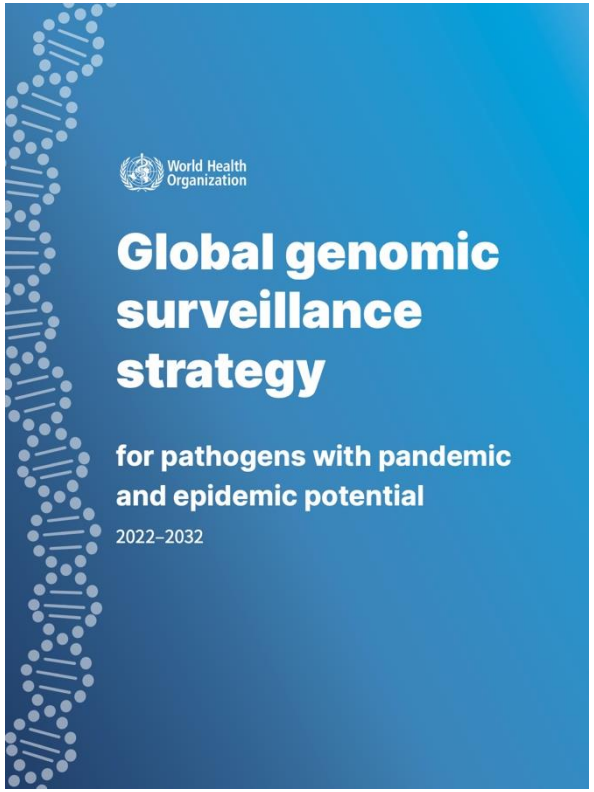
Monitoring and evaluating public health pathogen genomics

South and Southeast Asia Pathogen Genomics Prioritization and Implementation Workshop

12 September 2024

Monitoring and evaluating pathogen genomics

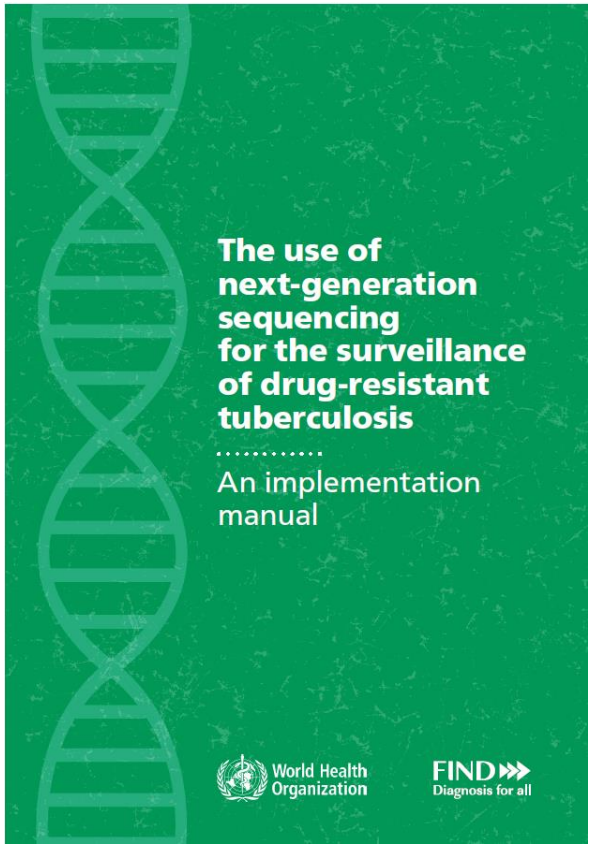
Monitoring and evaluation is key to understand progress towards and drive the achievement of the strategy's results



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

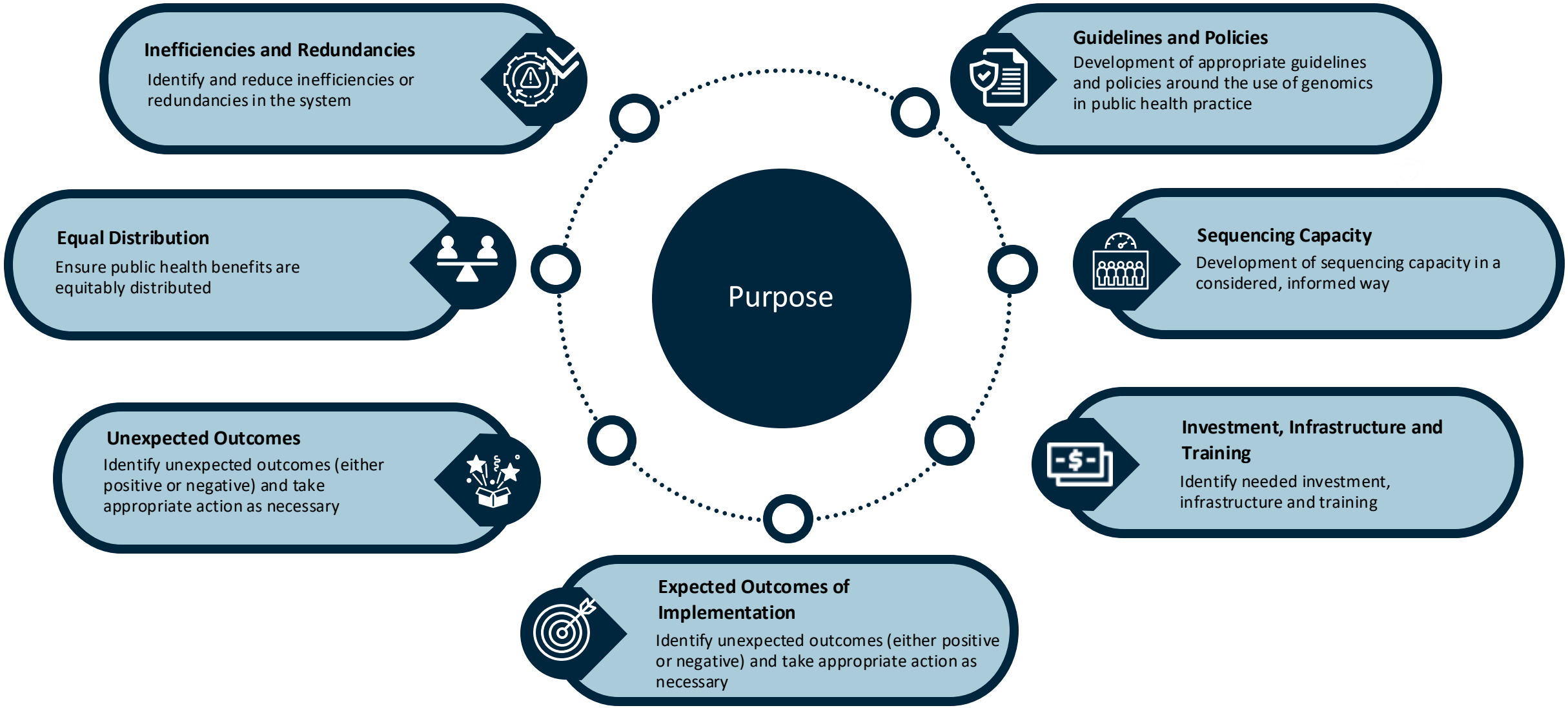
Monitoring and evaluating pathogen genomics

A framework for M&E of the impact of NGS is essential to inform decision-making.



The use of next-generation sequencing for the surveillance of drug-resistant tuberculosis:
an implementation manual. Geneva: World Health Organization; 2023

Purpose of evaluating public health pathogen genomics



Monitoring and evaluating pathogen genomics

- Guidance on M&E is lacking
- Strong focus on sequencing capacity, rather than public health implementation

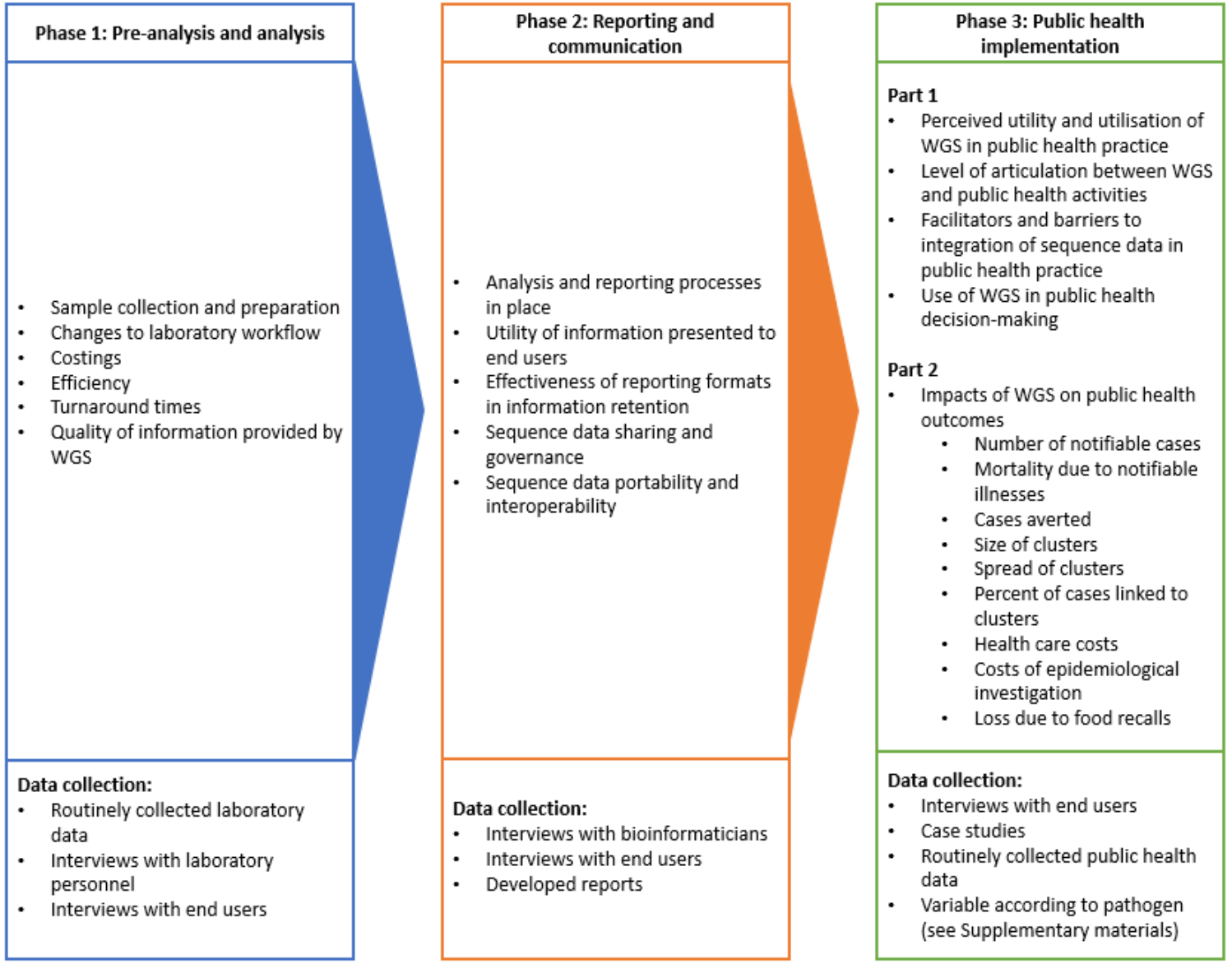
For cross-cutting aspects of this strategy, a number of high-level measures should also be monitored to ensure that all countries have access to genomic surveillance. Measures including the following:

- 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.

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

Pathogen Genomics in Public Health Surveillance Evaluation Framework

- ‘Whole of system’ approach
- Focus on implementation in public health
- Three pathogen case studies:
  - Listeria monocytogenes
  - Mycobacterium tuberculosis
  - SARS-CoV-2



Ferdinand AS, Kelaher M, Lane CR, da Silva AG, Sherry NL, Ballard SA, Andersson P, Hoang T, Denholm JT, Easton M, Howden BP, Williamson DA. An implementation science approach to evaluating pathogen whole genome sequencing in public health. Genome Med. 2021 Jul 28;13(1):121. doi: 10.1186/s13073-021-00934-7. PMID: 34321076; PMCID: PMC8317677.

What we've learned: The literature

- Limited literature on evaluation of pathogen genomics
  - PG-PHASE is the only available pathogen genomics evaluation framework
  - Economic evaluations are small-scale, limited in scope and frequently not full cost-benefit analyses
  - No evaluations of the functionality or processes of pathogen genomics-informed surveillance

Ferdinand AS, Kelaher M, Lane CR, da Silva AG, Sherry NL, Ballard SA, Andersson P, Hoang T, Denholm JT, Easton M, Howden BP, Williamson DA. An implementation science approach to evaluating pathogen whole genome sequencing in public health. Genome Med. 2021 Jul 28;13(1):121. doi: 10.1186/s13073-021-00934-7. PMID: 34321076; PMCID: PMC8317677.

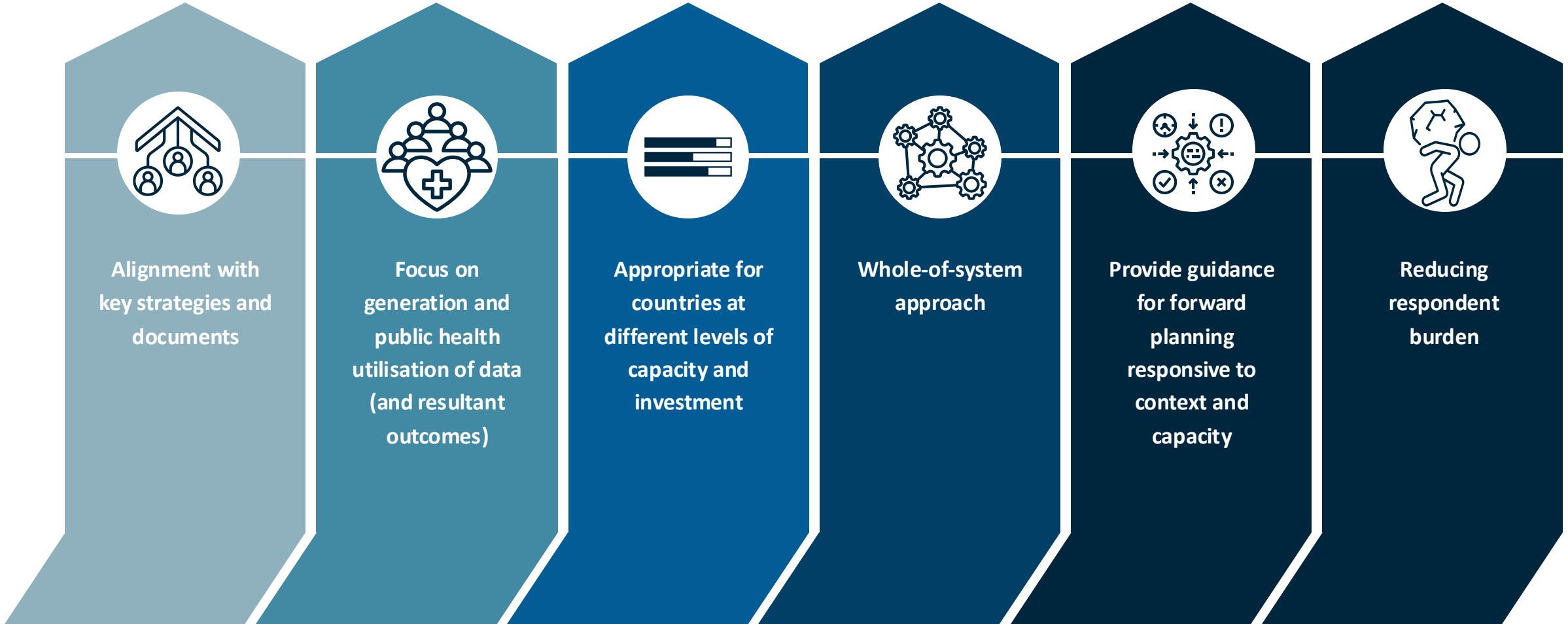
Tran, M., Smurthwaite, K. S., Nghiem, S., Cribb, D. M., Zahedi, A., Ferdinand, A. S., Andersson, P., Kirk, M. D., Glass, K., & Lancsar, E. (2023). Economic evaluations of whole-genome sequencing for pathogen identification in public health surveillance and health-care-associated infections: a systematic review. Lancet Microbe, 4(11), e953-e962. https://doi.org/10.1016/s2666-5247(23)00180-5

What we've learned: Our experience

- Need to address respondent burden
- Systems frequently not set up to easily capture relevant data
- Strong focus on sequencing and wet lab capacity
- Limited visibility across different parts of the system (and from different actors)
- Need for tools to clearly signpost areas for strengthening and capacity-building

Developing a pathogen genomics monitoring and evaluation tool

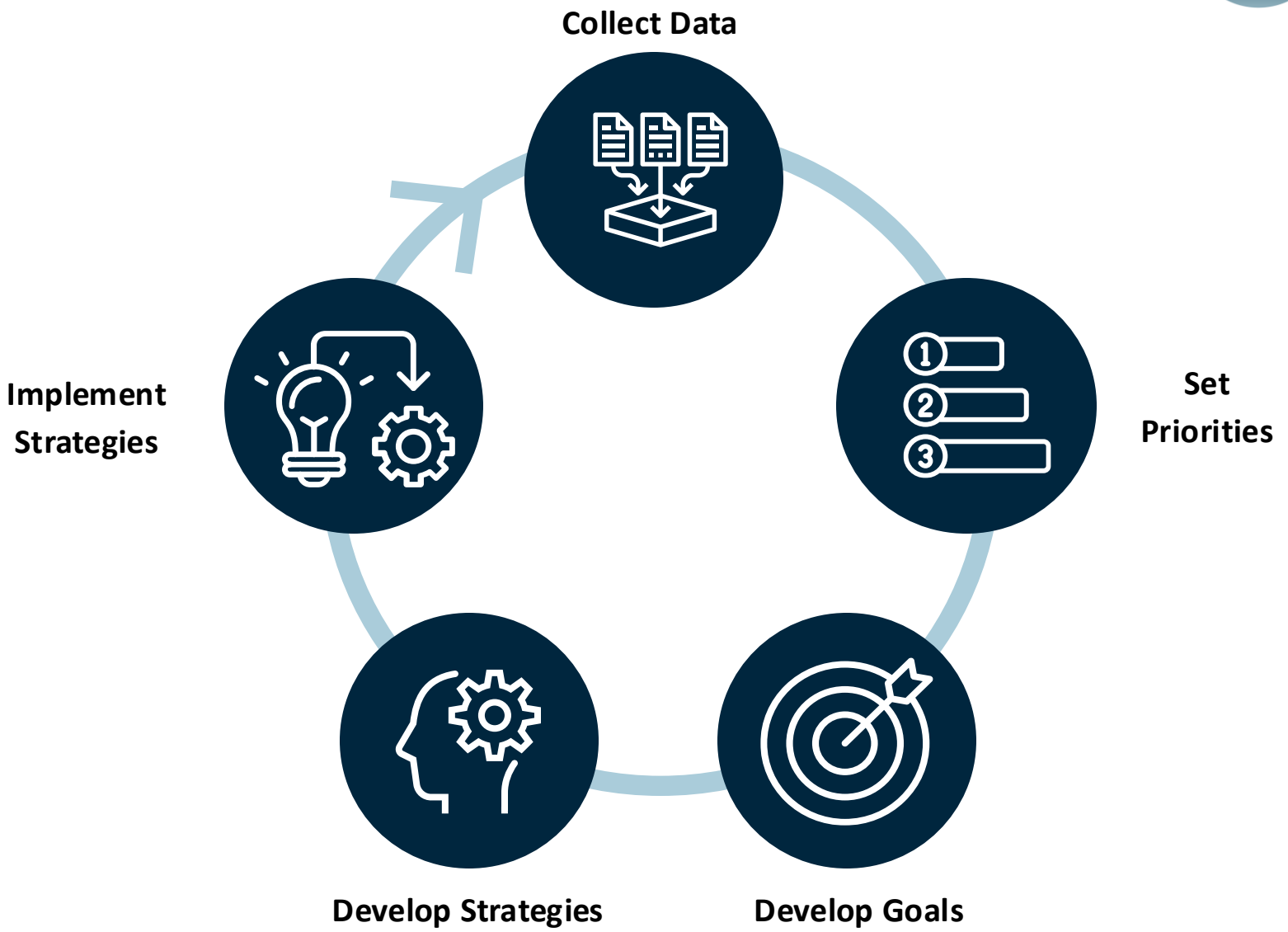
GUIDING PRINCIPLES



The ‘maturity model’ approach

Planning	Developing	Implementing	Delivering
• Public health pathogen genomics practices in the planning stages. • Little to no capacity for or access to sequencing, or sequencing delivers little or no public health benefit.	• Growing but inconsistent public health pathogen genomics practices. • Sequencing and implementation capacity is being developed, but it is uneven across the system. • Examples of good practice, but full benefit from sequencing is not realised.	• Practices are established and consistent. • Pathogen genomics is routinely and appropriately used to inform public health decision-making and implementation. • Benefits are equitably distributed across the population.	• Public health decision-making and policy development strongly benefits from the integration of pathogen genomics data in surveillance. • The pathogen genomics-informed surveillance system is regarded as an outstanding example.

The ‘maturity model’ approach



Tool structure

Six Sections

- Genomics-informed surveillance and policy
- Specimen selection, collection and referral
- Laboratory workflow
- Bioinformatics and analysis
- Reporting and communication
- Implementation in public health practice

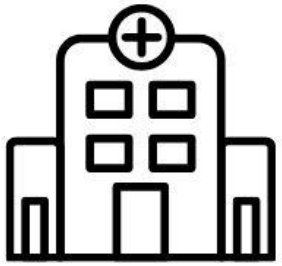
→ **Up to six sub sections per section**

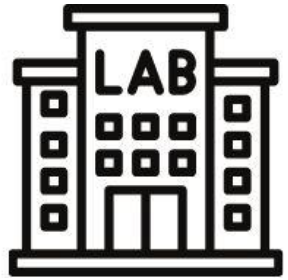
→ **Responding to items in each sub-section provides indication of current maturity level**

Tool structure

- For use against a single ‘system’
  - May be national for small or centralised countries
  - Sub-national for large or federated countries

- Sections can be completed separately or together
- Some sections to ideally be completed jointly between a public health laboratory and health department





Section 1: Genomics-informed surveillance and policy

01

Alignment with public health objectives and priorities

02

Development of a costed implementation plan

03

Required financial resources for implementation and ongoing costs

04

Addressing regulatory, importation and ethical issues

05

A plan to monitor implementation and impact of sequencing

Section 1: Genomics-informed surveillance and policy

	Planning	Developing	Implementing	Delivering
Sub-section 1.1: Alignment with public health objectives and priorities	Policy to support public health pathogen genomics has not been developed, or there is no alignment between genomics policy and broader public health objectives and priorities	Policies regarding public health pathogen genomics have been developed but are limited in scope and do not align with broader public health objectives and policies	Public health pathogen genomics policy has been developed and there is some socialisation with broader health policy, but alignment is inconsistent	Public health pathogen genomics policy has been developed and socialised to align with identified public health objectives and priorities
Sub-section 1.2: Development of a costed implementation plan	No implementation plan developed	Implementation plan has been developed but no costing data applied	Implementation plan has been developed and costing data applied but with limited transparency	Fully costed implementation plan has been developed with transparent methods of identifying costs
Sub-section 1.3: Required financial resources for implementation and ongoing costs	There is insufficient funding allocated to support key pathogen genomics surveillance (PGS) processes for 1 year	Sufficient funding is secured to support key PGS processes for 1 year	Sufficient funding is secured to support key PGS processes for 2-4 years	Sufficient and sustainable funding for PGS is secured to support key processes for 5+ years
Sub-section 1.4: Addressing regulatory, importation and ethical issues	Policy to support public health pathogen genomics has not been developed, or does not address regulatory, importation or ethical issues	Policies regarding public health pathogen genomics have been developed but are limited in scope and do not address regulatory, importation or ethical issues	Public health pathogen genomics policy has been developed and addresses some regulatory, importation or ethical issues	Public health pathogen genomics policy has been developed and addresses regulatory, importation or ethical issues
Sub-section 1.5: A plan to monitor implementation and impact of sequencing	No monitoring and evaluation plan developed	Monitoring and evaluation plan has been developed but does not take a whole-of-system approach and/or no resources have been allocated	Monitoring and evaluation plan has been developed but does not take a whole-of-system approach or inadequate resources have been allocated	Monitoring and evaluation plan has been developed using a whole-of-system approach and adequate resources have been allocated

Section 2: Specimen selection, collection and referral

01

Sequencing strategy informed by public health requirements

02

Sampling strategy and representativeness (including geographic and population coverage)

03

Sufficient sequencing capacity to respond to sequencing strategy

04

Diversity of samples processed per week

Section 3: Laboratory workflow

01

Training, competency and retention of laboratory staff

02

Sampling, sample processing capacity and turnaround time

03

Staff, equipment and reagent costs

04

Quality outcomes

05

Participation in global assessment programs for sequencing and bioinformatics

Section 4: Bioinformatics and analysis

01

Capacity to use bioinformatics tools and software to analyse data

02

Adequate data storage capacities

03

Computational power for analytical throughput

04

Connectivity and ability to connect to international data repositories

05

Sequence quality assessment processes

06

Analyse/interpret bioinformatics results

Section 5: Reporting and communication

01

Interaction with publicly available genomics repositories

02

Staff expertise in genomic epidemiology across laboratory and public health settings

03

Competency and knowledge requirements of end users

04

Appropriateness of information received by end users (i.e., relevance to surveillance objectives, appropriate to end-user level of understanding)

05

System interoperability to facilitate data archiving, tracing and sharing

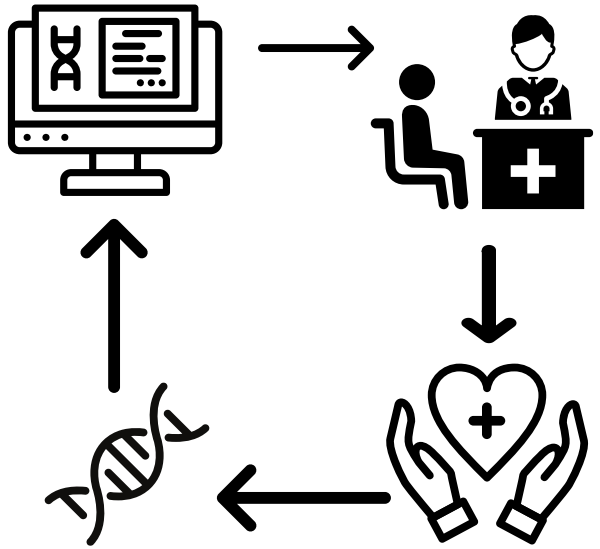
06

Working relationships between public health laboratories and public health departments

Section 6: Implementation in public health practice

Section 6a: Contribution to public health implementation

- Contribution to public health policies and identified priorities
- More precise allocation of investigative resources
- Contribution to appropriately tailored and targeted public health interventions
- Perceptions of affected communities

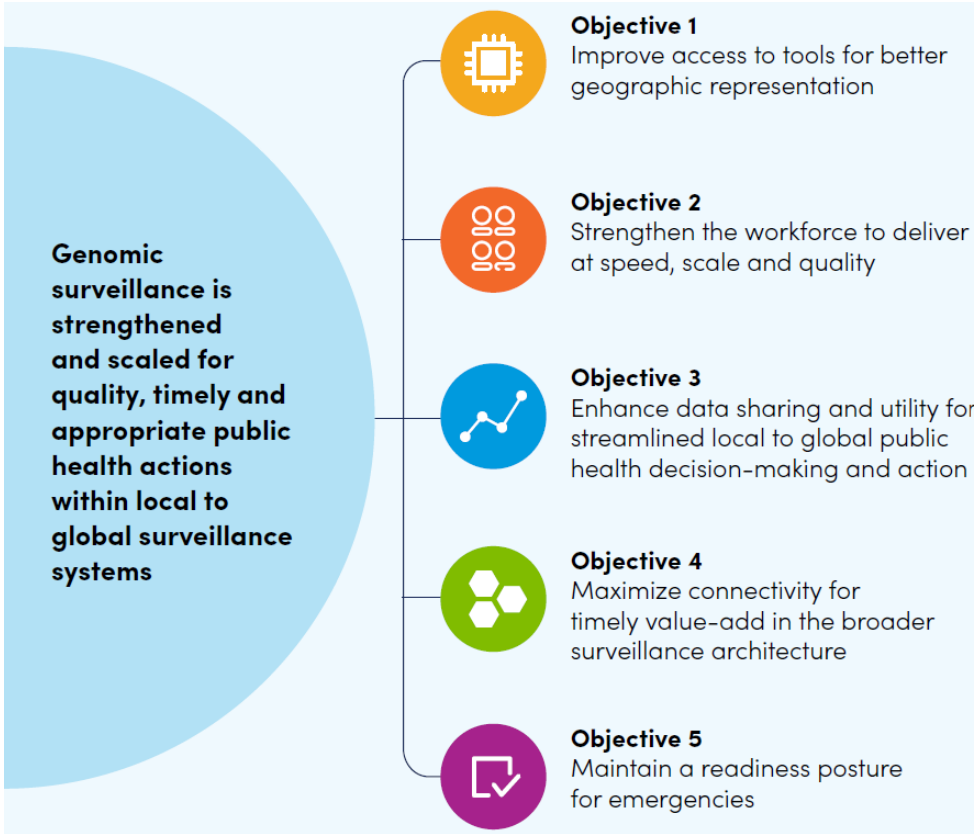


Section 6b: Quantitative impacts on public health outcomes

- Time between identification of clusters and public health action
- Proportion of cases linked to identified clusters
- Number of notifiable illnesses
- Health care costs due to notifiable illnesses

Alignment with key guidance documents

Global genomic surveillance strategy



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

IPSN Country Capacity Framework

Hybrid Domestic Capacity

Leverages partner sequencing and surveillance resources to use genomics for public health decision-making, with limited to no domestic sequencing for monitoring priority pathogens

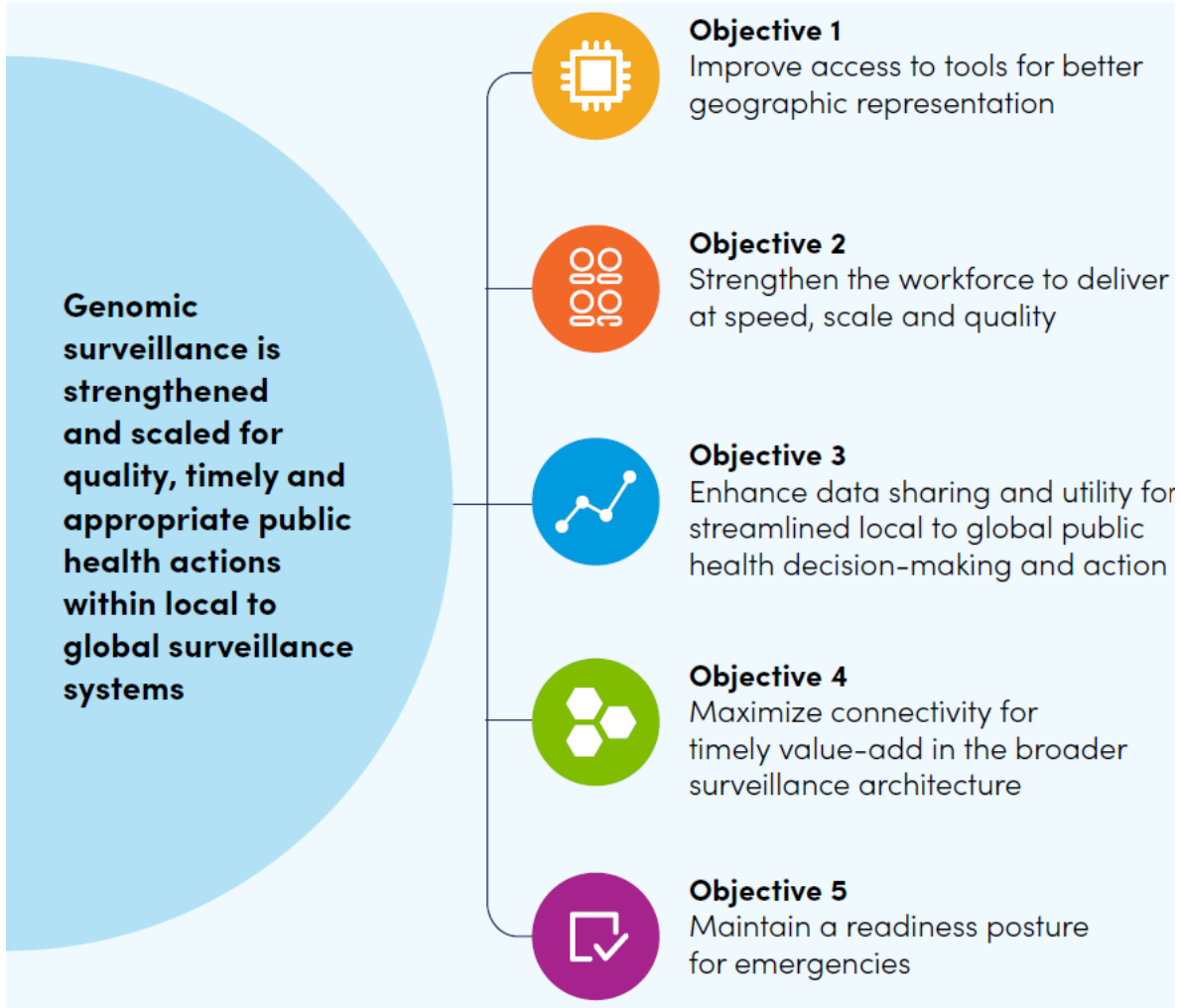
Integrated Domestic Capacity

Leverages partner resources for strategic support, R&D, supply chain consolidation, and QA, to supplement full domestic sequencing for monitoring priority pathogens

Regional/Global Support Capacity

Coordinates regional/global surveillance efforts; provides strategic leadership and support for training, R&D, QA, sequencing, and rapid scale-up; and funds donor programs to enable partner priorities

Alignment with Global genomic surveillance strategy



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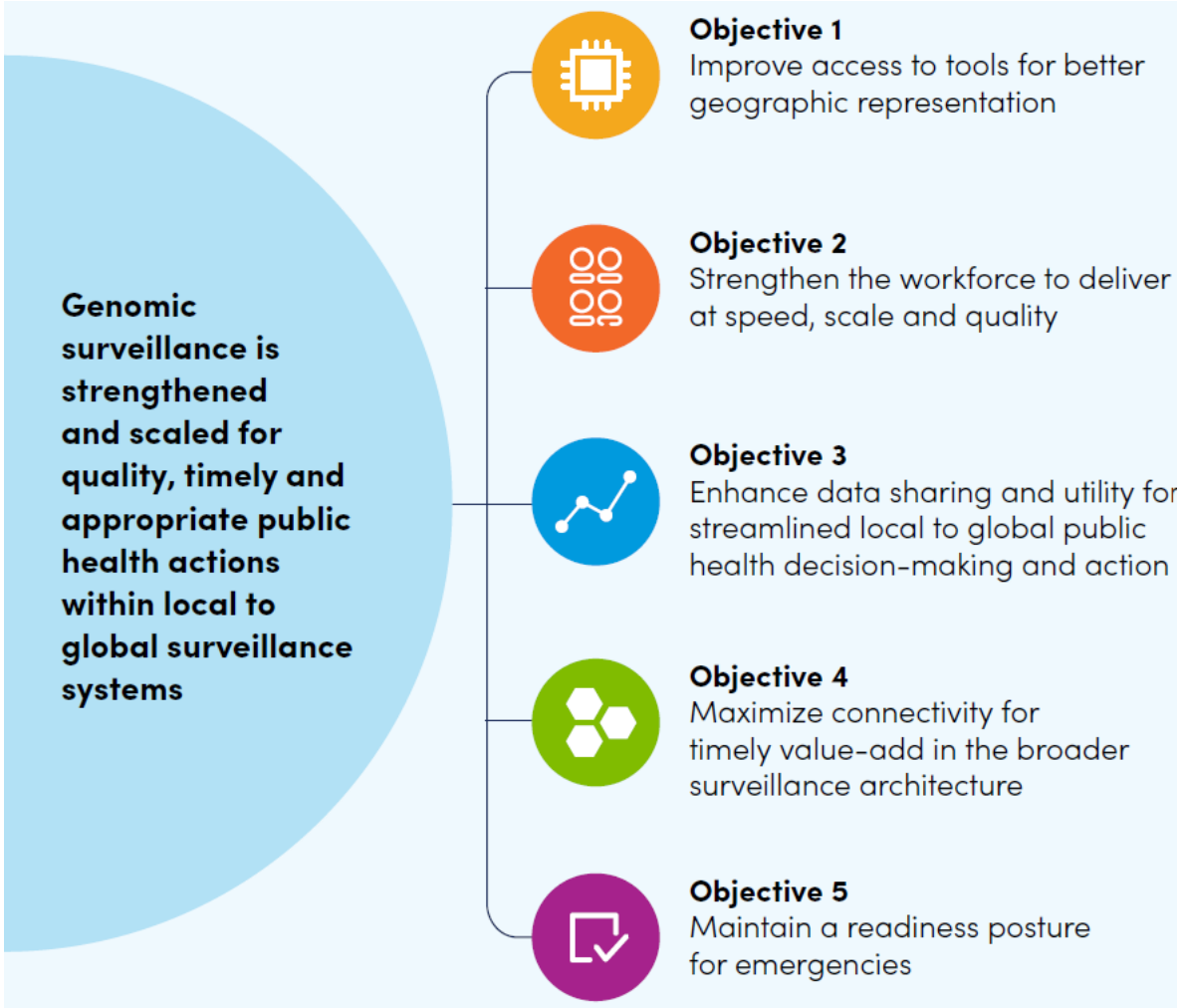
Alignment with Global genomic surveillance strategy



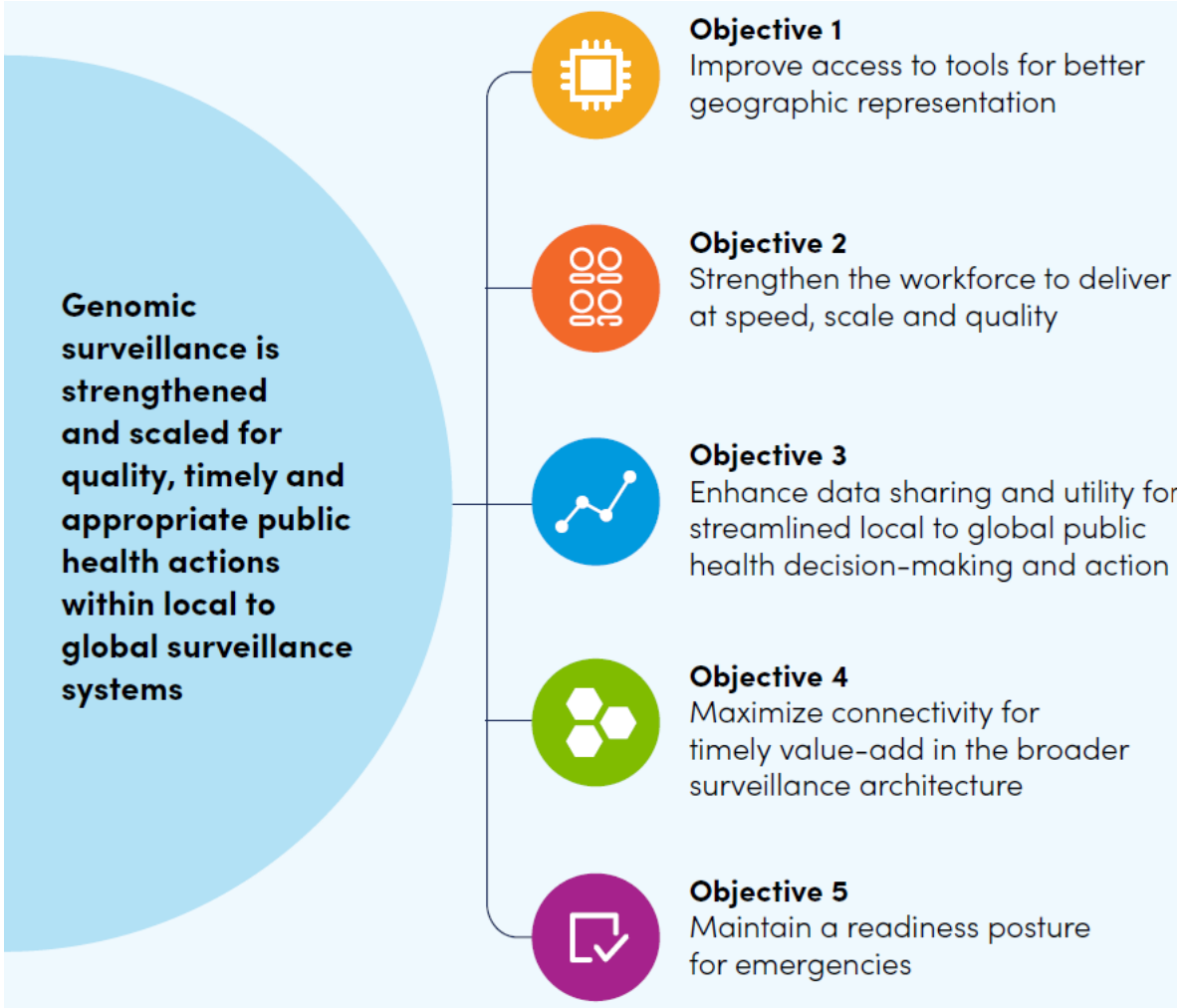
Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032

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.

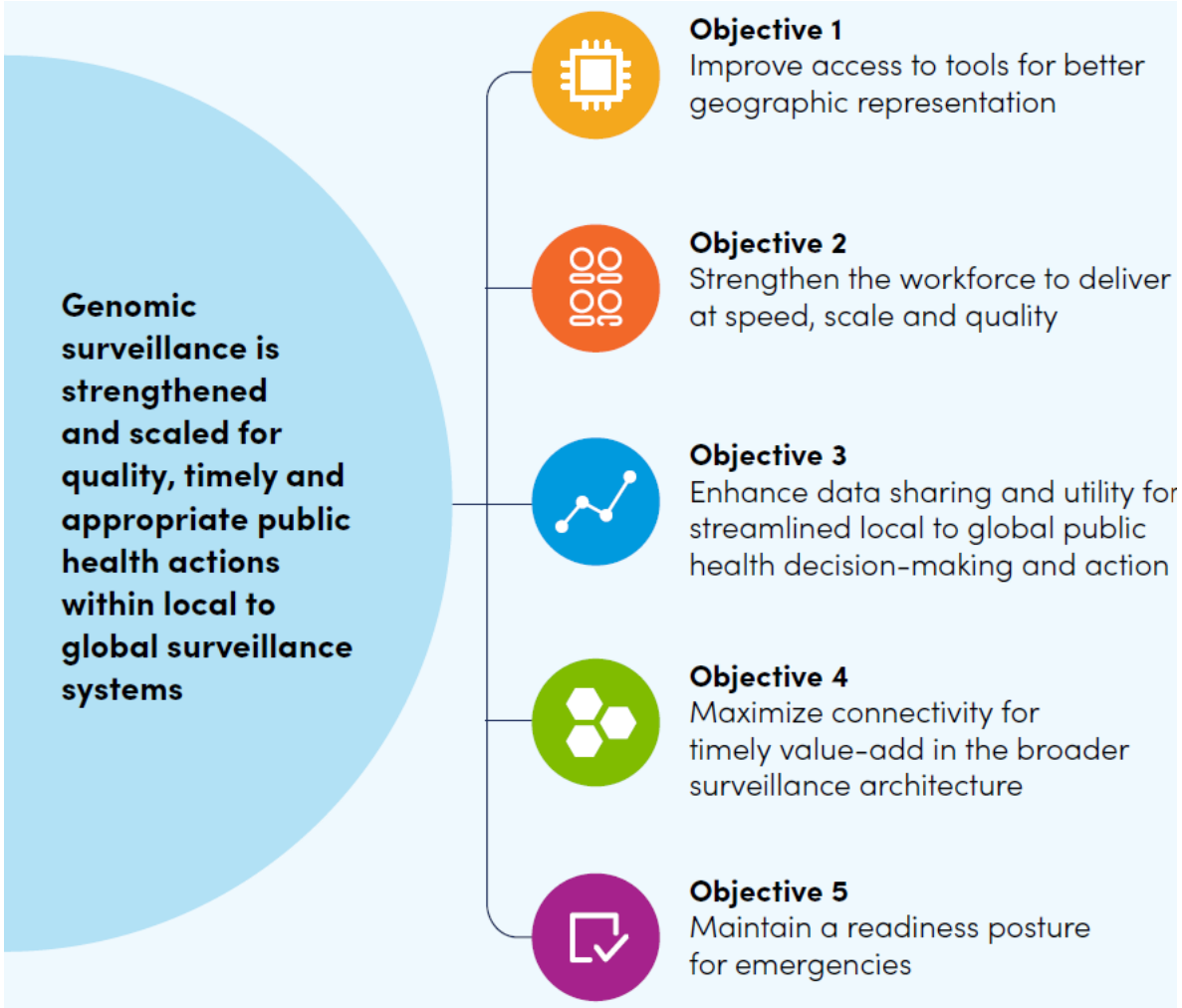
Alignment with Global genomic surveillance strategy



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

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

Alignment with Global genomic surveillance strategy



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

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.

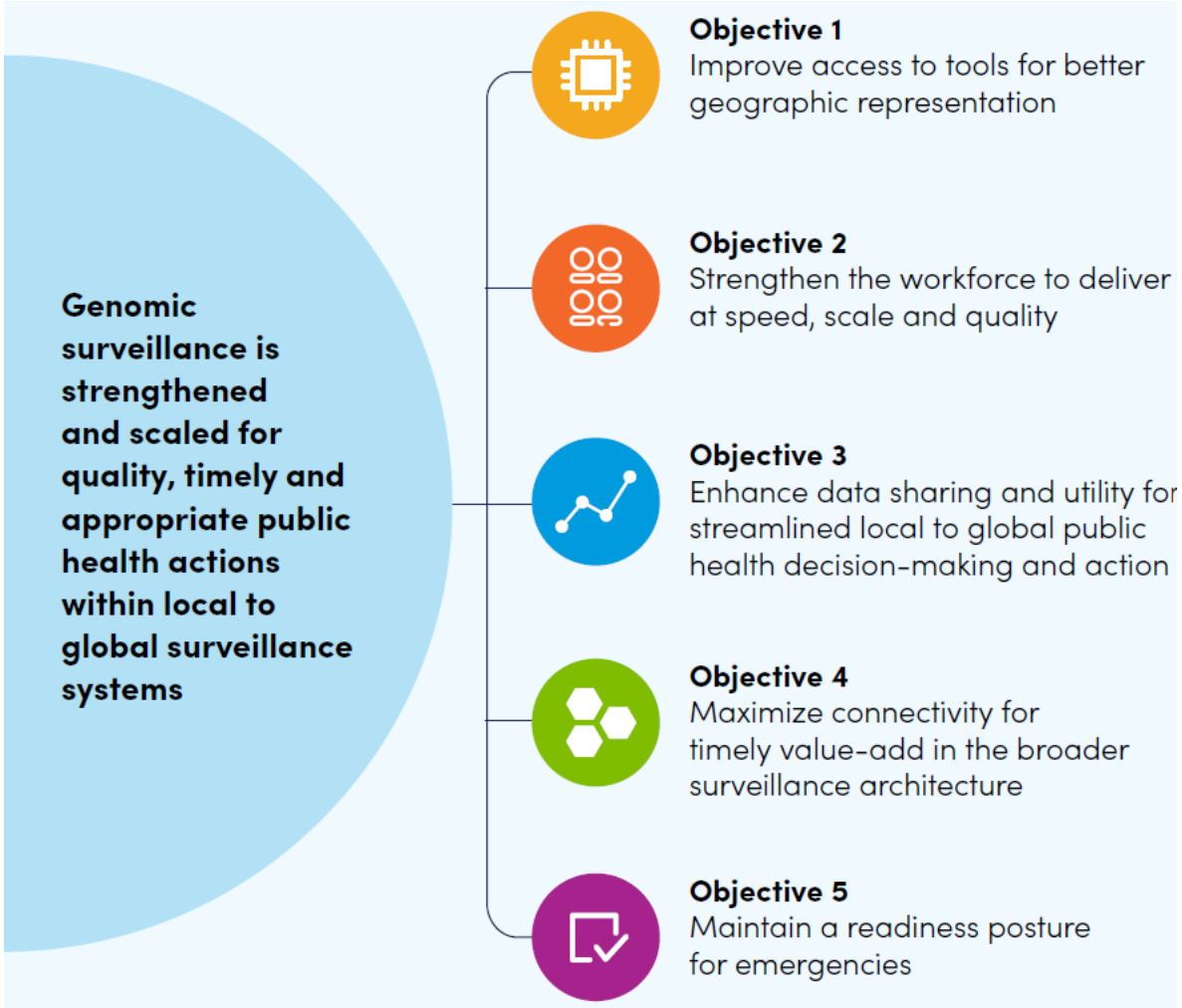
Establish data sharing and access principles that are widely agreed upon and explicit to foster transparency for rapid and equitable dissemination.

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.

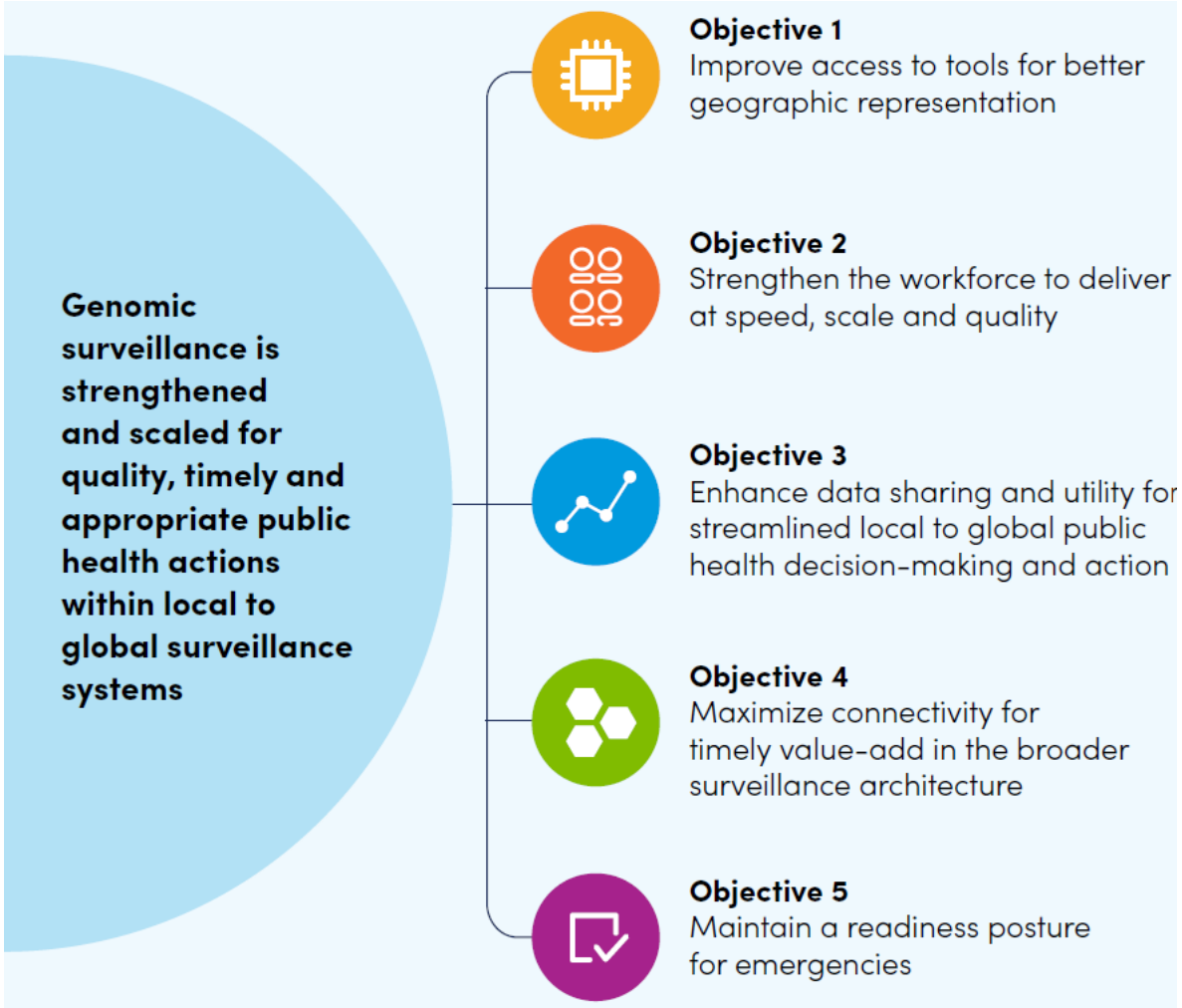
Alignment with Global genomic surveillance strategy



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

- 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**.

Alignment with Global genomic surveillance strategy



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

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.

Alignment with IPSN Country Capacity Framework

Hybrid Domestic Capacity

Leverages partner sequencing and surveillance resources to use genomics for public health decision-making, with limited to no domestic sequencing for monitoring priority pathogens

Integrated Domestic Capacity

Leverages partner resources for strategic support, R&D, supply chain consolidation, and QA, to supplement full domestic sequencing for monitoring priority pathogens

Regional/Global Support Capacity

Coordinates regional/global surveillance efforts; provides strategic leadership and support for training, R&D, QA, sequencing, and rapid scale-up; and funds donor programs to enable partner priorities

- ☑ Assesses domestic capacity to use genomics for public health decision-making
- ☑ Assesses additional staff capacity to support sequencing strategy and peak sequencing times
- ☑ Assesses additional instrumentation and reagents to support sequencing strategy and peak periods
- ☑ Assesses current and potential capacity to support other laboratories as part of a referral system
- ☑ Assesses overflow capacity in addition to routine genomics work

Progress to date and next steps

Literature review	Completed
Develop tool structure	Completed
Develop sub-section maturity model matrices	Completed
Develop sub-section items	Completed
Complete tool first draft	Completed
Consultation, piloting and revision	October 2024
Finalisation of monitoring and development tool	November 2024
Further development of documentation, user manual and technical guides; approach for ongoing update as required	January 2025-June 2025

Acknowledgements

CPG Pathogen Genomics M&E Tool Working Group

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