
Harmonization of regulatory approaches, governance and standards for data, digital health and artificial intelligence in the health sector

Report by the Director-General

Introduction

1. In 2025, the Seventy-eighth World Health Assembly decided to extend the global strategy on digital health 2020–2025 to 2027 and to request the Director-General to develop, guided by the global strategy on digital health 2020–2025 and in consultation with Member States and stakeholders, a draft global strategy on digital health for the period 2028–2033, to be submitted for consideration by the Eightieth World Health Assembly, through the Executive Board at its 160th session.¹
2. Following the Health Assembly, some Member States proposed the inclusion of the following three items on the provisional agenda of the Executive Board at its 158th session: precision medicine; regulatory and ethical governance of data and artificial intelligence in the health sector; and digital health transformation for resilient health systems. In October 2025, noting that the three proposals were linked to digital health and timely in the light of the fast-moving nature of developments in artificial intelligence, the Officers of the Board and the Director-General recommended the inclusion of these topics on the agenda under one consolidated item.² The present report responds to that recommendation.
3. This consolidated approach to these three topics illustrates that the safe and effective implementation of virtual care, precision medicine and artificial intelligence for health depends on robust data and digital health foundations. These foundations – encompassing governance, policy, ethics, regulatory maturity, standards, interoperability and digital public infrastructure – enable countries to collect, analyse and use data to effectively guide health interventions while also leveraging digital functionality to optimize quality of care. Harmonized regulatory frameworks and coherent governance are therefore essential to sustain a health systems approach to digital transformation.

¹ Decision WHA78(22).

² See Note for the record, 2 October 2025.

4. This report considers the context, challenges and opportunities for digital transformation in health systems; priorities for strengthening the data and digital health foundations; the role of the Secretariat; and considerations for the development of a draft global strategy on digital health for the period 2028–2033.

5. For precision medicine, the report focuses on elements related to data and digital health foundations, while recognizing the wider potential of advances in genomics, pharmacogenomics, transcriptomics, metabolomics, microbiomics, bioinformatics and more, to create shifts towards more predictive, preventive, personalized and participatory health systems. The safe and effective implementation of precision medicine will also require, *inter alia*, a well-structured decision-making ecosystem capable of prioritizing medical interventions and medicines that deliver the greatest benefits for patients and communities.

Context, challenges and opportunities for digital transformation in health systems

6. The health sector is undergoing profound transformations driven by advances in artificial intelligence and other digital technologies, in data science, bioinformatics, genomics proteomics and pharmacogenomics. This period of rapid innovation is happening in a context of competing fiscal priorities and often misaligned funding models.

7. Many Member States face complex digital landscapes characterized by parallel, fragmented systems with limited interoperability, resulting in compromised quality and increasing maintenance costs. Such systems include electronic health record systems, laboratory and logistics management information systems, metadata registries, aggregate health information systems, and household survey and disease surveillance platforms.

8. These challenges are undermining the collection, safe storage, sharing, analysis, use and timely reporting of reliable data. This has direct implications for the realization of the full potential of precision medicine, artificial intelligence and digital health transformation for disease surveillance and response, supply chain management and delivery of essential health services.

9. An integrated health systems approach to digital investments will strengthen the potential for impact and sustainability and help to improve the quality and coverage of essential health services while also increasing the availability of aggregated data to inform decision-making, economic modelling and monitoring of progress towards universal health coverage and the Sustainable Development Goals.

10. Artificial intelligence offers new opportunities to enhance access to care and the efficiency and quality of such care, including through precision medicine. However, this depends on high-quality local data, robust standards-based data systems and sound governance following ethical principles of data collection, use and sharing. Without reliable, representative and interoperable data, artificial intelligence risks amplifying biases and inefficiencies rather than addressing them. To ensure that artificial intelligence is effective and contributes to equity, safety and public trust, artificial intelligence governance must be embedded into health systems through frameworks for benchmarking against defined criteria, data protection, ethical use and accountability.

Priorities for foundational strengthening

11. **Health information and data systems foundations.** A critical first step towards successful implementation of digital health and artificial intelligence will be to recognize the importance of data and digital systems and strengthen Member States' foundational data governance and underlying digital infrastructure. WHO has made progress in guiding some of these foundations, including structures and standards, through a renewed focus on policies, WHO Data Principles, and strategies to support more effective management and coordination throughout the data journey – from data collection to storage, sharing, analysis and use for the development of policies, programmes and budgets. Health information systems are essential for generating the high-quality, continuous and unbiased data required for any artificial intelligence or precision health tool to work effectively. Integrating geospatial data and digital microplanning approaches can further enhance the accuracy, granularity and usability of these core data systems, enabling countries to visualize coverage gaps, plan services with precision and reach underserved populations.

12. As part of its commitment to advancing health equity, the Secretariat has developed several resources, including the Health Inequality Data Repository and the Health Equity Assessment Toolkit, to promote and strengthen health inequality monitoring activities. Prioritizing investment in these core data systems and the capacity to deliver on them establishes Member State autonomy and ownership over the data life cycle, builds essential national data governance capacity and ensures that digital transformation is built on credible, equitable and locally relevant data foundations that directly support national health goals.

13. **Digital health foundations.** Successful digital transformation of health systems relies on strengthening core foundational enablers anchored in the building blocks of the WHO–ITU National eHealth Strategy Toolkit: leadership and governance; strategy and investment; legislation, policy and compliance; workforce; infrastructure; standards and interoperability; and services and applications.

14. Such foundations can be established and reinforced through context-specific implementation and application of core regulatory frameworks, norms and international standards guided by, for example, WHO Data Principles, the WHO SMART guidelines and the WHO Family of International Classifications. Strengthening these foundations is an essential prerequisite for well-governed infrastructure and interoperable technologies and the generation of representative, quality data. It provides a basis for responsible use of technologies and a person-centred health systems approach that accelerates progress towards universal health coverage.

15. **Ethical and regulatory foundations.** Member States have emphasized the need for harmonized global standards and capacity-building in the regulatory oversight and ethical governance of artificial intelligence. The rapid proliferation of artificial intelligence applications has outpaced regulatory capacity in many settings, increasing risk to patients and systems. Through its tripartite collaboration with ITU and WIPO, WHO is developing frameworks for artificial intelligence performance and quality benchmarking, transparency and validation to ensure safety, accountability and quality. These activities complement WHO's normative and capacity-building work on information and communications technologies for ministries of health, national ethics institutions, national regulators and developers.

16. These foundations, and others, are especially important to ensure equitable and fair access to precision medicine interventions. Health systems will increasingly need to be equipped to address issues including patient privacy, informed consent, governance and stewardship of genetic and health data, data protection, benefit-sharing algorithmic bias, equitable access to innovation, and diversity and inclusivity in research and application, all while respecting national laws.

Role of the Secretariat

17. The Secretariat is supporting countries to address the above challenges and transition from siloed data and digital projects to coherent national health information systems based on sound data foundations and digital architectures. WHO's leadership in digital health and data systems is anchored in resolution WHA71.7 (2018) on digital health, which mandated the Secretariat to provide guidance, promote standards and build capacity for digital transformation in health systems. These efforts are advanced through the global strategy on digital health 2020–2027, the Global Initiative on Digital Health and the Global Initiative on Artificial Intelligence for Health, a collaboration with ITU and WIPO supporting the responsible, ethical and evidence-based use of artificial intelligence in health. WHO is also hosting key global digital public infrastructure in the form of the Global Digital Health Certification Network, enabling the issuance of verifiable personal health records within and across borders.

18. WHO's normative and technical work spans digital health, data and artificial intelligence governance, providing countries with integrated frameworks, tools and capacity-building mechanisms to strengthen their ability to utilize digital technologies for health. Key products include: the WHO Family of International Classifications; WHO's Youth-centred digital health interventions: a framework for planning, developing and implementing solutions with and for young people; the WHOSMART Guidelines; digital transformation handbooks; health data governance principles and policies; the WHO Guidance on Ethics and Governance of Artificial Intelligence for Health; and the SCORE for Health Data Technical Package. The World Health Data Hub supports countries in applying data governance, defragmenting siloes and harnessing data for policy, analytics and decision-making. Collectively, these initiatives provide the foundation for safe, interoperable and resilient data and digital health systems worldwide.

19. The Secretariat is also providing normative guidance and technical support to enhance the equitable access to genomics and other relevant innovations and technologies that underpin precision medicine. A road map for genomics and precision medicine is outlined in recent WHO guidance and in a report of the WHO Science Council.³ The Secretariat will further outline guiding principles and ethical and technical standards, and will provide support to Member States, particularly low- and middle-income countries, upon request, to develop policies, prioritize and implement interventions, and establish governance mechanisms, regulatory frameworks and capacity-building initiatives that enable the safe, effective and equitable application of precision medicine.

³ See [Guidance for human genome data collection, access, use and sharing](#). Geneva: World Health Organization; 2024 and [Accelerating access to genomics for global health: promotion, implementation, collaboration, and ethical, legal, and social issues: a report of the WHO Science Council](#). Geneva: World Health Organization; 2022 (accessed 22 December 2025).

Implementation of the global strategy on digital health 2020–2027 and preparation of its successor

20. WHO's work on data, digital health and artificial intelligence aims to strengthen health systems by ensuring timely, reliable and trustworthy data and high-quality service delivery. Rigorous data science, digital systems and artificial intelligence will be harnessed so that every Member State can monitor progress, improve accountability and ensure the delivery of people-centred, equitable, sustainable and resilient health services for all.

21. To enhance regulatory approaches, governance and standards for data, digital health and artificial intelligence, areas of work being advanced by the Secretariat include, for example: developing guidance and standards to strengthen health information systems and digital public infrastructure; promoting and providing technical support for local data and digital governance, production and ownership, and for related standards and interoperability; and coordinating global and national stakeholders and partners, including WHO collaborating centres, around data, digital and artificial intelligence priorities for health and related support to countries.

22. Equity must remain central to the digital transformation of health. Integrating gender, human rights and equity considerations across digital health policies, strategies and tools is essential to ensure that innovation drives inclusion, especially to meet the needs of marginalized populations. A rights-based and equity-oriented approach will ensure that digital health contributes to universal health coverage.

23. These and related areas of work will be further articulated in the draft global strategy on digital health for the period 2028–2033, which will be driven by Member States and informed by regional and global consultations with experts and diverse stakeholders. The draft global strategy will provide a coherent framework for collective action to advance a safe, equitable, sustainable, data-driven and artificial intelligence-enabled digital transformation of health systems.

Action by the Executive Board

24. The Board is invited to note the report and provide guidance to the Secretariat by considering the following questions:

- Regarding the scope and priorities for the draft global strategy on digital health for the period 2028–2033:
 - How should health data, information systems and artificial intelligence be incorporated as interconnected pillars?
 - What priority areas of governance, policy and financing relating to digital transformation require greater focus?
- In the evolving global health context, what partnership and development approaches will be most effective in supporting resilient, essential data and digital health infrastructure, including as a foundation for the safe and effective application of precision medicine, and how might Member States and partners contribute?