Supporting stronger health data governance legislative frameworks

Rwanda Case Study

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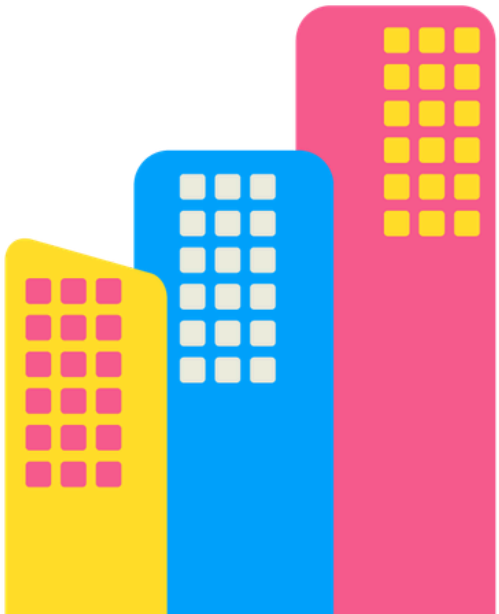


Background

The digitalisation of health systems and the rapid development of digital tools and Artificial Intelligence (AI) for health has increased the amount of health data that is collected and used. As a result, the issue of how health data is governed is a rising concern amongst populations and growing on political agendas. Health data needs to be effectively and equitably governed to safeguard data privacy and rights, mitigate risks of data misuse, and support responsible data use for improved health outcomes and public benefit. Particularly important is the need to ensure robust legislative and regulatory frameworks are in place to establish the legal guardrails for this to happen and hold data stewards accountable.

Transform Health works with governments, national stakeholders and regional partners to strengthen national health data governance legislative and regulatory frameworks. This is supported through Transform Health's technical support approach and tools, including:

- Health Data Governance Principles, which provide equity and rights-based guidance for the governance of health data;
- National health data governance legislative and regulatory landscape assessment tool, which provides a framework to review the legal landscape;
- Health data governance Legislative blueprint (Model Law) and its Implementation Guide, which provide a legislative guide to support in strengthening national laws and frameworks.

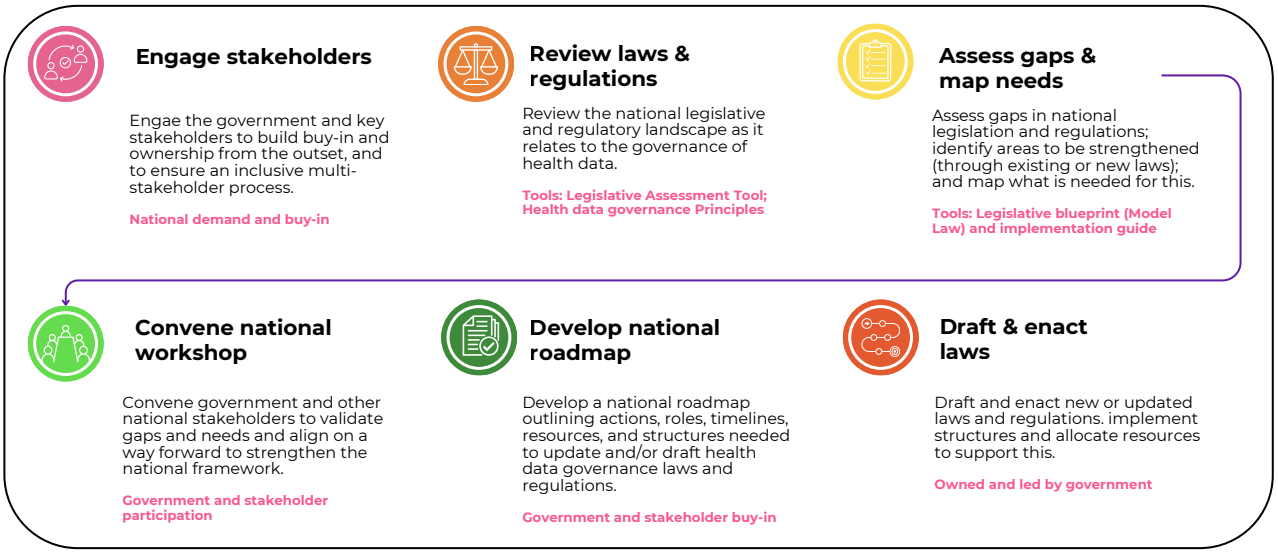
In Rwanda, Transform Health worked with Health Informatics in Africa (HELINA) and the Rwanda Health Informatics Alliance (RHIA), together with government and national stakeholders to review and strengthen the health data governance legislative and regulatory environment.

Objectives and scope

The primary objective was to work with and support the government to strengthen their national health data governance legislative and regulatory framework, through the development of a national actionable implementation roadmap that charts the way forward for this to happen. This entailed the following:

- **REVIEW AND ASSESS:** Reviewing the national legislative and regulatory landscape as it relates to the governance of health data to assess gaps and identify areas to be strengthened (through existing or new laws) and mapping how and what is needed.
- **CHART THE WAY FORWARD:** Developing a national roadmap to take forward the drafting and/or updating of national laws and regulations, setting out actions, roles and responsibilities, and timelines, as well as capacity, financial resources and other structures that would need to be established.
- **NATIONAL OWNERSHIP:** Ensuring national ownership and buy-in from both government and other stakeholders that need to be involved (Responsible, Accountable, Consulted, Informed) to update, draft, or enact legislation.
- **INCLUSIVE MULTI-STAKEHOLDER PROCESS:** Facilitating an inclusive multi-stakeholder process, including civil society and communities, to validate gaps and needs and to align on a way forward.

This work included the following key steps:



Approach and process in Rwanda

In Rwanda, a multistakeholder consultative approach was adopted, involving 24 national and government stakeholders. This included representatives from the Ministry of ICT, the Ministry of Health, and the WHO country office, among others. The engagement aimed to build government ownership and stakeholder buy-in of the process and the resulting roadmap from the outset. It also ensured a broad range of perspectives were reflected.

A comprehensive landscape review was conducted to assess existing health data governance laws, regulations, and related frameworks, including strengths, gaps and needs. The review also sought to identify recommended actions to strengthen national legislation and regulations.

National workshops were then convened to bring together key stakeholders - government officials, healthcare practitioners, legal experts, data protection authorities, and civil society representatives - to discuss and validate the findings of the landscape review. These consultations also supported the development of an actionable roadmap outlining how Rwanda could implement the recommendations in practice.

Key laws in Rwanda relevant to health data governance

2021
Data Protection and Privacy Law (DPP)

2020
Ministerial Instructions Governing Private Health Facilities

2018
Cyber Crimes Law

2017
Law Establishing the Cyber Security Authority

2015
Law Governing the Organisation of the Community-Based Health insurance Scheme

2008
Law Establishing the National Council of Nurses

This section provides a timeline and brief snapshot of the laws and regulations in Rwanda relevant to health data governance.

Rwanda's **Data Protection and Privacy Law (DPP)** is the primary legislation governing data privacy and protection. It aligns text and phrasing with the **European Union's General Data Protection Regulation (GDPR)**, and other references.

There is no general health or primary healthcare law. Strategy documents and legally binding ministerial instructions guide health system functioning, however, content on data governance is sparse. The Ministerial Instructions Governing Private Health Facilities is a Ministerial directive with content relevant to health data governance.

Rwanda's **Cyber Crimes Law** creates a legal framework to prosecute cyber-related crimes. It focuses on fines and culpability rather than preventative security protocols more relevant to data governance. The National Cyber Security Authority (NCSA)'s legal standing granted through this law gives its "standards" and "directives" authority similar to regulations. The Data Protection and Privacy Law's oversight body, the Data Protection Office, is also housed within the NCSA Rwanda has also ratified key regional and international conventions on human rights and cybersecurity.

While the Law governing the organisation of the **Community-Based Health Insurance Scheme (CBHI)** does not self-define as universal health coverage legislation, it serves a similar purpose. It articulates that those failing to enroll and not qualifying for assistance can be fined. Rwanda is signatory to the **African Union Convention on Cyber Security and Personal Data Protection** (the "Malabo Convention") and the **African Charter on Human and Peoples' Rights**.

Legislative landscape review - key strengths, challenges and gaps

	Strengths	Challenges and gaps
Laws and policies	Rwanda has established a strong legislative foundation through its Data Protection and Privacy Law (DPP), which closely aligns with the European Union's General Data Protection Regulation (GDPR). The law clearly defines the responsibilities of organisations handling personal data, outlining the obligations of data controllers and processors. It also grants data subjects specific rights, including access to their data, the right to request corrections, and the conditions under which their data may be deleted. Rwanda is also a signatory to the African Union Convention on Cyber Security and Personal Data Protection (the "Malabo Convention") and the African Charter on Human and Peoples' Rights, reinforcing its commitment to regional and international standards.	Rwanda currently has no health-specific digital legislation, nor legal provisions addressing emerging technologies such as artificial intelligence (AI). Broader governance mechanisms do not yet fully cover the health sector, resulting in limited focus on health-specific data governance. In addition, there are no frameworks for whistleblower protection, adjudication of data disputes, or open access to anonymised and non-identifiable health data. These gaps collectively limit transparency, accountability, and the ethical use of health information.
Implementation & oversight	Chief Digital Officers (CDOs) have been appointed in all sectoral ministries to coordinate with Rwanda's Data Protection Office, ensuring structured oversight and effective governance of data protection initiatives. Since the enactment of the Data Protection and Privacy Law, Rwanda's political leadership has demonstrated sustained commitment, supported by growing public awareness of data subject rights. There is also increased national attention to the purposes and conditions under which personal data is collected, processed, and shared, reflecting a deepening culture of data responsibility across sectors.	At the implementation level, consent processes remain weak in many health facilities, with insufficient safeguards to protect sensitive health data. The absence of a comprehensive health data governance framework also hinders consistent application of privacy and security standards across institutions. Despite progress at the policy level, and growing national attention around personal data, public awareness of data rights remains limited. Many health professionals and institutions also lack the capacity to effectively manage, secure, and ethically use health data. These gaps in understanding and practice contribute to ongoing concerns about legal and ethical compliance in the health sector.
Technical and infrastructure	The government has made significant investments in secure data exchange and storage systems, providing a strong foundation for digital health systems and emerging technologies. Private health facilities are required to comply with national interoperability standards, enabling the Ministry of Health to access and use health data for evidence-based decision-making. These investments and standards together ensure that Rwanda's digital transformation efforts are underpinned by robust data governance and infrastructure resilience.	Data security and encryption measures remain inadequate, exposing health data to potential risks. The national interoperability framework is still under development, which constrains seamless data exchange between systems and limits the Ministry of Health's ability to leverage data for decision-making.

Recommendations to strengthen the health data governance legislative and regulatory environment in Rwanda

To strengthen Rwanda's health data governance framework, coordinated action is required from the Government of Rwanda, the Ministry of Health, the Ministry of ICT and Innovation, the Rwanda Information Society Authority (RISA), and relevant regulatory bodies, in collaboration with civil society and the private sector.

Laws and Policies

- The government should update existing legislation to close gaps in privacy, security, and consent, and to regulate the use of emerging technologies such as artificial intelligence (AI) in healthcare. Whistleblower protections and clear mechanisms for resolving data-related disputes should be introduced, along with provisions enabling open access to anonymised health data for research and policy purposes.

Implementation and Oversight

- Dedicated oversight mechanisms should be established—either through a new body or by expanding the mandate of existing institutions—to ensure compliance and manage grievances. Ongoing stakeholder engagement and regular reviews of the legal and policy framework will be essential to keep governance systems responsive to evolving technologies and health sector needs.

Technical and Infrastructure

- Targeted investments are needed to strengthen data security, including the adoption of standardised encryption protocols and consistent enforcement mechanisms. The national interoperability framework should be fully implemented to enable seamless and secure data exchange across health systems.

Capacity Building and Awareness

- Training programmes for healthcare professionals, policymakers, and IT specialists should be prioritised to enhance understanding of health data governance, risks, and responsibilities. Rwanda Information Society Authority (RISA) institutional capacity should be reinforced to address health-specific data governance issues. In parallel, public awareness campaigns should empower citizens with knowledge of their health data rights and the importance of data protection.

Actionable implementation roadmap

The following section sets out priority steps to update key national legislative instruments, which and conduct inclusive public consultations to ensure the revised legislation reflects stakeholder priorities and safeguards public trust. Subsequent steps entail the updated legal framework undergoing a formal legislative approval process. Parallel efforts will focus on establishing and strengthening institutional structures to support effective enforcement, alongside targeted capacity-building initiatives and ongoing monitoring to ensure the consistent adoption and implementation of the updated regulations.

Step 1: Mobilise key stakeholder and establish technical working groups

Actions	Lead actors and partners
• Convene national validation workshops bringing together government ministries, IT associations, private medical practitioners, and civil society actors. • Formally launch the Health Data Governance Technical Working Group (TWG) and assign clear institutional drafting roles for each targeted law.	Lead: Rwanda Health Informatics Alliance (RHIA) _____ Partners: Ministry of Health (MOH), Rwanda Biomedical Centre (RBC), Rwanda Information Society Authority (RISA), Ministry of ICT & Innovation (MICT)

Step 2: Drafting and technical review

Actions	Lead actors

• Update the **Data Protection Act** (law relating to the protection of personal data and privacy - amendment)
  ◦ Integrate health-specific data sub-categories and explicit definitions of health data layers to isolate clinical files from generic personal identifiers.
  ◦ Introduce formal legal frameworks for whistleblower protection tailored specifically to health facilities and personnel reporting data breaches.
  ◦ Establish structured statutory pathways and grievance remediation frameworks for the rapid adjudication of clinical data disputes.
  ◦ Create explicit windows allowing open access to anonymised and non-identifiable health data to safely facilitate national health research and policy design.
	Ministry of ICT

• Update the **Ministerial Instructions Governing Private Health Facilities** (proposed for replacement/upgrade via a formal regulatory mandate)
  ◦ Transition these instructions into an enforceable National Interoperability Mandate applicable across both public and private sectors.
  ◦ Legally require all health information systems (including Electronic Medical Records, Health Management Information Systems, and logistics applications) to natively adopt and implement the unified HL7 FHIR open data standard.
  ◦ Introduce statutory administrative fines and compliance licensing reviews for public or private facilities utilizing fragmented digital silos.
	Ministry of Health

Step 2: Drafting and technical review (contd.)

Actions	Lead actors

• Update the **National Artificial Intelligence Policy / Emerging Healthcare Technology Regulations** (proposed new regulatory framework)
  ◦ Clarify healthcare-specific health data categories and establish explicit ethical boundaries, liabilities, and accountability vectors for AI-driven clinical decisions.
  ◦ Institute statutory mandates requiring pre-deployment audits regarding the ethical sourcing of health data used to train clinical algorithms.
  ◦ Mandate active, continuous monitoring protocols to detect and eliminate algorithmic bias in healthcare diagnostic tools.
	Ministry of Health

Step 3: Public and stakeholder consultation

Actions	Lead actors and partners
• Launch national budgeted public data literacy campaigns to educate citizens on the distinction between raw clinical records and anonymised research data • Conduct field-level technical review workshops with representatives from decentralized District Hospitals and Health Centers to guarantee compliance feasibility	Lead: Ministry of Health (MOH) and Rwanda Health Informatics Alliance (RHIA) ——— Partners: National Cyber Security Authority (NCSA), local civil society networks, and hospital management boards

Step 4: Legislative approval

Actions	Lead actors and partners

• Seek legislative approval of the updated legislation through the national legislative process, including:
  ◦ Policy Conceptualization and Drafting: The line ministry (Ministry of Health) develops a clear concept note and drafts the initial legal text, working alongside technical committees (such as the Health Data Governance Technical Working Group) and consulting local stakeholders.
  ◦ Inter-Ministerial Stakeholder Validation: The draft text is subjected to multi-stakeholder technical reviews and validation workshops involving partner ministries (Ministry of ICT and Innovation, Ministry of Justice) and regulatory agencies (RISA, NCSA) to align provisions across sectors.
  ◦ Cabinet Submission and Executive Approval: The finalized draft law is presented by the line minister to the Cabinet of Rwanda for policy validation and formal authorization to submit the bill to parliament.
  ◦ Parliamentary Enactment and Committee Scrutiny: The approved bill is forwarded to Parliament (Chamber of Deputies), where it undergoes first reading, is assigned to the relevant technical committee for line-by-line scrutiny, and faces a plenary debate and vote.
  ◦ Presidential Assent and Gazetting: Once passed by Parliament, the legislation receives Presidential assent and is officially published in the Official Gazette of the Republic of Rwanda, establishing it as a legally binding, enforceable statute.
	Lead: Ministry of Health
	———
	Partners: Ministry of Justice, Ministry of ICT and Innovation, National Cyber Security Authority (NCSA),Rwanda Information Society Authority (RISA)

Step 5: Institutional preparation

Actions	Lead actors and partners
• Establish the dedicated Health Data Governance (HDG) Unit, outlining its human resource roles and core operational budget. • Form the multi-disciplinary Ethical Review Board to monitor algorithmic bias and dataset sourcing. • Upgrade facility-level hardware resources and stabilize internet bandwidth allocations directly at local health centers to support secure communication.	Lead: Rwanda Information Society Authority (RISA) _____ Partners: Ministry of Health (MOH), Rwanda Biomedical Centre (RBC)

Step 6: Early implementation and monitoring

Actions	Lead actors
Roll out comprehensive training programs for healthcare practitioners, data processors, and IT personnel on data security and high governance standards	Ministry of Health (MOH) and Rwanda Information Society Authority (RISA)
Enforce the mandatory adoption of standardised encryption protocols and launch baseline interoperability system audits	Ministry of Health (MOH) and Rwanda Information Society Authority (RISA)
Empower the Health Data Governance Technical Working Group to conduct bi-monthly meetings and compile quarterly oversight reports to track roadmap adherence	Ministry of Health (MOH) and Rwanda Information Society Authority (RISA)

Overview and acknowledgements

This case study highlights Rwanda's efforts to strengthen the health data governance legislative and regulatory framework through a collaborative, country-led process. It outlines the approach taken to review the national legislative landscape, identify strengths and gaps, engage stakeholders from across government, regulation, academia, civil society and the private sector, and develop a practical roadmap for strengthening health data governance. It also shares lessons and recommendations that can inform similar reform efforts in other countries.

The case study was developed by Transform Health with the Pan African Health Informatics Association (HELINA) and the Rwanda Health Informatics Association (RHIA), who led the process in Rwanda. We are grateful to the organisations that have been engaged in the process, including the national stakeholder workshops, where the findings of the landscape review were validated and the priorities and actions set out in the Roadmap were shaped.

Stakeholders engaged in the process include: Rwanda Ministry of Health · Rwanda Ministry of ICT and Innovation · Rwanda Biomedical Centre · Rwanda Information Society Authority · Rwanda National Cyber Security Authority · World Health Organization · Society for Family Health · HISP Rwanda · Rwanda Health Informatics Association (RHIA) · Pan African Health Informatics Association (HELINA) · OAZIS Health · Light Choice Health · Bio-Pharmacy.

Transform Health is a global coalition of organisations that work to harness the potential of digital technology and the use of data to achieve universal health coverage (UHC) by 2030. To learn more about Transform Health visit: www.transformhealthcoalition.org.

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All of Transform Health's health data governance tools and resources - including the Health Data Governance Principles, the Legislative Blueprint, national landscape reports, and the assessment tool - are publicly available on our dedicated health data governance website. This website was established as an indepedent platform, to foster collaboration and ownership of this agenda across the sector.

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