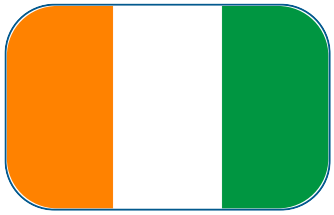
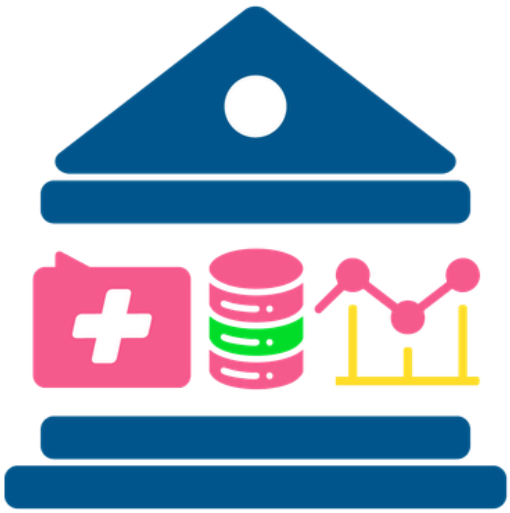
# Supporting stronger health data governance legislative frameworks

## *Côte d'Ivoire Case Study*





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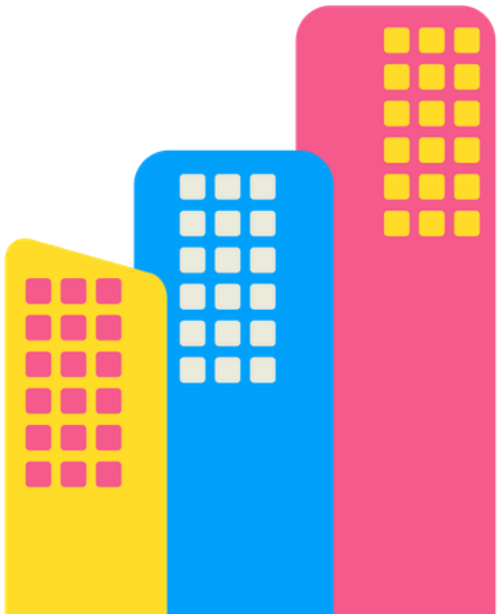


# Background

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.

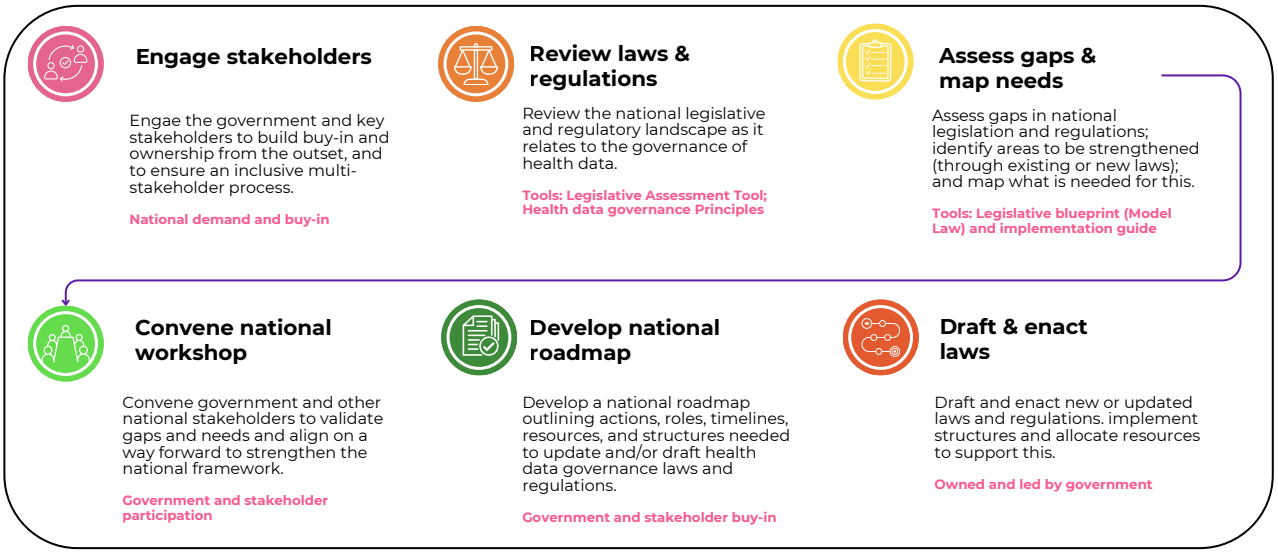
In Côte d'Ivoire, Transform Health worked with Health Informatics in Africa (HELINA) and the Ivorian Society of Biosciences and Medical Informatics (SIBIM), together with government and national stakeholders to review and strengthen the health data governance legislative and regulatory environment.

# 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 Côte d'Ivoire

In Côte d'Ivoire, a multistakeholder consultative approach was adopted, involving 33 national and government stakeholders. This included representatives from the Ministry of Health(MSHP-CMU), the ICT Ministry (MTNIT), the legislatures Institutions (National Assembly, senate), the Social Security Agency(CNPS) , the health professional councils (ONMCI, ONCDCI, PSPSCI) , ICT regulatory Agency(ARTCI), NGO's (SIBIM, FACACI) 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 Malawi could implement the recommendations in practice.

This process was facilitated through the Ivorian Society of Biosciences and Medical Informatics (SIBIM) and led by a legal expert, with technical support from HELINA and Transform Health.

# Key laws in Côte d'Ivoire relevant to health data governance

2024

Law No. 2024-352 of 6 June 2024 on electronic communications

2021

Law No. 2021-555 of 27 September 2021 on the organisation and functioning of the National Order of Physicians of Côte d'Ivoire

2021

Decree No. 2021-916 of 22 December 2021 adopting the General Information Systems Security Framework (RGSSI) and the Critical Infrastructure Protection Plan (CIPP)

2019

Law No. 2019-678 of 3 July 2019 on hospital reform

2017

Law No. 2017-803 of 7 December 2017 on the orientation of the information society in Côte d'Ivoire

2013

Law No. 2013-451 of 19 June 2013 on the fight against cybercrime

2013

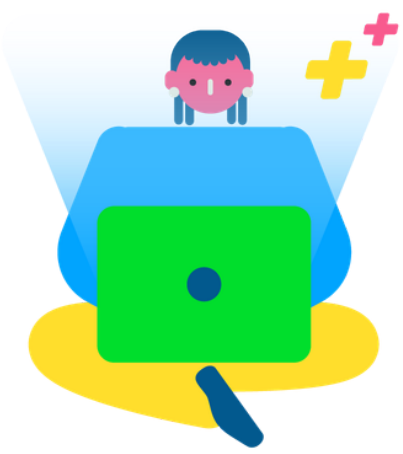
Law No. 2013-450 of 19 June 2013 on the protection of personal data

This section provides a timeline and brief snapshot of the laws and regulations in Côte d'Ivoire relevant to health data governance.

Côte d'Ivoire's legal framework is built on a horizontal data protection regime, sector-specific texts on cybersecurity, telemedicine, and a series of regional and continental instruments ratified by the country. The **Constitution of the Republic of Côte d'Ivoire** establishes fundamental rights including the right to privacy and the protection of personal life, which form the constitutional foundation for any sectoral framework on health data. The **Law No. 2013-450 of 19 June 2013 on the protection of personal data**; establishes the ICT regulatory agency as the national supervisory authority but it does not contain sector-specific provisions for health.

The **Law No. 2013-451 of 19 June 2013 on the fight against cybercrime**; criminalises unauthorised access to information systems, data interference and identity theft. Although it provides general protection it does not address the specificities of health information systems. The **Decree No. 2018-361 of 29 March 2018 on the legal regime of telemedicine** is the only sectoral health law specifically addressing a digital health practice.It defines telemedicine acts and conditions of practice. However, it is insufficient on data governance and health data security.

Côte d'Ivoire' has ratified the **ECOWAS Supplementary Act A/SA.1/01/10 of 16 February 2010 on the protection of personal data** a regional harmonisation instrument establishing a common framework for data protection in West Africa and the African Union Convention on **Cybersecurity and Personal Data Protection (Malabo Convention, 2014)**.



# Legislative landscape review - key strengths, challenges and gaps

| | Strengths | Challenges and gaps |
|---|---|---|
| **Laws and policies** | Law 2013-450 of 19 June 2013 provides a horizontal data protection foundation applicable to all sectors including health.<br><br>Côte d'Ivoire has ratified the AU Malabo Convention (2014) and the ECOWAS Supplementary Act A/SA.1/01/10 on personal data protection showing a clear regional and continental anchoring. | There is an absence of a sectoral specific law on health data which also means patients have no law governing their right to their health data.<br><br>The existing telemedicine framework (Decree 2018-361) lacks provisions on end-to-end data security, infrastructure standards and mandatory data-management training. |
| **Implementation & oversight** | The ICT regulatory Agency(ARTCI) is the national data protection supervisory authority under Law 2013-450, with sanctioning power applicable across all sectors including health.<br><br>The government has also established a national cybersecurity authority, with a legal basis in Decree 2021-916 (general security framework for information systems). | There is an absence of a regulatory body dedicated to digital health which results in fragmented governance with initiatives and responsibilities spread across multiple stakeholders perpetuating data silos. |
| **Technical and infrastructure** | There has been progressive deployment of Electronic Health Records /Health Information Systems in a number of public and private health facilities, providing a technical base to converge on common standards.<br><br>The national broadband and telecommunications infrastructure is under ICT regulatory Agency (ARTCI) supervision as such enabling secure digital exchanges. | There is absence of a cybersecurity framework specific to health information systems and there is no national incident reporting platform. There is a lack of interoperability standards as the health information systems do not communicate reliably across facilities. |

# Recommendations to strengthen the health data governance legislative and regulatory environment in Côte d'Ivoire

To strengthen Côte d'Ivoire's health data governance legislative and regulatory framework, coordinated action is required from the Government of Côte d'Ivoire, including the Ministry of Health, Public Hygiene, the Ministry of Digital Transition and Digitalisation and relevant regulatory bodies, in collaboration with civil society and the private sector.

## Laws and Policies

- Update existing legislation to close gaps in privacy, security, and consent, and to regulate the use of emerging technologies such as AI in healthcare.
- Introduce whistleblower protections and clear mechanisms for resolving data-related disputes within the sectoral instruments, including protection for facility staff reporting security incidents or non-compliance, and a graduated dispute-resolution pathway between citizens, health facilities, and the sectoral regulator.

## Implementation and Oversight

- Establish dedicated oversight mechanisms - either through a new sectoral body or by expanding the mandate of existing institutions - to ensure compliance and manage grievances.
- Implement mandatory logging and traceability of accesses to health data at facility level, monitored monthly by the Health Personal Data Correspondent, with sample audits carried out quarterly by the sectoral regulator and automated correlation for anomaly detection by the Sectoral CSIRT-Santé.

## Technical and Infrastructure

- Invest in expanding the digital infrastructure and connectivity to ensure all health facilities, including in rural districts, have access to digital tools and reliable connectivity. This includes the full operational commissioning of the Ministry of Health, Public Hygiene and Universal Health Coverage data centre and the deployment of the national health-incident reporting platform (toll-free number) operated by the Sectoral CSIRT-Santé.
- Establish a national health data classification framework as a supportive activity to underpin the cybersecurity and hosting instruments, developed through a multi-stakeholder workshop and validated by the Directorate of Legal Affairs and Litigation, Directorate of IT and Digital Health, Telecommunications Regulatory Authority of Côte d'Ivoire and National Informations Systems Security Agency.

## Capacity Building and Awareness

- Prioritise training programmes for healthcare professionals, policymakers, and IT specialists to enhance understanding of health data governance, risks, and responsibilities.
- Carry out public awareness campaigns to empower citizens with knowledge of their health data rights and the importance of data protection.
- Strengthen the capacity of legislative and judicial institutions through targeted briefings for parliamentarians of the Health and Digital Affairs Commissions of the National Assembly and the Senate, and continuing education on health data protection for magistrates and legal counsel handling data-related disputes.

# 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 |
|---|---|
| • Mobilise key institutional partners for the health data governance legislative strengthening process.<br>• Identify lead agencies and technical working groups for each of the priority legislative instruments in the roadmap.<br>• Determine roles and responsibilities of key stakeholders. | Lead: Société Ivoirienne de Biosciences et d'Informatique Médicale (SIBIM)<br>———<br>Partners: Ministry of Health (MOH), Ministry of ICT & Innovation (MICT) |

## Step 2: Drafting and technical review

| Actions | Lead actors |
|---|---|
| • Update the **Sectoral Law on Health Data**<br>◦ New law. Complementing Law 2013-450, introducing health-specific provisions on end-to-end traceability, distinction between personal and aggregated data, processing rules for health information systems, secure intranet, access authorisation systems, and sanctions. | Directorate of Legal Affairs and Litigation, Directorate of IT and Digital Health, Telecommunications Regulatory Authority of Côte d'Ivoire |
| • Update the **Decree on Informed Consent and Patient Rights**<br>◦ New decree. Modalities of digital informed consent in health, conditions for withdrawal, exercise of access, rectification, opposition, portability and right-to-be-forgotten rights. | Directorate of Legal Affairs and Litigation |
| • Update the **Inter-ministerial Decree on Health Data Hosting**<br>◦ New decree. HDS-CI certification of health data hosting providers, national centralising health database hosted in Côte d'Ivoire (excluding research data), legal framework for an Ivorian sovereign cloud dedicated to health. | Ministry of Digital Transition and Innovation Technology and Telecommunications Regulatory Authority of Côte d'Ivoire |

## Step 2: Drafting and technical review (contd.)

| Actions | Lead actors |
|---|---|
| • Update the **Law on Secondary Use of Health Data**<br>  ◦ New law. Framework for secondary uses (research, epidemiological surveillance, government decision-making, training, transparency). Anonymisation and pseudonymisation conditions, role of ethics committees, prior authorisations. | Directorate of Legal Affairs and Litigation |
| • Update the **Amendment to the Telemedicine Framework**<br>  ◦ Amendment to the existing telemedicine legal framework. End-to-end data security and confidentiality, technical infrastructure standards, authorisation to practise, mandatory training for practitioners in data management. | Directorate of Legal Affairs and Litigation and Directorate of IT and Digital Health |

## Step 3: Public and stakeholder consultation

| Actions | Lead actors and partners |
|---|---|
| • Carry out public consultation on updated draft legislation, including consulting key stakeholders. | Lead: The lead agency of each instrument, as designated in Step 2, in coordination with the Task Force.<br><br>Partners: National Assembly and Senate (Health and Digital Affairs Commissions), regulatory bodies, civil society and academic institutions. |

## Step 4: Legislative approval

| Actions | Lead actors and partners |
|---|---|
| • Seek legislative approval of the updated legislation through the national legislative process, including:<br>  ◦ Submission of finalised drafts to the Cabinet of the Minister of Health for technical endorsement<br>  ◦ For laws: passage to Council of Ministers, then deposit at the National Assembly and Senate; first and second reading; navette procedure; final vote<br>  ◦ For decrees: examination by the Council of State, then signature by the Prime Minister or the President<br>  ◦ For orders: signature by the relevant Minister | Lead: For laws: Directorate of Legal Affairs and Litigation in coordination with the Cabinet of the Minister of Health for the parliamentary process. For decrees: the lead ministry designated in Step 2, in coordination with the General Secretariat of the Government. For orders: the Directorate of Legal Affairs and Litigation on behalf of the Minister of Health.<br><br>Partners: General Secretariat of the Government, Council of State, National Assembly (Health Commission and Digital Affairs Commission), Senate, President of the Republic's Cabinet for promulgation. Awareness briefings organised for parliamentarians and produced by the Task Force secretariat (SIBIM). |

## Step 5: Institutional preparation

| Actions | Lead actors and partners |
|---|---|
| • Production of explanatory guides for the benefit of patients and health professionals<br>• National training programmes and awareness campaigns on patient rights, targeting health professionals and consumers. | Lead: Directorate of Legal Affairs and Litigation and Directorate of IT and Digital Health coordinated by the Task Force during the pre-establishment period.<br><br>Partners: SIBIM (communication and campaign design), regulatory bodies, civil society and media partners (radio, TV, press) |

## Step 6: Early implementation and monitoring

| Actions | Lead actors |
|---|---|
| Establishment of a quarterly monitoring committee under for each adopted instrument | Directorate of Legal Affairs and Litigation and Directorate of IT and Digital Health |
| Conduct institutional health data governance supportive supervision to mentor institutions on the application and use of the health data governance instruments | Directorate of Legal Affairs and Litigation and Directorate of IT and Digital Health |
| Field technical support to health facilities and Electronic Health Records/Health Information Systems operators facing compliance difficulties, delivered through the technical assistance unit created under law on cybersecurity of Health Information System and mobile audit teams under Directorate of IT and Digital Health authority. | Directorate of IT and Digital Health |
| Adjustment of implementing orders and technical guides based on identified difficulties; publication of updated versions where necessary. | Health Personal Data Correspondents |

## Overview and acknowledgements

**This case study highlights Côte d'Ivoire'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 health service delivery, 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 Société Ivoirienne de Biosciences et d'Informatique Médicale (SIBIM), who led the process in Côte d'Ivoire. 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: Côte d'Ivoire Ministry of Health, Public Hygiene and Universal Health Coverage · Côte d'Ivoire Ministry of Digital Transition and Innovation Technology · Côte d'Ivoire Directorate of Health and Pharmacy Establishments and Professions · Côte d'Ivoire National Institute of Public Health · Côte d'Ivoire National Social Security Agency · Félix Houphouët-Boigny University · Federation of Active Consumer Associations of Côte d'Ivoire · Polyclinique Internationale Sainte-Anne-Marie · Société Ivoirienne de Biosciences et d'Informatique Médicale (SIBIM).**

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.

Transform Health