

Model Law on Health Data Governance: FAQs

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1. About the draft model law on health data governance

1.1 What is the draft model law on health data governance?

The model law provides a foundational structure for the ethical management, protection and use of health data, emphasising the balance between individual privacy and the collective benefits of health data utilisation. By setting out core principles and standards, it seeks to foster a harmonised approach to health data governance that respects the diverse legal, cultural, and societal landscapes of different nations. It also aims to build consensus across countries and stakeholders around the core principles and standards that should be addressed through national legislation and regulation for the effective and equitable governance of health data. It serves as a resource for countries to strengthen their national approaches, by offering guidance to countries aiming to integrate the principles and standards into their existing national legislation and frameworks, or develop new laws where and if needed. The Model Law is designed to be non-prescriptive and allows for flexibility and adaptability to local contexts and needs.

1.2 Why do we need stronger health data governance legislation and regulation?

The increased digitalisation of health systems has increased the amount of health data that is collected and used. Data is a vital tool to strengthen health systems, improve policy and decision-making, respond to health emergencies, improve patient care, further medical innovation, and ultimately improve health outcomes and advance Universal Health Coverage. However, the rules to govern the collection and use of data have not kept pace with the growing potential for data to support better health and well-being, nor the potential harms arising from data misuse.

To fully harness the potential of health data for public benefit and improved health outcomes, while also managing risks, protecting individual rights, and ensuring people's data is protected from misuse, it is important for governments to strengthen the governance of health data through more robust and equitable legislation and regulation. A strong legislative and regulatory environment would hold all actors in the country involved in the collection and use of that data accountable; provide various actors in the country with avenues for redress in case people's rights are being violated or data is being misused; and establish a predictable environment for the private, not for profit and public sectors operating in the country. This would lay the foundation for improved public trust in health data systems where individuals feel protected, respected and in control of their data while allowing institutions working to protect the health and well-being of the population to access and use it for public benefit.

1.3 Why do we need a model law on health data governance and what purpose would it serve?

While several countries and regions are taking steps to strengthen health data governance legislation and regulation, approaches vary and there is no overarching consensus around core elements that should be addressed through national legislation and regulations for the effective and equitable governance of health data.



We believe that there is value in countries and other stakeholders coming together to learn from each other, identify best practices, understand where there are gaps, and build a level of consensus and alignment around essential elements for health data governance that should be addressed through national legislation and regulation. It would also help establish a level of harmonisation in national approaches, thereby fostering greater legal coherence across jurisdictions, which would strengthen trust and collaboration between countries and facilitate cross-border data sharing, with the needed protections in place. Importantly, it would be a resource for governments to support them in strengthening their national approaches.

1.4 Who is the model law on health data governance for and how should it be used?

The model law on health data governance is first and foremost for governments. It serves as a reference framework for the ethical management, protection and use of health data, providing guidance and sample model legal text to assist countries with their efforts to strengthen their national legislation and frameworks dealing with health data governance.

The model law is not meant to be prescriptive in any way or dictate to countries what their health data governance laws and frameworks should look like, but rather serves as reference text for the drafters of legislation. Different parts of this model law may need to be inserted into different existing laws and regulations within a country rather than being adopted as a single Health Data Governance law.

1.5 How has the draft model law on health data governance been developed and who has been involved?

The drafting of the model has been led by a team of legal experts, with guidance from an expert advisory group. To inform the current draft, Transform Health and partners have carried out seven multi-stakeholder regional consultations in October and November 2023 (led by AEHIN, HELINA and RECAINSA), consulting nearly 500 stakeholders from across 65 countries to learn from experiences and gather insights and perspectives on what is needed to strengthen health data governance legislation and regulation. This was followed by national legislative and regulatory landscape reviews, as well as a review of relevant literature, strategies, reports and instruments. The draft has been informed by the equity and rights-based health data governance principles, the OECD Recommendation on Health Data Governance, European Union General Data Protection Regulation (GDPR), the Health Insurance Portability and Accountability Act (HIPAA), standards issued by the International Organization for Standardization (ISO) 27799, the Council of Europe's Convention 108, the World Health Organizations' (WHO) Guidelines on Data Privacy and Protection in Health Information Systems, the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS Guidelines), the OECD Privacy Guidelines and Recommendations of Health data Governance, the International Conference of Data Protection and Privacy Commissioners (ICDPPC) Resolutions, the United Nations Convention on the Rights of Persons with Disabilities (CRPD), and the Health Data Charter by the Global Partnership for Sustainable Development Data, among other national, regional and international commitments and best practice.

The current public consultation period (7-30 April 2024) aims to gather wide stakeholder and expert feedback on the draft, with the aim of strengthening and validating it, while building consensus, alignment and support around the core elements.

The process of developing the model law has been designed to be inclusive and collaborative, to bring in a diversity of perspectives to inform its development and to ensure its legitimacy and ownership. Transform Health has been actively engaging a wide range of stakeholders and experts, including governments, international organisations, civil society, research institutions, and private-sector actors in the co-creation process.

1.6 What are the Health Data Governance Principles and how do they relate to the draft model law?

The [Health Data Governance Principles](#) have helped inform the development of the model law, among other national, regional and international commitments and best practice. The Principles - which are clustered around three key objectives of protect people, promote health value, and prioritise equity - were launched on World Health Day (7 April) 2022, with the aim of aligning policymakers and other stakeholders around a shared vision of equitable health data governance, where all people and communities can share, use and benefit from health data. The Principles have already been endorsed by more than 150 organisations and governments.

The Principles bring a human rights and equity lens to the use of data within and across health systems and are oriented towards supporting sustainable and resilient public health systems that can deliver Universal Health Coverage. They were developed through an inclusive, bottom-up process bringing together contributions from over 200 stakeholders across diverse geographies, sectors and stakeholders. This included eight global and regional workshops covering Sub-Saharan Africa; the Middle East and North Africa; South, East, and Central Asia; Latin America and the Caribbean; and Europe, North America, and the Pacific, as well as a youth-specific workshop and a one-month public consultation.

2. About the consultation period on the draft model law on health data governance

2.1 What are the objectives of the consultation process?

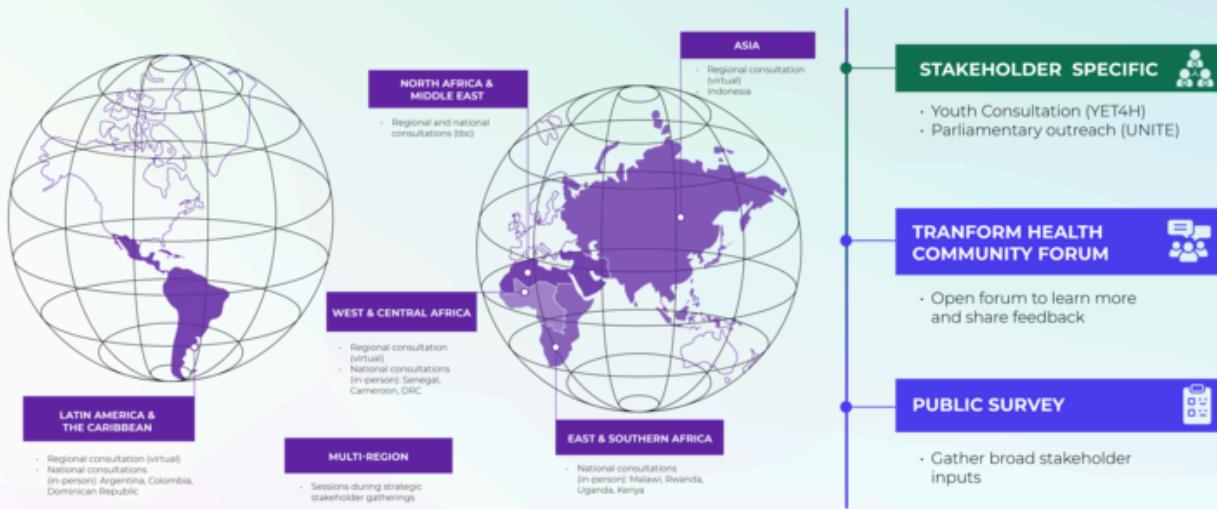
The objectives of the consultations period are to:

- **Solicit stakeholder and expert input** on the draft model law on health data governance, including feedback on the content and how it is framed.
- **Strengthen and validate the draft** through government and stakeholder inputs and addressing gaps.
- **Build consensus and alignment** across countries and stakeholder groups on the core elements in the draft model law on health data governance.
- **Galvanise political will and support** for the draft model law on health data governance, with the aim of it being endorsed by governments, as part of a global health data governance framework, through a World Health Assembly resolution and other relevant regional convenings/processes.
- **Facilitate an inclusive approach** to the development of the draft model law on health data governance by gathering input and perspectives from a diverse set of stakeholders.

2.2. When is the public consultation period and how long will it last?

The consultation period launched on the 7th of April 2024, World Health Day. The consultation period will last from the 7th until the 30th of April.

2.3 What does the consultation period entail and how can people provide feedback on the draft model law?



The consultation period will have different components, including a widely disseminated survey that will be available on the consultation page where anyone can provide their feedback on the draft Model Law. The draft Model Law and survey will be available in five languages (English, French, Spanish, Portuguese and Arabic). A community forum will take place on the 29th of April, which will be open to all stakeholders to learn more about the Model Law and provide feedback. Register to join the Community forum here: tinyurl.com/HDGModelLaw-Forum

In-person consultations are taking place in Africa (Cameroon, DRC, Malawi, Rwanda, Senegal, Uganda) and Latin America (Argentina, Colombia, Dominican Republic), with regional virtual consultations in Africa, Asia and Latin America and the Caribbean. Stakeholder-specific engagement includes a consultation with youth (organised by YET4H) and outreach with parliamentarians (through UNITE) and private sector (through the digital connected care coalition). Targeted interviews will be carried out with national, regional and global experts.

The consultation period will engage and solicit feedback from a wide range of stakeholders and experts, including (but not limited to):

- Government representatives (Ministry of Health, ICT/digital transformation, others as relevant)
- Regulators and legislators in government and private practice
- Lawyers and legal experts from the Ministry of Justice and the national bar associations.
- Data protection officers/authorities
- Information commissioners
- Parliamentarians
- Academia/think tanks

- Multilateral organisations and technical agencies (e.g. national/regional WHO representatives, World Bank, OECD)
- Regional bodies and development banks (e.g EAC, ECOWAS, WAHO, WHO AFRO, WPRO, SEARO, ect)
- Civil society
- Youth representatives
- Donors
- Private sector representatives

2.4 How will feedback from the consultation period be used?

Feedback received during the consultation period will be used to refine and strengthen the draft model law on health data governance. A revised draft will be presented during a side event draft on the 28th of May, during the World Health Assembly. The side event will convene a conversation with governments and experts around what is needed to take the model law forward to ensure government endorsement and implementation.

3. What will happen after the consultation period?

3.1 Government leadership to ensure stronger health data governance legislation, including support for the model law and a a global health data governance framework

Government leadership on this agenda is critical. We urge governments to endorse a global health data governance framework containing the model law through a World Health Assembly resolution in May 2025, as well as through regional processes and mechanisms (e.g. through an African Common endorsed by the AU). This would build on growing recognition and consensus on the need to strengthen health data governance, as set out in numerous global, regional and national strategies, reports and initiatives. This would further support the wide political and stakeholder support, including at the 76th World Health Assembly in May 2023 where the Ministries of Health of Cameroon, India, Maldives, Philippines and Sri Lanka co-hosted a [side event](#) on the issue, with strong support and commitment for this agenda.

As we look towards the 77th World Health Assembly in May 2024, we urge governments to:

- Champion the model law on health data governance (as the basis of a global framework), for endorsement by governments through the World Health Assembly and relevant regional mechanisms and processes.
- Express support for a global health data governance framework (including a World Health Assembly resolution on this for endorsement in May 2025) during official World Health Assembly proceedings this year.
- Endorse the [health data governance principles](#), which provide a foundation for stronger legislation and regulation and the global health data governance framework.

3.2 What will happen at the 77th World Health Assembly in May 2024?

Building on growing political support around the need to strengthen health data governance legislation and regulation, including during last year's World Health Assembly, Transform Health, Africa CDC, OECD, WHO, Health Data Collaborative, AeHIN, HELINA, and RECAINSA will host a side event during the 77th World Health Assembly, "Stronger Health Data Governance through Country Leadership and Consensus". The draft model law on health data governance will be presented during the session, followed by an expert panel on the importance of strengthening legislative and regulatory approaches. This will be followed by a government response panel to build consensus and explore how to take this agenda forward through a World Health Assembly resolution and what is needed to support national implementation.

We also encourage governments to express support for a global health data governance framework, and a World Health Assembly resolution on this for endorsement in May 2025, during official World Health Assembly proceedings this year.

3.3 Who will 'own' the model law on health data governance?

The model law on health data governance will be a public good, available as a resource for governments to build consensus, establish a level of harmonisation across countries, and strengthen national approaches. Ultimately, we want to see governments take forward the model law and endorse it through a World Health Assembly Resolution, as part of a global health data governance framework. Government leadership to take this forward is critical.

3.4 Will the model law and regulation be revised in future?

To remain relevant in the fast-evolving domain of digital health, the model law will need to be agile so that it can be reviewed and updated as necessary.

Further questions

If you have any questions or would like to get involved, please send us an email at info@transformhealthcoalition.org.