in-country capability to perform next generation sequencing.
- Countries sharing genomic data to publicly accessible databases or as guided by WHO programmes.
- Countries participating in global quality assessment programmes for sequencing and bioinformatics.
- Countries participating in surge exercises to test genomic surveillance systems.

“ In its convening role, WHO will facilitate the global monitoring of strategy implementation, and work with countries and partners to conduct necessary reviews and course-corrections.”

Indicators for genomic surveillance should be monitored for each 'routine' pathogen use case since functional capacities underpin readiness for pandemics and epidemics. Implementation plans developed by countries and partners should include monitoring frameworks and align with this strategy's results hierarchy.

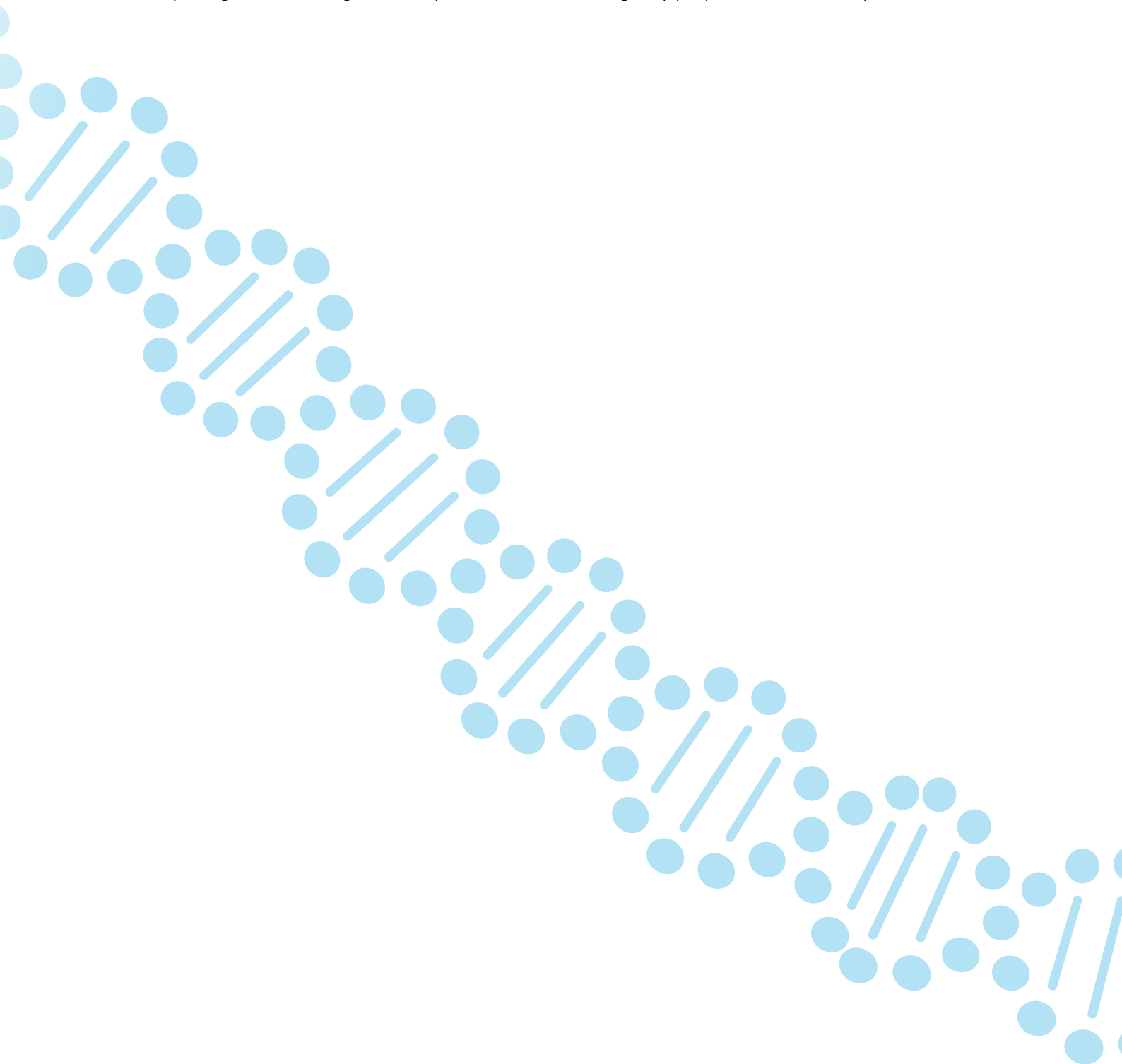
In its convening role, WHO will facilitate the global monitoring of strategy implementation, and work with countries and partners to conduct necessary reviews and course-corrections. Periodic landscape analyses and case studies will be used to understand the qualitative aspects of implementation and help refine and shape collective progress.

¹ Access to genomic sequencing may be through international collaboration including WHO collaborating centres. Timely is defined as triggering genomic sequencing within seven days of event or pathogen detection.

WAY FORWARD

In line with the strategy's results hierarchy, implementation plans constructed around each of the five objectives are needed. Implementation plans at all levels should be critically linked and made coherent with country level contexts, needs and priorities while also recognizing and enabling global surveillance needs. WHO will facilitate and support, as needed, the development of country, regional and global implementation

plans. Genomic surveillance stakeholders and partners play a key role in advocating, supporting, technically and financially enabling the implementation of the strategy. This engagement will be critical throughout the strategy's life cycle. Ultimately, this will all serve to advance the World Health Assembly's call in May 2021 for countries to strengthen genomic surveillance capacities in emergency preparedness and response.



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ANNEX 1: STRATEGY DEVELOPMENT AND STAKEHOLDER ENGAGEMENT

The development of this strategy was a collaborative, coherent and transparent effort, with inputs from multiple stakeholders including WHO Member States, academia, intergovernmental agencies, donors and philanthropies. The process is described below.

A global workshop on the use and scale-up of sequencing to monitor SARS-CoV-2 evolution was held on 19 March 2021. This workshop was attended by 1001 participants from 106 Member States, and had representatives from national health authorities, academia, donors and civil society organizations. The workshop set the foundation for the development of this global strategy based on the momentum from the COVID-19 pandemic while recognizing the need for broader pathogen-agnostic approaches to anticipate future early warning alert and response needs.

Following the World Health Assembly Resolution 74.7 in May 2021 that called on Member States to strengthen genomic surveillance in emergency preparedness and response, WHO initiated a series of internal discussions among the three levels of the Organization to assess gaps, needs and opportunities. Inputs were received from different global programmes and secretariats that implement or support genomic surveillance activities such as for HIV, influenza, measles/rubella, polio, antimicrobial resistance, foodborne illness, arboviral diseases and viral hemorrhagic diseases. The above processes resulted in the drafting of the Strategy's results hierarchy to kick-start broad and intensive engagement with Member States and external partners.

A series of informal and expert consultations were conducted in July to November 2021 which focused on the scope of the Strategy, the opportunities and challenges experienced in different contexts, and the lessons learnt from application of genomic surveillance for different use cases including acute outbreak management, new and emerging pathogen response, management of

epidemic-prone or seasonal pathogens, continuing public health risks, and disease eradication. These consultations were conducted by WHO headquarters and regional teams to capture a broad representation of Member States, disease network experts, technical and programmatic partners including the ACT-Accelerator partners. These preliminary consultations facilitated the development of the Strategy draft.

On 25 November 2021, WHO briefed Member States about the Strategy, its development process and progress, and its alignment with the expectations set forth in the Assembly's Resolution 74.7. Member States were informed that the Strategy was developed to be country-focused, pathogen agnostic and anchored to existing networks and capacities. The Strategy was also developed to account for the diverse landscape and needs, and in efforts to support countries and ensure interoperability for global surveillance coherence. During that briefing and discussion, Member States were requested to encourage the participation of relevant institutions and stakeholders in an upcoming global consultation as well as the global public consultation period.

An advanced draft version of the Strategy was posted on the WHO website on 1-15 December 2021 for global public consultation. Structured inputs on the draft were solicited through an online form. During this two-week global public consultation period, a virtual global consultation was held on 8 December to brief all stakeholders and interested parties about the Strategy. WHO set the scene and presented a summary of the strategy. Five moderated sessions were held engaging 20 experts from a variety of fields relevant to genomic surveillance to discuss and exchange views in line with the Strategy's five objectives. The global consultation was attended by 853 participants from 114 Member States, with representatives from Ministries of Health, government institutions, intergovernmental agencies, donors, academia, industry, civil society and philanthropic organizations.

The consultations held in December 2021 generated 89 sets of feedback from Member States, academia, industry, civil society, donors, philanthropies and intergovernmental agencies. Of these, 45% were from low- and middle-income countries. The inputs focused on a few key themes: contextualization of genomic surveillance in the broader surveillance architecture including

One Health, recognition of the importance of data sharing and access-benefit sharing, strengthening the monitoring and evaluation aspects, and elaborating on sustainability and the role of partnerships for genomic surveillance as a global public good. These inputs were used by WHO to finalize the Strategy and prepare for its launch in March 2022.

WHO thanks Member States and all stakeholders and partners who engaged in the Strategy development process while responding to the COVID-19 pandemic. WHO thanks partners listed below who engaged heavily in the global consultations and ACT-Accelerator partnership that generated momentum for genomic surveillance. WHO looks forward to working with many more partners alongside Member States to implement the vision set out in this strategy in years to come.

- Africa Centres for Disease Control and Prevention
- ASEAN Dx Initiative
- Bill and Melinda Gates Foundation
- Coalition for Epidemic Preparedness Innovations
- Child Health Research Foundation - Bangladesh
- Clinton Health Access Initiative
- Diagnostics Development Hub
- United Nations Food and Agriculture Organization
- Foundation for Innovative New Diagnostics
- International Association of National Public Health Institutes
- Institute of Genomics and Integrative Biology - India
- National Institutes of Health - United States of America
- Oswaldo Cruz Foundation - Brazil
- PATH
- Rockefeller Foundation
- Centers for Disease Control and Prevention - United States of America
- Wellcome Trust
- World Economic Forum

ANNEX 2: KEY WHO ASSETS FOR THE STRATEGY

- **International Health Regulations (IHR, 2005)** Laboratory and surveillance comprise core capacities of the IHR (2005). Aligning this strategy with the IHR (2005) helps countries strengthen policies, systems and the workforce in a way that facilitates and fulfils international obligations for public health emergencies. The IHR (2005) monitoring and evaluation framework provides countries with various approaches to review and strengthen implementation of the laboratory core capacity including genomic sequencing.
- **WHO's global footprint** In addition to its headquarters, WHO has six regional offices and 152 country offices that provide leadership, policy dialogue, strategic support, technical assistance and service delivery. This global footprint enables the roll-out of different public health initiatives, and will be a critical driver and resource to coherently strengthen genomic surveillance for preparedness and response.
- **WHO Hub for Pandemic and Epidemic Intelligence** With a focus on strengthening pandemic and epidemic intelligence through better data, better analytics and better decisions, the Hub in Berlin is a fulcrum for innovation and good practices to maximize data utility and public health action. Serving all WHO Member States, the Hub will facilitate the global coherence of genomic data into international surveillance systems to directly inform public health action.
- **Public health laboratory strengthening** Building genomic surveillance capacities is contingent on having a strong foundational national laboratory system. WHO's body of work through country, regional and global teams, including the Public Health Laboratory unit based in WHO Office in Lyon-France, strengthen the essential public health functions of laboratories for pandemic and epidemic preparedness and response. The WHO Lyon Office is at the centre of international laboratory support for country readiness and focuses on the specific needs of resource-limited and vulnerable countries.
- **Disease specific networks with genomic surveillance use cases** There is a breadth of laboratory and surveillance experience across existing disease specific networks globally. Experiences within established systems such as the Global Influenza Surveillance and Response System (GISRS), Global Polio Laboratory Network (GPLN), HIV ResNet, Antimicrobial Resistance GLASS, INFOSAN, as well as tuberculosis, measles, rubella and arbovirus networks need to be harnessed and leveraged at country, regional and global level. Opportunities for collaboration and economies of scale should continually be advocated through this strategy.
- **International Pathogen Surveillance Network – Global Pandemic Radar (IPSN)** Taking the lens of connectivity, the IPSN builds on the existing landscape of networks and initiatives for pathogen genomic surveillance to advocate for and strengthen global coverage and capacity so that there is an interconnected mesh of genomic centres and other institutions that would enable the detection and full characterization of current and future epidemics involving known and emerging diseases before they become pandemics.
- **Global Outbreak Alert and Response Network (GOARN)** GOARN is a network of partners across all regions at the core of global coordination for international support. The Emerging and Dangerous Pathogens Laboratory Network is a critical component of support mobilization. Many GOARN partners are among the global leaders in genomic surveillance and this expertise can be rapidly mobilized to continue to contribute to provide country and regional support for readiness and response to emergencies.
- **BioHub** The WHO BioHub is a recent initiative to establish a coordinated mechanism for the provision of biological specimens. The intent is to provide a safe, reliable and transparent mechanism for Member States to share and request materials on a voluntary basis, whilst ensuring fairness in access to any benefits arising from this.
- **Research and Development (R&D) Blueprint** The R&D Blueprint is a global strategy to facilitate rapid activation of research and development during epidemics. It aims to fast-track availability diagnostics, vaccines and therapeutics that can be used to save lives and avert large scale crises, with a pre-defined list of priority pathogens, including "Disease X".

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