2025 REPORT

AI GOVERNANCE IN HEALTH

Global Landscape

HEALTH AI
The Global Agency for Responsible AI in Health

contact@healthai.agency

www.healthai.agency

HEALTH AI
The Global Agency for Responsible AI in Health

AI GOVERNANCE IN HEALTH

Global Landscape

Amanda Leal
AI Governance and Policy Specialist
HealthAI - The Global Agency for Responsible AI in Health

Paula Eugenia Kohan
Lawyer and Consultant in Health and Technology Policy
CLIAS - Centro de IA y Salud para América Latina y el Caribe

Dr. Peiling Yap
Chief Scientist
HealthAI - The Global Agency for Responsible AI in Health

AI Governance in Health: Global Landscape
© 2025 HealthAI – The Global Agency for Responsible AI in Health
Geneva, Switzerland

Some rights reserved. This work is licensed under the Creative Commons Attribution–NonCommercial–ShareAlike 3.0 IGO license (CC BY-NC-SA 3.0 IGO).
https://creativecommons.org/licenses/by-nc-sa/3.0/igo/

Suggested citation:
HealthAI – The Global Agency for Responsible AI in Health. AI Governance in Health: Global Landscape. Geneva, Switzerland; 2025 Dec.

Disclaimer:
Specific regulatory approaches or policies mentioned in this report and their analysis do not constitute endorsement or recommendation, nor should they be considered as the official views of HealthAI or any of its affiliates or partners. This document, including designations and any map, is without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries, and to the name of any territory, city, or area.

For inquiries regarding rights and permissions, please contact:
contact@healthai.agency

Published: December 2025

ACKNOWLEDGEMENTS

Our sincerest gratitude to HealthAI's colleagues and HealthAI's Global Regulatory Network members who provided a critical review of the report and the country landscape chapters. This report was made possible with institutional funding support from HealthAI's donors.

The China country analysis was co-written with Dr. You Wu, Associate Professor, School of Healthcare Management, Tsinghua Medicine, Tsinghua University; Muxue Liang, PhD Student, School of Biomedical Engineering, Tsinghua Medicine, Tsinghua University; and Yinting Zheng, Master Student, School of Hospital Management, Tsinghua University.

The United States country analysis was co-written with Dr. Sara Gerke, Dipl-Jur Univ, MA, Associate Professor of Law and Richard W. & Marie L. Corman Scholar, College of Law, Associate Professor, European Union Center, University of Illinois Urbana-Champaign, Champaign, IL.

CONTENTS

FOREWORD

Peiling Yap
Chief Scientist
HealthAI – The Global Agency for Responsible AI in Health

Merely a year has passed since the publication of the inaugural version of our AI Governance in Health Global Landscape Report in 2024, yet we have witnessed significant geopolitical shifts and technology advancements leading to notable changes in the global governance landscape. The past year has also seen the work of HealthAI progress from being a strategy to concrete implementations through the establishment of our Global Regulatory Network (GRN), which will strengthen the AI in health governance capacity of each country member and promote multilateral collaboration, as well as the growth of our Community of Practice (CoP), which currently has more than 400 institutional members from governments, international organizations, civil society, academia and industry across more than 75 countries. Through this AI Governance in Health Global Landscape 2025 Report, we hope to provide a comprehensive analysis of the current governance landscape, with deep dives into eight selected jurisdictions, to our members and the wider AI in health community.

Interestingly, within this report, several global governance trends have emerged: Software as a Medical Device (SaMD) regulations are serving as foundations of AI governance in health, more robust and innovative approaches are needed for post-market surveillance, regulators are seeking a delicate balance between horizontal AI laws and vertical health tech regulations, and there is a need for data governance which can support AI systems that recombine data in ways that generate new, high-risk inferences.

These trends are the reasons why we do what we do at HealthAI with our partners and collaborators. Alongside our knowledge strengthening activities with our GRN and CoP members, our work on establishing a Global Early Warning System to detect AI adverse events in health and a Global Public Directory for registered AI solutions in health contributes to global efforts in establishing a vigorous governance ecosystem that will allow for responsible AI innovations to thrive.

I have often been asked by the AI in health community how we can move from pilots to widespread scale of AI innovations across health systems. My answer is an analogy with cars and roads. No matter how shiny and promising our cars (AI innovations) can be, without proper roads to drive on and traffic rules to adhere to (governance ecosystem), these cars will never see the light of the day. Even worse, accidents and harm to citizens will occur. At HealthAI, we believe that proper governance can act as a filter for responsible and viable AI innovations in health. We hope that this report can provide inspiration to national and regional efforts in strengthening AI governance in health, which will ultimately help unlock the transformative potential of AI innovations to better serve our health systems and citizens, and achieve measurable improvements in health and well-being for all.

My deepest gratitude to HealthAI's colleagues and collaborators from the Center for Artificial Intelligence and Health for Latin America and the Caribbean (CLIAS), Tsinghua University and the University of Illinois Urbana-Champaign, whose knowledge and expertise have made this report and its country chapters a reality. I am also grateful to our GRN members who have provided critical review of the country analyses. Finally, I would like to thank our funders for their continued support, allowing us to embark on this knowledge creation journey.

EXECUTIVE SUMMARY

Rising stakes for AI governance in health

The geopolitical race for AI leadership is reshaping health systems worldwide, yet conventional metrics of AI success—computing infrastructure, frontier research capacity, and investment flows—fail to account for health risks and equity implications. As AI tools are deployed in clinical decision-making, surgery, mental health, and wellness applications, the primary barriers to responsible AI at scale are not technological but governance-related. The policy frameworks implemented today will determine whether AI advances global health equity or amplifies existing disparities.

Today's global governance environment is characterized by a kaleidoscope of overlapping coordination initiatives, divergent data regimes, and underdeveloped metrology for evolving AI systems. Software as a Medical Device (SaMD) frameworks remain the primary regulatory pathway for AI in health. Yet, existing structures—designed for static devices—struggle to accommodate adaptive AI systems and post-deployment algorithm changes. Furthermore, the expanding gray zone of wellness and general applications that fall outside traditional medical device classification but have considerable public health impacts must be urgently addressed.

Cross-jurisdictional patterns

This report analyzes the landscape of AI governance in health in eight countries: Brazil, China, India, Singapore, the United Kingdom, the United States, Vietnam, and Zambia. The results reveal convergent trajectories: all are building multi-layered governance architectures combining national AI strategies, data protection legislation, digital health infrastructure, and risk-based medical device regulation aligned with IMDRF principles. In addition, countries are seeking to advance digital sovereignty by investing in national digital health platforms as foundational infrastructure for AI deployment. Yet implementation maturity varies significantly, with persistent gaps between strategic ambitions and operational enforcement capacity, particularly in adaptive AI oversight, emerging AI uses that challenge traditional frameworks, and post-market surveillance practices.

Four cross-cutting challenges emerge: (1) *regulatory fragmentation*—multiple agencies with overlapping mandates and limited coordination mechanisms; (2) *adaptive AI governance gaps*—insufficient frameworks for continuously learning systems that evolve post-deployment; (3) *infrastructure inequity*—uneven electricity, connectivity, and digital literacy between urban and rural regions; and (4) *the policy-practice divide*—the distance between ambitious strategic visions and enforceable, sector-specific regulations with adequate institutional capacity.

Paths forward

Ultimately, the policy frameworks, regulatory mechanisms, and governance structures implemented today will shape whether AI becomes an instrument of health democratization or disparity amplification. The countries analyzed demonstrate that while there is no single model for governing AI in health, shared principles—safety, transparency, accountability, and equity—can guide diverse national approaches toward a common objective: ensuring that AI translates into measurable improvements in health for all. Achieving this will require not only technical and regulatory innovation but sustained political will, investment flows, cross-sectoral coordination, and a commitment to centering health and human rights as core metrics of success in the global AI race.

Drawing from the findings of this report, the following actions are recommended to advance responsible AI governance in health:

For national governments and health ministries

- Establish or strengthen formal inter-agency coordination mechanisms, such as dedicated AI councils or cross-ministerial working groups, and invest in capacity-building.
- Adopt policy-making designs that include participatory processes and evidence-based approaches.
- Prioritize investment in foundational infrastructure—particularly electricity, broadband connectivity, and digital health platforms—and in society-wide AI literacy initiatives.

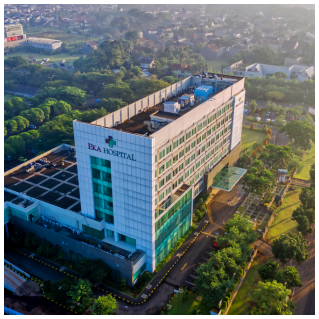
For national regulatory authorities

- Develop explicit, sector-specific guidance for AI-enabled medical devices within existing SaMD frameworks, addressing the full product lifecycle, including post-market surveillance of adaptive and continuously learning systems.
- Support regulatory reliance frameworks and mutual recognition agreements to reduce duplication and accelerate market access for safe technologies.
- Expand the use of regulatory sandboxes to test innovative AI health technologies under controlled conditions, generating real-world evidence to inform future regulatory standards.

For international organizations and standard-setting bodies

- Facilitate the harmonization of baseline technical and governance standards and promote dialogue with the international community beyond like-minded countries.
- Advance international coordination for cross-border risk mitigation strategy and coordinated action for responsible AI in health.

For AI developers and healthcare institutions



- Implement robust transparency and accountability mechanisms throughout the AI lifecycle, including algorithm documentation, bias audits, and clear protocols for human oversight.
- Establish internal incident-reporting systems and contribute to sector-wide early-warning mechanisms to identify and address safety threats, performance drift, or unintended consequences in deployed AI systems.

For civil society, patient groups, and academia

- Advocate for co-led, structured, evidence-based participatory processes to ensure that diverse voices—particularly those of affected communities—are incorporated into AI governance.
- Support research on the health equity implications of AI deployment and contribute to the development of evaluation frameworks that measure AI's impact on health outcomes across populations.

SECTION 1

INTRODUCTION

Major Shifts in Health and AI Governance Landscape (2024-2025)

A critical challenge to the global regulatory landscape of AI and health in the past year has been the intensifying competition for AI leadership among countries and across sectors that reverberates through healthcare systems worldwide. The geopolitical race for AI dominance is deepening tensions in the world stage, with each aspiring AI leader seeking advantage through investment, diplomacy, trade strategies, policies, and regulations [1]. In parallel, countries lagging in the ramping AI race pursue the promise of "leapfrogging" into AI-driven development, while still grappling with investment shortages, limited capacity, and infrastructure gaps [2][3]. A variety of countries have also elevated AI governance as a high national priority in their agendas, though important considerations regarding what the extent of the race is and what it means to win remain unclear [4][5].

Although the AI race is often framed as a geopolitical, innovation, national security, and economic competitiveness issue [6], it is also affecting public health systems. However, the metrics for success in the AI race most referred to—computing infrastructure, electricity grids capacity, frontier AI research capacity, quality data, and investment flows—don't account for health risks that are raising concerns across critical dimensions.

The lack of representative data in AI tools may perpetuate or amplify health disparities worldwide [7]; the risk of significant societal impact in areas such as mental health has risen with unregulated conversational AI offering treatment, advice, or companionship to millions [8]; and concerns that expanding computational infrastructure and data centers may severely impact the environment and, consequently, health outcomes in surrounding communities have grown exponentially [9].

Policymakers across different contexts must recognize this interdependence: health actors cannot afford to treat AI as a technical or economic issue beyond their purview, just as AI governance bodies cannot treat health as merely another vertical among many. AI advancement without corresponding improvements in health indicators represents a failure for responsible AI and sustainable development goals.

Concrete policy actions are key to addressing those concerns and steering AI governance towards an approach that brings health and equity as central metrics.

Unlocking answers to global challenges

As explored in this report, the primary challenges to achieving responsible AI in global health at scale are not technology but governance related. Meanwhile, the stakes are getting higher: new AI tools are being deployed to support clinical decision-making [10] and surgery [11], while many others are flooding the market of digital applications for mental health [12] and "wellness" [13], an emerging category that includes AI companions and shows signs of significant societal impact [14][15].

Governance barriers may be overcome with sufficient human effort and co-operation [16]. However, a global governance landscape with multiplying overlapping international coordination efforts, divergent data regimes, conflicting regulatory frameworks, and incompatible standards undermines much-needed common baselines for AI development and deployment across jurisdictions. For that reason, advancing integrated policies and regulations for AI in health and seeking a set of minimum common denominators among countries will be key to securing AI's potential to advance global health.

The policy frameworks, regulatory mechanisms, and governance structures we implement today will determine whether AI becomes an instrument of health democratization or disparity amplification. This report explores AI governance developments relevant for health across jurisdictions.

The following sections provide a comprehensive analysis of the current landscape and pathways forward. **Section 2** provides a timeline overview of updates in the international landscape for AI governance and health, highlighting the wealth of convenings and instruments launched in the past year. **Section 3** analyzes emerging regulatory frameworks and trends, emerging best practices, and persistent gaps in AI and data governance in health. **Section 4** provides a deep dive into the AI governance and health ecosystem in eight selected countries. Finally, **Section 5** synthesizes these findings into actionable recommendations, proposing concrete mechanisms for ensuring that AI translates into measurable improvements in global health outcomes.

SECTION 2

OVERVIEW OF UPDATES TO THE AI GOVERNANCE AND HEALTH LANDSCAPE

TIMELINE:

The timeline below highlights important developments for AI governance in health around the world, between June 2024 and August 2025.

June, 2024

G20 Health Working Group – III Meeting
Salvador, Brazil
Outcome: AI regulation highlighted as a priority for equitable access in health technologies.

OECD Ministerial Council Meeting (MCM)
Paris, France
Outcome: Updated OECD AI Principles, stronger emphasis on AI safety, privacy, and governance.

Council of Europe Framework Convention on AI (adopted)
Strasbourg, France
Outcome: First binding treaty on AI and human rights, opened for signature Sept 2024.

July, 2024

Global IndiaAI Summit 2024
New Delhi, India
Outcome: GPAI Global Health track; coordination on AI for Global South health challenges.

World Artificial Intelligence Conference (WAIC 2024)
Shanghai, China
Outcome: Signing of the Shanghai Declaration on Global AI Governance – principles including health.

African Union Continental AI Strategy launched
Addis Ababa, Ethiopia
Outcome: AI governance as a central element of Africa's AI development and deployment.

Aug, 2024

PAHO/Bahamas Regional Workshop on AI in Public Health
Nassau, Bahamas
Outcome: Plans for national AI-for-health strategies and stronger data/AI governance.

Sept, 2024

UN Summit of the Future
New York, USA
Outcome: Adoption of the Pact for the Future and the UN Global Digital Compact.

Africa AI Governance Roundtable (Summit of the Future side-event)
New York, USA
Outcome: Commitment to inclusive AI governance frameworks and bridging Africa's digital divide.

Oct, 2024

G7 Toolkit for Artificial Intelligence in the Public Sector
Paris, France
Outcome: Practical guide to support policymakers in translating trustworthy, safe and secure AI principles into public sector policies.

Nov, 2024

AI in African Health Conference
Kampala, Uganda
Outcome: Ecosystem-building for AI in health; emphasis on ethical frameworks and sustainable policies.

Dec, 2024

GPAI Summit 2024
Belgrade, Serbia
Outcome: Multilateral discussions on responsible AI, including healthcare.

Jan, 2025

PAHO/World Bank/IDB "Digital Health Innovations & AI" Webinar
Virtual (LAC focus)
Outcome: Shared best practices for AI adoption in LAC health systems.

IMDRF's "Good machine learning practice for medical device development - Guiding Principles"
Virtual (global)
Outcome: Consensus-building among regulators on best practices for AI in medical devices

Feb, 2025

AI Action Summit
Paris, France
Outcome: Investments announced in the European AI industry via the InvestAI initiative

Mar, 2025

WHO/ITU/WIPO Global Initiative on AI for Health (GI-AI4H) Meeting
Geneva, Switzerland
Outcome: Progress on global benchmarking, standards, and ethical guidance for health AI.

Apr, 2025

Global AI Summit on Africa
Kigali, Rwanda
Outcome: Landmark resolution to establish a $60 billion fund aimed at building a robust AI ecosystem across Africa.

May, 2025

Council of Europe Conference on AI in the Health Sector
Helsinki, Finland
Outcome: Recommendations on "meaningful human control" and safeguarding patient rights.

Future Digital Health International Congress (FDHIC 2025)
São Paulo, Brazil
Outcome: Strengthened a regional knowledge-sharing hub; 20+ AI in health applications showcased.

Jun, 2025

Africa Health ExCon – Health Data Governance Roundtable
Cairo, Egypt
Outcome: Agreement to develop a Continental Health Data Governance Framework by 2026.

UNESCO Global Forum on AI Ethics
Bangkok, Thailand
Outcome: Renewed commitments to UNESCO AI Ethics principles; pledges from tech companies.

Publication of ISO/IEC 42005
Outcome: Guidance for organizations conducting AI system impact assessments.

Jul, 2025

MENA Regional Workshop on AI for Health Systems Transformation
Cairo, Egypt
Outcome: Consensus on urgent need for national/regional AI-for-health strategies.

AI for Good Global Summit 2025 + AI Governance Dialogue
Geneva, Switzerland
Outcome: ITU AI standards launched; AI Standards Database; guidance on multimedia deepfakes.

Africa AI Health Forum
Kumasi, Ghana
Outcome: Focus on AI in public health; highlighted generative AI opportunities and ethical issues.

World Artificial Intelligence Conference (WAIC 2025)
Shanghai, China
Outcome: Global AI Action Plan (13-point roadmap); proposal for a new global AI cooperation body.

Aug, 2025

UN General Assembly's 79th session
New York, United States
Outcome: Resolution 79/325 establishing two new mechanisms to promote international cooperation on AI: a Global Dialogue on AI Governance and an Independent Scientific Panel on AI.

SECTION 3

EMERGING REGULATORY APPROACHES AND TRENDS FOR AI IN HEALTH

The past year has been marked by a surge in regulatory and governance initiatives across jurisdictions. Numerous national AI strategies and policies with diverse approaches to governing AI development and deployment were launched. Although divergence among those initiatives is a natural consequence of legitimate sovereignty and allows for solutions fit for each context [17], the borderless character of AI applications calls for international coordination around baseline standards across jurisdictions.

In AI governance for medical devices, there are multiple standard-setting and coordination initiatives with overlapping but distinct membership influencing regulatory developments in this field. The International Medical Device Regulators Forum (IMDRF), established in 2011, with regulatory authorities from 10 jurisdictions and over 20 affiliate members, stands out as a major international standard-setter in AI and software as a medical device regulation [18].

in parallel, the Global Harmonization Working Party (GHWP), founded in 1996 with an initial Asian focus, has expanded to 32 member countries—particularly in the Global South—and gained global prominence, with membership for both regulatory authorities and industry [19]. While some countries participate in both initiatives, they have different governance structures, regional emphases, and stakeholder engagement approaches. As of June 2025, GHWP withdrew its membership from IMDRF [20], reflecting evolving dynamics in international coordination and pointing to a similar trend as seen in AI governance—a kaleidoscope of coordination initiatives.

Beyond medical devices, it's crucial to analyze recent developments at the data governance level, a growing regulatory domain with global implications. For instance, recent national digital sovereignty measures such as the data localization requirements under the European Health Data Space Regulation risk impacting cross-border data flows worldwide [21].

The challenge posed by the kaleidoscope landscape is precisely that the sensitive nature of health data and direct patient safety implications require a sufficiently specific and coherent set of policies, practices, and standards across the AI lifecycle—from data governance to algorithm development, clinical deployment, and evaluation [16]. Coherence among policies and standards, both at the national and international level is thus critical for responsible AI governance in health—as it is for fostering trust, another crucial element in this sensitive field. Yet, from a governance and regulatory perspective, when jurisdictions pursue incompatible approaches and lack structured policy-making dialogue mechanisms, achieving this coherence becomes exponentially more difficult.

This section presents an overview of how the main regulatory fronts for AI governance in health are taking shape, with both sector-specific initiatives, such as the regulation of SaMD or the protection of health-related personal data, and cross-cutting instruments, such as horizontal AI laws. The points explored below aim to serve as a foundation for better understanding the regulatory trajectories of the countries analyzed in Section 4.

3.1. Regulation of SaMD at the crux of AI and health regulation

One of the key regulatory spaces for AI in health remains the regulation of Software as a Medical Device (SaMD), which by default includes AI as a Medical Device (AIaMD). When it comes to integrating AI into existing frameworks, there have been advances across jurisdictions, but limitations persist. The frameworks often do not fully encompass the AI challenges—such as the increasingly complex data lifecycle, post-deployment changes, transparency and interpretability limitations, and underdeveloped metrology and standards.

Although progress has been made, across jurisdictions, stakeholders still contend with different specifications and definitions of AI and SaMD. In addition, the regulatory gray zone for the use of AI-enabled medical devices in-house at hospitals and AI applications that do not fall under the medical device classification remains unaddressed in many jurisdictions.

Meanwhile, several socio-technical mechanisms are emerging to address some of those challenges. One example of an effort to increase transparency is the introduction of specialized labeling frameworks, such as model cards and nutrition facts-style labels for AI/ML-based medical devices. The labels are conceived to evolve dynamically with adaptive systems [22]. National regulatory authorities also spearhead efforts: The U.S. FDA, for instance, emphasizes the importance of transparency for AI/ML-based medical devices, including publicly identifying when such devices use foundation models and encouraging developers to include relevant information in summaries. However, as this report explores, broader legislative and policy efforts are needed to address the evolving challenges at the intersection of AI, medical devices, and the broader health domain, a matter whose remit is split between multiple regulatory authorities, government institutions, and stakeholders.

The SaMD framework is generally centered on licensing devices for commercialization based on safety and efficacy requirements. The definition of a medical device is broad but highly focused on clinical activity. In 2013, through IMDRF, the framework was upgraded to introduce the concept of software as a medical device, and more recently Artificial Intelligence and Machine-Learning enabled SaMD (AI/ML-SaMD) [23].

Because of its clinical scope, however, it excludes public health and wellness applications and struggles with incorporating general-purpose AI, such as large language model-based applications. Although jurisdictions adopt different terminologies and nuances for the concept of SaMD and AI, some converge in common principles [24] but would benefit from increased coordination.

Another overlooked issue refers to AI-enabled medical devices developed or deployed in-house for closed healthcare networks, in hospitals and its affiliated clinics. Such devices may not fall under the purview of regulatory frameworks in many jurisdictions [25]—and have weaker requirements in others [26]. The lack of clarity governing in-house AI use creates uncertainties about oversight, lifecycle monitoring, and addressing unintended outcomes, factors that are usually evaluated at market entry. Some argue that, without unified oversight, locally developed or continuously updated systems risk forming a parallel ecosystem of unregulated medical AI [27].

3.1.1. AI's impact on medical devices' post-market oversight

The regulatory journey for standalone AI as a medical device (AIaMD) or those embedding AI is also facing challenges with the rise of devices that adapt to real-world data post-deployment (also called "unfixed" or "unlocked" devices). Existing medical device frameworks were conceived for static devices, and regulators have been struggling to monitor "unfixed" or adaptive AI devices over their lifecycle [25][28][29]. Because enforcement capacity is limited, many agencies remain heavily geared toward pre-market clearance, relying on periodic audits or voluntary reporting for post-market surveillance, which may fail to catch emergent errors, algorithmic drift, or bias that develops post-deployment. Consequently, updates or continuous learning that are not anticipated in the clearance dossier may jeopardize safety assurance.

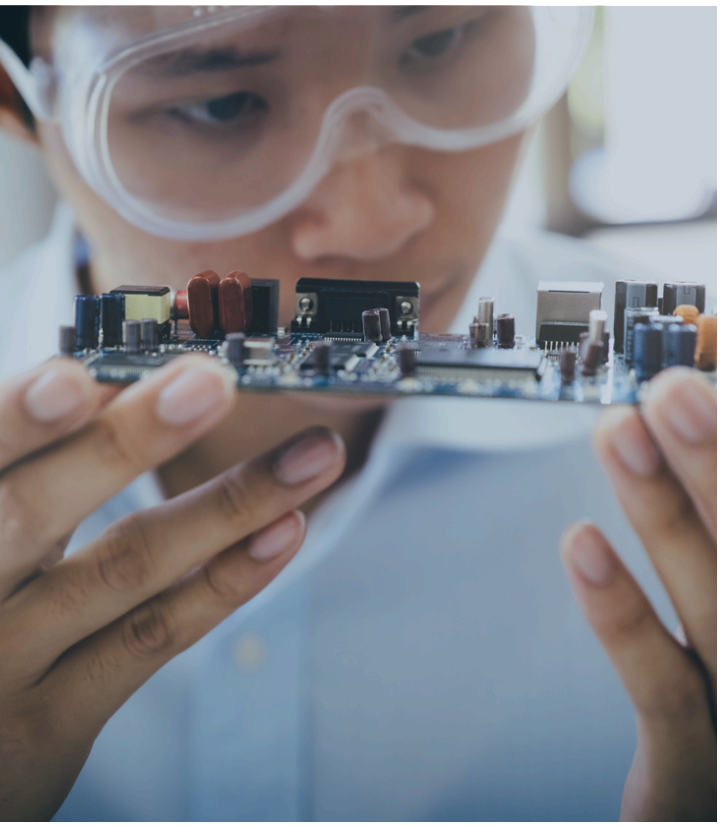
This mismatch underscores the need for regulatory innovation: expanded authority and funding for lifecycle oversight, mandatory reporting of real-world performance, algorithm change protocols, and effective incident-response mechanisms, including retract or rollback systems, in case of adverse events.

3.1.2. Post-market surveillance and Predetermined Change Control Plans (PCCPs)

Despite those challenges, some jurisdictions are moving to bridge the gap in post-market surveillance in the age of AI. In 2023, the UK's MHRA along with the U.S. FDA and Health Canada have published the predetermined change control plans (PCCP) guiding principles, emphasizing that changes in adaptive medical devices must be "focused and bounded," risk-based, evidence-driven, transparent, and assessed throughout the total product lifecycle (TPLC). Since 2025, the U.S. FDA accepts Predetermined Change Control Plans (PCCPs) as part of an initial submission, allowing certain algorithmic modifications post-approval without triggering full reauthorization [31].

Health Canada's 2025 guidance also embedded the PCCP concept, with pre-approved change protocols under license terms [32].

Post-market surveillance (PMS) and PCCPs are complementary tools regulators use to manage the safety of AI-enabled SaMD over time. Post-market surveillance refers to the continuous monitoring of a device's performance and safety after it is placed on the market or deployed in a clinical setting. It includes collecting real-world data, detecting performance drift or bias, and implementing corrective actions when necessary.



- In practice, PCCPs allow developers to specify in advance what aspects of an AI system (such as model parameters or datasets) may change, how these changes will be controlled, and what evidence will demonstrate safety after updates.
- PMS ensures that manufacturers or health institutions remain accountable for a device's ongoing reliability rather than treating approval as a one-time event.
- Together, PMS and PCCPs enable a total product lifecycle approach that supports innovation in adaptive AI systems while maintaining regulatory oversight and patient protection.

Around the globe, regulatory developments to fill post-market uncertainties brought by adaptive AI point to a potential paradigmatic shift in pre-market review, with foresight of structured changes, increased lifecycle monitoring and ex-ante governance, rather than a reliance on resubmissions and redressal.

3.2. Intersection of general AI legislation and health across jurisdictions

General or horizontal AI regulations—comprehensive rules that apply to AI use across sectors—gained traction worldwide in recent years with the pioneer EU AI Act process and the rise of general-purpose AI [33]. When it comes to AI's impact on health, the horizontal AI regulation proposals represent an additional layer of requirements that may partially overlap and reinforce specialized health tech regulations such as Software as a Medical Device (SaMD) regulation, a measure much needed considering the increasing gap between the software technology medical regulations sought to govern and the evolving AI capabilities.

The key governance challenge is making sure these general AI laws will complement sector-specific medical rules rather than overburden actors if conflicting, duplicative requirements are left unaddressed.

3.2.1. The EU AI Act

In the European Union, policymakers aimed for complementarity, seeking alignment between the AI Act implementation and Medical Device Regulation (MDR) to facilitate compliance. This process is being led by the European Commission's advisory bodies Medical Device Coordination Group (MDCG) and the Artificial Intelligence Board (AIB), comprised of representatives from member States and experts. Recent joint guidance by MDCG and IAB from June 2025 clarified the overlap between the EU AI Act's and the EU MDR's tiered risk-based approach: Medical device AI systems that fall under Annex XVI or that require a notified body assessment under the EU MDR— class I (sterile, measuring, reusable surgical), IIa, IIb, and III—must comply with both legal frameworks (Art. 43(3), AI Act) [34]. In practice, the classification of the risk category under the EU MDR will define whether a device will be considered high-risk under the EU AI Act. Ensuing obligations include robust risk management that ensures traceability, documentation, and usability throughout the device's lifecycle, quality management system, as well as transparency measures. Both regulations emphasize the need for human oversight through system design that allows for human intervention in critical decision-making processes.

What is not yet clear for AI systems used in or as medical devices is whether the same notified body that conducts the conformity assessment for the EU MDR may also conduct the assessment for EU AI Act conformity, a proposal the notified bodies in Europe have been advocating for [35]. Their intent is to avoid duplicating assessments of the same product under two regulatory regimes.

However, in practice, coordination remains complex. Member States must designate notifying authorities and accredited notified bodies under the AI Act (Art. 28, 31), and the full enforcement of medical device AI provisions only becomes applicable from 2 August 2027 (AI Act Art. 113(c)). On the other hand, this expanded mandate for notified bodies could significantly increase demand and would warrant investment to strengthen their capacity and availability, considering they already face a bottleneck for MDR certifications [36]. In addition, national regulators must consider whether it is desirable to conflate two different mandates in the same authority, and the potential risks for the effective application and oversight of the EU AI Act. Member States will need to strike a balance between simplifying the regulatory implementation pathway for AI technologies that face simultaneous regulations while also preserving the AI Act's intent of imposing strict requirements when it comes to high-risk AI systems.

The interplay of those regulations also means the developers of AI medical devices must implement requirements, such as quality management system (QMS), risk assessments, and technical documentation, that satisfy both MDR and the AI Act. Although a clear limitation is established between the MDR and the EU AI Act, with the latter only covering the AI system component, many requirements overlap, and further clarification may be needed as stakeholders start to roll out their compliance actions to meet both regulations' requirements. In sum, further clarity about the notified bodies competency, member States definitions of national regulatory authorities, and guidelines focused on the enforcement stage will help actors set a smoother compliance path.

3.2.2. Peru's AI Law

Outside Europe, countries are also grappling with balancing AI governance and health-sector rules. Peru offers a recent example of horizontal AI legislation with its groundbreaking Law No. 31814 of 2023 [37]. This law established one of Latin America's first comprehensive AI framework, taking inspiration from international models like the EU AI Act [38]. Peru's AI Law adopts a risk-based approach, defining prohibited AI practices, high-risk applications, obligations for transparency, human oversight, and data governance. It positions AI as a driver of economic and social development, explicitly encouraging AI deployment in public services, including healthcare [39]. Regarding framing, Peru's legal text adopts an aspirational and promotional tone, defining AI as a national asset to be rolled out in sectors from health to defense, and includes mentions to ethics and human rights. Analysts have cautioned that Peru's flurry of AI legislation may risk being "symbolic"—aligning with global norms in theory but without deep integration into sectoral oversight or strong enforcement mechanisms [40].

Operationalizing Peru's AI Law

Building on the legal and aspirational foundation of the AI Law, the Peruvian Government approved the Decree 115-2025-PCM in September 2025, which seeks to operationalize it [41].

The decree further details institutional responsibilities, sectoral coordination, and implementation timelines. In addition, it introduces detailed rules on transparency, human oversight, algorithm audits, registration mechanisms, and prohibited practices, such as manipulative or discriminatory AI uses. The Presidency of the Council of Ministers, through its Secretariat of Government and Digital Transformation, is appointed the central authority for AI governance. This body oversees national registries, risk classification, and compliance monitoring.

According to the decree, high-risk systems, such as those deployed in health, education, or public administration, must undergo formal risk assessments, ensure human supervision, and provide documentation on data governance and algorithmic transparency. These requirements mark a significant advance beyond the promotional tone of the 2023 law, which had emphasized innovation and economic growth. The decree further aligns AI deployment with data protection norms, which are covered in Peru's Personal Data Protection Law [42]. It also introduces institutional coordination channels between the Digital Transformation Secretariat and specialized regulators like DIGEMID under the Ministry of Health.

In healthcare, AI-enabled diagnostic software or decision-support systems now fall under both medical device supervision and the new AI oversight framework. Developers must demonstrate clinical safety and efficacy to DIGEMID, while also fulfilling AI-specific duties regarding transparency, bias evaluation, and ongoing monitoring. Although the system aims to bridge gaps between digital innovation and patient protection, operational overlap remains a risk. The absence of sector-specific annexes means that the enforcement effectiveness will depend on ad-hoc coordination between the health and digital authorities. Peru's experience illustrates an incremental approach, building from declarative AI strategies toward enforceable governance architectures. Health remains a crucial sector to watch out for when it comes to securing the promises of a risk-based, rights-oriented regulation.

3.2.3. South Korea's AI Basic Act

South Korea has taken a structured approach by enacting both an AI-specific general law and a new sectoral law for digital health. In January 2025, South Korea passed the AI Basic Act, (formally, the "Basic Law on the Development of Artificial Intelligence and Establishment of Trust"), to be enforced in January 2026 [43]. This comprehensive law focuses on risk mitigation and covers topics ranging from government support for AI R&D and infrastructure to keep Korea competitive to deployment. It establishes a unified AI governance framework, classifying AI systems by risk level, mandating transparency and human oversight for high-impact AI [44].

The AI Basic Act's framework includes multi-stakeholder oversight, such as a national AI commission and an AI safety research institute. It encourages AI business operators to form internal AI ethics committees to align with the government's trust and safety objectives. Importantly, the Act also imposes obligations on foreign AI providers whose services impact the South Korean market: In cases where those providers lack a Korean address and exceed user or revenue thresholds, they must appoint a domestic representative and comply with the Act's requirements [45]. The intent is to ensure that offshore companies cannot circumvent enforcement by operating solely abroad.

In parallel, recognizing the unique needs of medical AI, South Korea's Ministry of Food and Drug Safety (MFDS) rolled out the Digital Medical Products Act, which took effect in January 2025. This act specifically regulates digital health products, including software as a medical device (SaMD), health support software, and even combination products (drugs coupled with digital apps). Much like the traditional Medical Devices Act, it requires manufacturers or importers of these digital health tools to obtain MFDS authorization and comply with safety and quality standards. Essentially, South Korea created a dedicated legal framework to handle the approval and monitoring of AI-driven medical tech under its health authority, alongside the broader AI Basic Act under its tech governance policy [44].

To avoid conflict between the AI Basic Act and the Digital Medical Products Act, South Korea clarified that, if a requirement is specifically covered by the latter, the medical products law takes precedence. For aspects not addressed (for instance, algorithmic transparency to users, or AI ethics training), the Basic Act's provisions would still apply to the AI component of the medical product. In practice, a company bringing an AI diagnostic app to South Korea must get MFDS approval under the digital health law and ensure that its AI development and deployment meet the governance standards of the AI Basic Act.

Takeaways from the EU, Peru, and South Korea

The experiences of the EU, Peru, and South Korea illustrate the delicate balance regulators seek between horizontal AI rules and vertical health-tech regulations worldwide.

All three jurisdictions recognize that AI in healthcare holds immense promise but also poses unique risks that neither horizontal AI laws nor traditional medical regulations alone can fully address. The EU AI Act represents a bold effort to introduce AI safety requirements on top of medical device laws–an approach that could become a global reference if it succeeds in enhancing safety without overburdening developers and deployers. Peru's early adoption of an AI law shows a commitment to responsible AI but also exposes the need for enforcement and coordination to operationalize those principles. South Korea's coordination between the general AI and the medical products regulations offers a path for mitigating regulatory conflicts and promoting cooperative oversight. A common thread is the importance of implementation: establishing strong institutional coordination within government, training regulators, accrediting assessors (such as notified bodies or equivalent), and guiding industry through compliance will be key for real-world impact.

3.3. Data governance in health

Data governance is a central element for regulating AI in health. However, current data governance frameworks often fail to cover the full AI data lifecycle, including the collection, linkage, reuse, and inference of data across clinical, research, and consumer environments. These limits become particularly visible when general-purpose models, including large language models, become part of care pathways or indirectly influence clinical decisions [46].

- When it comes to data protection, legal systems have developed different architectures to manage rightsholders' data and its intersection with health. In **the European Union**, the framework combines the **General Data Protection Regulation (GDPR)** with sectoral health rules that emphasize purpose limitation, data minimization, impact assessments, and the recognition of enforceable individual rights [47][48].

- In February 2025, the European Union enacted the **Electronic Health Data Space Regulation**, which increases individuals' rights and control over their health information and promotes portability, laying the groundwork for increased interoperability in the European healthcare system. In addition, the regulation mandates Member States to designate digital health authorities for the planning and implementation of standards for access to and transmission of electronic health data [49].

- In **the United States**, the approach remains fragmented and sectoral. **The Health Insurance Portability and Accountability Act (HIPAA)** is the primary federal law for health data protection but applies only to certain entities, which leaves may leave a significant amount of health-related data flows from mobile applications, wearables, or digital platforms outside its scope if not related to covered entities [50][51][52]. Stricter requirements and an expanded scope may be passed by state legislation. For instance, Washington State's HB1155 of 2023, known as My Health My Data Act, became the first privacy-focused state law in the U.S. to cover health data beyond the scope of HIPAA. Notably, it sets obligations such as affirmative consent to any entity collecting health-related data [53].

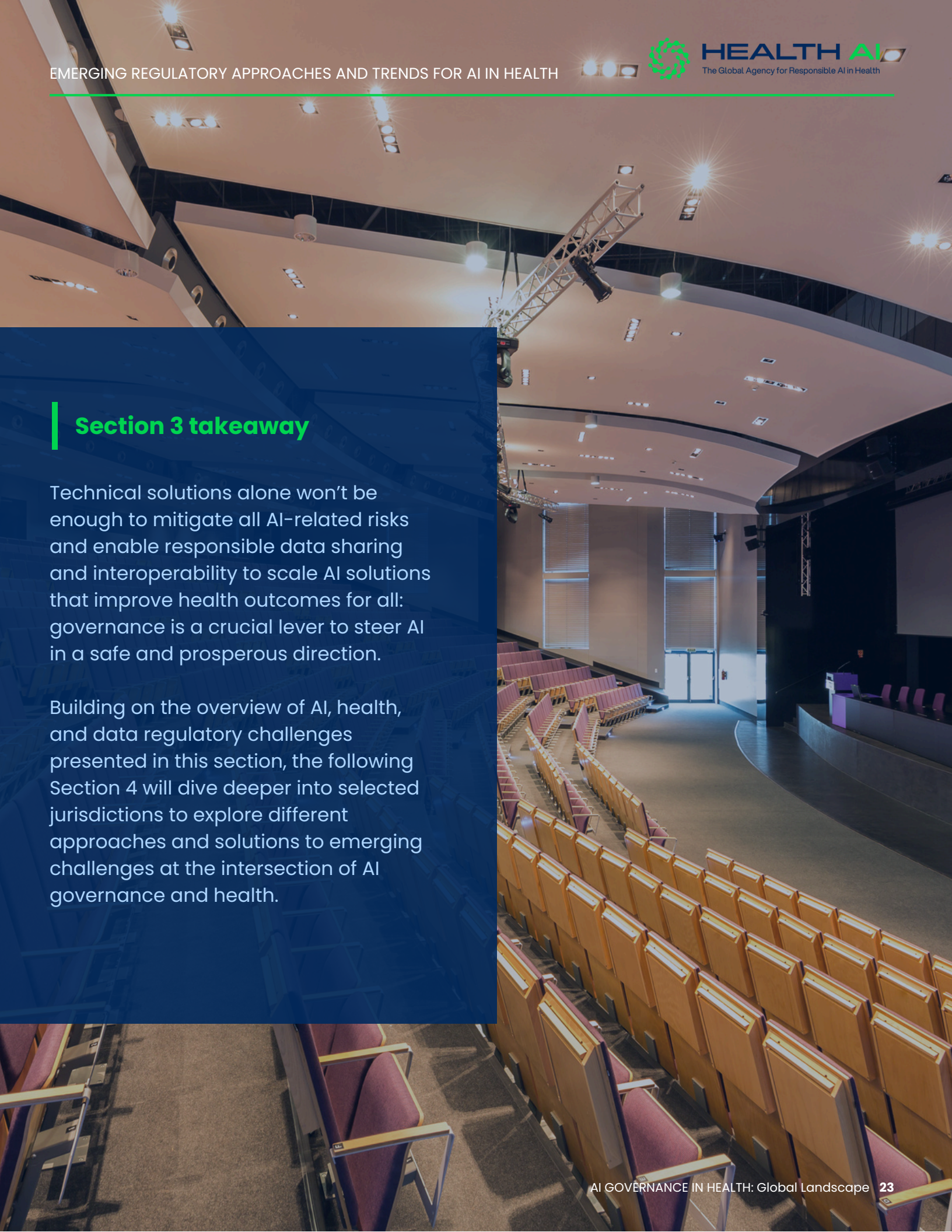
- In Brazil, the **General Data Protection Law (Lei Geral de Proteção de Dados, LGPD)** remains a key normative basis for AI regulation when it comes to its intersection with data governance, considering that a horizontal AI law is still pending in Congress. LGPD draws heavily from the EU GDPR principles and is implemented through sectoral decrees and additional governance instruments [54][55].

- Beyond LGPD, recent federal initiatives are expanding a more integrated data governance architecture in health. These initiatives include the creation of national health data spaces, the clarification of lawful bases for secondary uses, and the adoption of principles such as proportionality and public interest in the Unified Health System (SUS) [56]. This broader policy arc connects LGPD principles to data interoperability and to the National Health Data Network (Rede Nacional de Dados em Saúde, RNDS), an initiative similar to the European Health Data Space, aimed at promoting interoperability between public and private health information systems. It also creates new demands for governance mechanisms that ensure access control, auditability, and large-scale opt-out systems [57].

Each of those regulatory frameworks mentioned above face the same challenge: AI systems recombine data in ways that generate new, high-risk inferences that go beyond the original consent or lawful purpose [46][58]. Moreover, the data protection regulations should be coupled with health-data policies and infrastructures.

The main challenge is not the creation of new rights, but the development of robust governance structures and regulatory capacity to make these rights effective in practice.

Despite regulatory developments, two challenges remain for privacy and data protection in health. The first is drawing a line between health data and health-adjacent data. AI systems use electronic health records, but they also process information from other sources such as digital scribes, messaging systems, wearables, and consumer applications. These sources often fall outside traditional health-privacy laws, creating blurred boundaries and weakening informed consent. The second challenge is the addressing the growing risks of data de-anonymization. At large scales, re-identification becomes increasingly possible through cross-identification of data from different datasets that may enable reversing or inferring individual characteristics.



Section 3 takeaway

Technical solutions alone won't be enough to mitigate all AI-related risks and enable responsible data sharing and interoperability to scale AI solutions that improve health outcomes for all: governance is a crucial lever to steer AI in a safe and prosperous direction.

Building on the overview of AI, health, and data regulatory challenges presented in this section, the following Section 4 will dive deeper into selected jurisdictions to explore different approaches and solutions to emerging challenges at the intersection of AI governance and health.

References

[1] Bradford A. Digital Empires: The Global Battle to Regulate Technology [Internet]. 2023. Available from: https://scholarship.law.columbia.edu/books/367

[2] Alemayehu S. How AI can help to unlock the Global South's job market [Internet]. World Economic Forum. 2025 [cited 2025 Nov 13]. Available from: https://www.weforum.org/stories/2025/08/ai-global-south-jobs-market-wef/

[3] Khasru SM, Gillwald A, Sesan 'Gbenga, Zondi S. International AI Governance Framework: The Importance of G7-G20 Synergy [Internet]. Think 7 Canada 2025; 2025 [cited 2025 Nov 13]. Available from: https://www.cigionline.org/static/documents/TF1_Khasru_et_al_rev.pdf

[4] OECD's live repository of AI strategies & policies [Internet]. [cited 2025 Nov 13]. Available from: https://oecd.ai/en/dashboards

[5] Leicht A. In the Race for AI Supremacy, Can Countries Stay Neutral? [Internet]. AI Frontiers. 2025 [cited 2025 Nov 13]. Available from: https://ai-frontiers.org/articles/in-the-race-for-ai-supremacy-can-countries-stay-neutral

[6] Schmid S, Lambach D, Diehl C, Reuter C. Arms Race or Innovation Race? Geopolitical AI Development. Geopolitics. 2025;30(4):1907–36.

[7] Celi LA, Cellini J, Charpignon ML, Dee EC, Dernoncourt F, Eber R, et al. Sources of bias in artificial intelligence that perpetuate healthcare disparities—A global review. PLOS Digital Health [Internet]. 2022 Mar 31 [cited 2025 Nov 13];1(3). Available from: https://journals.plos.org/digitalhealth/article?id=10.1371/journal.pdig.0000022

[8] O'Brien M, Ortutay B. Study says AI chatbots need to fix suicide response, as family sues over ChatGPT role in boy's death. AP News [Internet]. 2025 Aug 26 [cited 2025 Nov 13]; Available from: https://apnews.com/article/ai-chatbots-selfharm-chatgpt-claude-gemini-da00880b1e1577ac332ab1752e41225b

[9] Tao Y, Gao P. Global data center expansion and human health: A call for empirical research. Eco-Environment & Health. 2025 Sept 1;4(3):100157.

[10] Korom R, Kiptinness S, Adan N, Said K, Ithuli C, Rotich O, et al. AI-based Clinical Decision Support for Primary Care: A Real-World Study [Internet]. 2025. Available from: https://cdn.openai.com/pdf/a794887b-5a77-4207-bb62-e52c900463f1/penda_paper.pdf

[11] Varghese C, Harrison EM, O'Grady G, Topol EJ. Artificial intelligence in surgery. Nature Medicine. 2024 May 1;30(5):1257–68.

[12] Torous J, Linardon J, Goldberg SB, Sun S, Bell I, Nicholas J, et al. The evolving field of digital mental health: current evidence and implementation issues for smartphone apps, generative artificial intelligence, and virtual reality. World Psychiatry. 2025;24(2):156–74.

[13] De Freitas J, Cohen IG. Unregulated emotional risks of AI wellness apps. Nat Mach Intell. 2025 June;7(6):813–5.

[14] Iyer P. New Research Sheds Light on AI 'Companions' | TechPolicy.Press [Internet]. Tech Policy Press. 2025 [cited 2025 Nov 13]. Available from: https://www.techpolicy.press/new-research-sheds-light-on-ai-companions/

[15] Angus DC, Khera R, Lieu T, Liu V, Ahmad FS, Anderson B, et al. AI, Health, and Health Care Today and Tomorrow: The JAMA Summit Report on Artificial Intelligence. JAMA. 2025 Nov 11;334(18):1650–64.

[16] Anderson B, Sutherland E. Collective Action for Responsible AI in Health [Internet]. OECD; 2024 Jan [cited 2025 Nov 13]. Report No.: 10. Available from: https://www.oecd.org/content/dam/oecd/en/publications/reports/2024/01/collective-action-for-responsible-ai-in-health_9a65136f/f2050177-en.pdf

[17] Al-Maamari A. arXiv.org. 2025 [cited 2025 Nov 14]. Between Innovation and Oversight: A Cross-Regional Study of AI Risk Management Frameworks in the EU, U.S., UK, and China. Available from: https://arxiv.org/abs/2503.05773

[18] International Medical Device Regulators Forum (IMDRF) | International Medical Device Regulators Forum [Internet]. 2025 [cited 2025 Nov 14]. Available from: https://www.imdrf.org/

[19] Global Harmonization Working Party [Internet]. [cited 2025 Nov 14]. Strategic Framework | GHWP. Available from: https://www.ghwp.org/our-work/strategic-framework

[20] International Medical Device Regulators Forum [Internet]. 2025 [cited 2025 Nov 14]. Voluntary Withdrawal of GHWP. Available from: https://www.imdrf.org/news-events/voluntary-withdrawal-ghwp

[21] Kuner C, Zanfir-Fortuna G. Geopolitical fragmentation, the AI race, and global data flows: the new reality [Internet]. https://fpf.org/. [cited 2025 Nov 14]. Available from: https://fpf.org/blog/geopolitical-fragmentation-the-ai-race-and-global-data-flows-the-new-reality/

[22] Gerke S. "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards [Internet]. Rochester, NY: Social Science Research Network; 2023 [cited 2025 Nov 15]. Available from: https://papers.ssrn.com/abstract=4404252

[23] Center for Devices and Radiological Health. FDA. FDA; 2025 [cited 2025 Nov 15]. Artificial Intelligence-Enabled Medical Devices. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices

[24] Fraser AG, Biasin E, Bijnens B, Bruining N, Caiani EG, Cobbaert K, et al. Artificial intelligence in medical device software and high-risk medical devices – a review of definitions, expert recommendations and regulatory initiatives. Expert Review of Medical Devices. 2023 June 3;20(6):467–91.

[25] Silva MD, Flood CM, Herder M. Regulation of Health-Related Artificial Intelligence in Medical Devices: The Canadian Story. UBC Law Review [Internet]. 2022 Dec;55(3). Available from: https://commons.allard.ubc.ca/ubclawreview/vol55/iss3/2

[26] Boyle G, Melvin T, Verdaasdonk RM, Van Boxtel RA, Reilly RB. Hospitals as medical device manufacturers: keeping to the Medical Device Regulation (MDR) in the EU. BMJ Innov. 2024 July;10(3):74–80.

[27] Gilbert S, Anderson S, Daumer M, Li P, Melvin T, Williams R. Learning From Experience and Finding the Right Balance in the Governance of Artificial Intelligence and Digital Health Technologies. J Med Internet Res. 2023 Apr 14;25:e43682.

[28] Babic B, Glenn Cohen I, Stern AD, Li Y, Ouellet M. A general framework for governing marketed AI/ML medical devices. npj Digit Med. 2025 May 31;8(1):328.

[29] Solaiman B, Mekki YM, Qadir J, Ghaly M, Abdelkareem M, Al-Ansari A. A "True Lifecycle Approach" towards governing healthcare AI with the GCC as a global governance model. NPJ Digit Med. 2025 June 5;8(1):337.

[30] Medicines and Healthcare products Regulatory Agency. GOV.UK. 223 AD [cited 2025 Nov 15]. Predetermined change control plans for machine learning-enabled medical devices. Available from: https://www.gov.uk/government/publications/predetermined-change-control-plans-for-machine-learning-enabled-medical-devices-guiding-principles

[31] U.S. Food and Drug Administration. Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions [Internet]. 2024. Available from: https://www.fda.gov/media/166704/download

[32] Health Canada. Government of Canada. 2023 [cited 2025 Nov 15]. Pre-market guidance for machine learning-enabled medical devices. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/pre-market-guidance-machine-learning-enabled-medical-devices.html

[33] Madiega T. General-purpose artificial intelligence [Internet]. European Parliamentary Research Service; 2023. Available from: https://www.europarl.europa.eu/RegData/etudes/ATAG/2023/745708/EPRS_ATA(2023)745708_EN.pdf

[34] Joint Artificial Intelligence Board, Medical Device Coordination Group. Interplay between the Medical Devices Regulation (MDR) & In vitro Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA) [Internet]. European Commission; 2025 June [cited 2025 Oct 25] p. 27. Report No.: AIB 2025-1, MDCG 2025-6. Available from: https://health.ec.europa.eu/document/download/b78a17d7-e3cd-4943-851d-e02a2f22bbb4_en?filename=mdcg_2025-6_en.pdf

[35] The European Association for Medical Devices of Notified Bodies. Team-NB Position Paper: European Artificial Intelligence Act [Internet]. 2025 [cited 2025 Nov 1]. Available from: https://www.team-nb.org/wp-content/uploads/2025/04/Team-NB-PositionPaper-EU-AI-Act-V2-20250409.pdf

[36] Aboy M, Minssen T, Vayena E. Navigating the EU AI Act: implications for regulated digital medical products. npj Digit Med. 2024 Sept 6;7(1):237.

[37] 1. Congress of the Republic of Peru. Ley que Promueve el Uso de la Inteligencia Artificial en Favor del Desarollo Económico y Social del País [Internet]. Ley N.° 31814 July 5, 2023. Available from: https://cdn.www.gob.pe/uploads/document/file/5038703/ley-que-promueve-el-uso-de-la-inteligencia-artificial-en-fav-ley-n-31814.pdf?v=1692895308

[38] OECD.AI Policy Observatory [Internet]. 2025 [cited 2025 Nov 16]. National Artificial Intelligence Authority. Available from: https://oecd.ai/en/dashboards/policy-initiatives/national-artificial-intelligence-authority-2323

[39] Daniel ML. Regional cooperation crucial for AI safety and governance in Latin America [Internet]. Brookings. 2025 [cited 2025 Nov 15]. Available from: https://www.brookings.edu/articles/regional-cooperation-crucial-for-ai-safety-and-governance-in-latin-america/

[40] Smart S, Montori VM. Harvard Kennedy School Carr-Ryan Center for Human Rights. 2025 [cited 2025 Nov 15]. Peru's AI Regulatory Boom: Quantity Without Depth? Available from: https://www.hks.harvard.edu/centers/carr-ryan/our-work/carr-ryan-commentary/perus-ai-regulatory-boom-quantity-without-depth

[41] Government of Peru. Decreto Supremo que aprueba el Reglamento de la Ley N° 31814, Ley que promueve el uso de la inteligencia artificial en favo [Internet]. Sept 9, 2025. Available from: https://cdn.www.gob.pe/uploads/document/file/8619777/7133522-decreto-supremo-n-115-2025-pcm.PDF?v=1757422328

[42] Congress of the Republic of Peru. Ley de Protección de Datos Personales [Internet]. Ley n. 2933 July 3, 2011. Available from: https://cdn.www.gob.pe/uploads/document/file/272360/Ley%20N%C2%BA%2029733.pdf.pdf?v=1618338779

[43] South Korea Ministry of Science and ICT. Basic Act on the Development of Artificial Intelligence and Creation of a Trust Foundation [Internet]. Law No. 20676 Jan 25, 2025. Available from: https://www.law.go.kr/%25EB%25B2%2595%25EB%25A0%25B9/%25EC%259D%25B8%25EA%25B3%25B5%25EC%25A7%2580%25EB%258A%25A5%2520%25EB%25B0%259C%25EC%25A0%2584%25EA%25B3%25BC%2520%25EC%258B%25A0%25EB%25A2%25B0%2520%25EA%25B8%25B0%25EB%25B0%2598%2520%25EC%25A1%25B0%25EC%2584%25B1%2520%25EB%2593%25B1%25EC%2597%2590%2520%25EA%25B4%2580%25ED%2595%259C%2520%25EA%25B8%25B0%25EB%25B3%25B8%25EB%25B2%2595/(20676,20250121)

[44] Choi SJ, Kim HW, Chin H, Ko HK, Chae S, Mo MY, et al. Global AI Governance Law and Policy: South Korea [Internet]. 2025 [cited 2025 Nov 16]. Available from: https://iapp.org/resources/article/global-ai-governance-south-korea/

[45] Andrews C. South Korea's AI Basic Act puts another AI governance regulation on the map [Internet]. IAPP. 2025 [cited 2025 Nov 16]. Available from: https://iapp.org/news/a/south-korea-s-ai-basic-act-puts-another-ai-governance-regulation-on-the-map

[46] Mello MM, Cohen IG. Regulation of Health and Health Care Artificial Intelligence. JAMA. 2025 May 27;333(20):1769–70.

[47] European Parliament, Council of the European Union. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC [Internet]. Document 32016R0679 Apr, 2016. Available from: https://eurlex.europa.eu/eli/reg/2016/679/oj

[48] Biasin E, Yaşar B, Kamenjašević E. New Cybersecurity Requirements for Medical Devices in the EU: The Forthcoming European Health Data Space, Data Act, and Artificial Intelligence Act. Law, Technology and Humans. 2023 Nov 21;5(2):43–58.

[49] European Parliament, Council of the European Union. European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 [Internet]. 2025/327 Feb 11, 2025. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

[50] U.S. Department of Human and Health Services [Internet]. 2008 [cited 2025 Nov 17]. Summary of the HIPAA Privacy Rule. Available from: https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

[51] Cortez N. The Mobile Health Revolution? [Internet]. Rochester, NY: Social Science Research Network; 2013 [cited 2025 Nov 17]. Available from: https://papers.ssrn.com/abstract=2284448

[52] Fowler LR. COVID-19 & the Myth of Health Data Privacy. Kansas Journal of Law & Public Policy. 2022;31(3):373–89.

[53] Slatter et al. HB 1155-2023-24 Addressing the collection, sharing, and selling of consumer health data [Internet]. 1155. Available from: https://app.leg.wa.gov/billsummary?BillNumber=1155&Initiative=false&Year=2023

[54] Federative Republic of Brazil. Lei Geral de Proteção de Dados Pessoais (LGPD) [Internet]. L13709/2018 Aug 14, 2018. Available from: https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13709.htm

[55] Canaan (Renan) G. The effects on local innovation arising from replicating the GDPR into the Brazilian General Data Protection Law. Internet Policy Review [Internet]. 2023 Feb 28 [cited 2025 Nov 17];12(1). Available from: https://policyreview.info/articles/analysis/replicating-gdpr-into-brazilian-general-data-protection-law

[56] Federative Republic of Brazil. D12560: Decree on the National Health Data Network and the SUS Digital Platforms [Internet]. 2025 [cited 2025 Nov 17]. Available from: https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2025/decreto/d12560.htm

[57] Dourado D de A, Aith FMA. A regulação da inteligência artificial na saúde no Brasil começa com a Lei Geral de Proteção de Dados Pessoais. Revista de Saúde Pública. 2022 Sept 9;56:80–80.

[58] JuLIA. JuLIA Handbook: Artificial Intelligence in Healthcare and the Protection of Health as a Fundamental Right [Internet]. European Commission; 2025 Aug. Available from: https://www.julia-project.eu/sites/default/files/2025-08/JuLIA%2BHandbook%2BAI%2Band%2BHealth_FINAL_AUGUST%2B2025-1.pdf

SECTION 4

COUNTRY ANALYSIS

Section 4 presents an analysis of national AI governance landscapes in health based on a comprehensive examination of the presence and scope of policies and regulations on AI, digital health, data governance, and medical device regulatory ecosystems.

In addition, we examine their intersections and influence on AI governance, development, and deployment in a country's health context. We further analyze information in the context of each country, considering its overall political and legal systems, constitutional structures, administrative traditions, and governance cultures.

Drawing on legislative, policy, and desk research, the report highlights innovative policy approaches, remaining gaps, governance challenges, and the progress jurisdictions have made in managing the complex interplay between advancing AI responsibly and improving their health systems.

This contextual approach aims at exploring how different dynamics shape the outcomes of policies and regulations. It also seeks to highlight the importance of developing governance solutions tailored to the local context: Transplanting regulatory structures across jurisdictions without a thorough analysis of structural differences may render regulations ineffective. However, learning from different jurisdictions' experiences allows countries to leapfrog in their policy development.

Ultimately, the analyses below aim to empower policymakers and regulators to identify potential drivers of successful AI policies and to recognize common threads across the countries evaluated. For each country, salient, high-impact themes are highlighted. Themes range from regulatory sandboxes, cross-border data exchange rules, and AI risk classification approaches to the integration of AI into existing medical device frameworks. Such insights aim to paint a picture of where a country is demonstrating leadership, where systemic gaps exist, and what the most significant challenges are.

The country landscapes presented in this section cover eight jurisdictions, six of which are part of HealthAI's Global Regulatory Network: Brazil, India, Singapore, Vietnam, the United Kingdom, and Zambia. In addition, China and the United States are analyzed. The sample of countries reflects a broad diversity of contexts in which AI in health is being developed and deployed, across different legal, regulatory, and governance environments. The countries analyzed represent distinct realities in terms of regulatory capacity, health system structures, resources, and levels of AI adoption maturity, each with its own successes and challenges, offering a wide spectrum of experiences and lessons learned

BRAZIL

1. Brazil is building a robust legal and policy foundation for responsible and human-centered AI governance in health

HIGHLIGHT:

Brazil's current AI governance landscape consists of ambitious policies for AI and digital health, as well as ongoing legislative debate on horizontal AI regulation. Together, these elements reflect a multifaceted approach aligned with international AI governance initiatives while advancing Brazil's unique perspective.

Brazil is progressively laying the foundations for a responsible, human-centered AI governance framework. This effort combines four key instruments: the Brazilian Strategy for Artificial Intelligence of 2021 (EBIA), the Digital Health Strategy for Brazil 2020-2028, the Brazilian Plan for Artificial Intelligence: AI for the Good of All (PBIA) 2024-2028, and the ongoing legislative process around Draft Bill No. 2.338/2023. Together, they outline a normative landscape with ethical principles, sectoral planning, and emerging regulatory mechanisms.

Launched in 2021 by the Ministry of Science, Technology, and Innovation (MCTI), the EBIA sets out Brazil's vision for trustworthy and inclusive AI, aligned with international frameworks, including the OECD and the G20 AI principles [1][2].

The strategy is structured around nine thematic axes, ranging from regulation and governance to workforce development and sectoral applications. Although the EBIA provided a conceptual foundation for Brazil's AI ambitions, its implementation across sectors has remained largely fragmented, lacking a dedicated institutional body for coordination or enforcement.

In response to the rise of generative AI, the government announced the preparation of an updated version of the strategy, which, as of October 2025, has not yet been officially released [3].

Meanwhile, the government released the PBIA, the Brazilian Plan for Artificial Intelligence, in July 2024 with a range of thematic areas and investment plans for until 2028. The plan includes 54 structuring actions for AI development, application, and governance in Brazil. Its execution relies on an inter-ministerial approach within government and a dedicated work stream to support the enhancement of Brazil's regulatory frameworks for AI [4]. Finally, PBIA sets out 13 ambitions for AI applications for the health sector and designates funding for each.

In the health sector, the Digital Health Strategy for Brazil 2020–2028, approved by the Ministry of Health and the subnational federative units, lays the groundwork for digital transformation through priorities such as governance, innovation, interoperability, and human resource development [5]. While it does not directly regulate AI, the Digital Health Strategy provides an institutional and infrastructural foundation that supports AI adoption in health, particularly through initiatives like the app Meu SUS Digital (formerly Conecte SUS)—an integrated personal health management platform, developed to unify citizens' health information [6]—, and the National Health Data Network (RNDS)—the Ministry of Health's official platform that integrates public and private health systems to enable the secure and standardized sharing of data [7].

Complementing these strategic policy efforts, Draft Bill No. 2.338/2023 aims to create a horizontal legal framework for AI based on risk classification. The bill introduces obligations for high-risk systems, including technical documentation, algorithmic impact assessments, and safeguards for human oversight, while also recognizing fundamental rights such as explanation, non-discrimination, and data protection [8]. These provisions align closely with the EU AI Act, particularly in their horizontal and risk-based approach, protection of individual rights, and emphasis on human oversight. Although health is identified as a high-risk domain, the bill does not yet include a specific chapter dedicated to it. Nor does it provide clear mechanisms for coordination with institutional actors responsible for developing or overseeing the national digital health infrastructure. It also remains silent on the intersection with existing regulatory frameworks for medical software and AI-based medical devices, which means further clarification will be crucial for its effectiveness.

Brazil's AI governance model is still under construction but shows a clear trajectory: from EBIA's and PBIA's governance strategy and investment, through sectoral digital planning with the health strategy, to the drafting of a horizontal legal framework. The challenge ahead lies in integrating these components into a coherent, enforceable system that ensures safe and responsible AI deployment, particularly in sensitive sectors like health, while honoring the country's commitment to inclusion, sustainability, and international alignment.

2. Brazil's risk-based and internationally aligned framework for SaMD and AI-enabled medical software

HIGHLIGHT:

Brazil regulates SaMD through a risk-based framework aligned with international standards. While not formally distinguishing AI-enabled software, ANVISA requires clinical justification and algorithm transparency for higher-risk systems and plans to update its rules to address AI more explicitly.

Brazil has developed a robust regulatory framework for Software as a Medical Device (SaMD) through the complementary application of the Brazilian Health Regulatory Agency's resolutions 751/2022—providing for risk classification for all medical devices—and 657/2022—which sets specific requirements for standalone medical software [9][10]. These resolutions align with international practices and incorporate definitions, classifications, and regulatory pathways consistent with the IMDRF frameworks. Under Brazilian law, any software with a medical purpose, such as diagnosis, prevention, monitoring, or treatment, is considered a medical device and must be classified according to its intended use and potential risk, ranging from Class I (low risk) to Class IV (high risk). RDC 657/2022 introduced technical specifications tailored to SaMD, including the possibility of providing digital instructions for use, mandatory information on system requirements, interoperability, cybersecurity, and version control, as well as procedures for software updates and algorithm transparency [11].

Although the Brazilian regulation does not formally distinguish between conventional software and AI-enabled software, ANVISA requires that SaMDs classified as higher risk include a description of their algorithms or routines, technical and scientific justifications for their intended use, and supporting evidence of clinical performance. In practice, this has included requests for information on algorithm behavior and validation processes when AI technologies are involved, particularly in systems based on machine learning or deep learning [12]. For adaptive or continuously learning models, ANVISA has not yet authorized any such product; if submitted, these would be treated as innovative technologies subject to enhanced scrutiny. Manufacturers would be expected to demonstrate sustained safety and effectiveness post-deployment and may need to submit updates for regulatory review if changes significantly alter clinical functionality.

SaMDs developed internally by health institutions for in-house use exclusively may be exempt from registration, provided they are low- or moderate-risk and not marketed externally. However, any commercial product must obtain prior authorization through either a notification (for Class I/II) or full registration (for Class III/IV), based on the risk classification defined in RDC 751/2022.

While ANVISA currently addresses AI technologies through the existing SaMD framework, it has announced a forthcoming revision of the resolution 657/2022 to formally incorporate provisions related to AI, machine learning, and algorithmically adaptive software.

This initiative, combined with Brazil's participation in global regulatory fora such as the IMDRF, underscores the country's intent to foster innovation while maintaining high standards of clinical efficacy, transparency, and risk control in AI-powered health technologies [13].

3. Digital health infrastructure as an enabler for scalable and contextualized AI governance

HIGHLIGHT:

Brazil's national digital health infrastructure provides the technical and institutional foundations for scalable, real-world AI deployment in health. These initiatives aim to enable interoperability, continuous data exchange, and algorithm validation, while supporting governance models tailored to Brazil's reality.

The Estratégia de Saúde Digital para o Brasil (EDS) 2020–2028, Brazil's digital health strategy, outlines the consolidation of national digital platforms as a central goal for enabling data-driven, equitable healthcare. The strategy explicitly highlights Meu SUS Digital and the RNDS National Health Data Network as key enablers of interoperability, continuity of care, and real-time data sharing across Brazil's Unified Health System, "Sistema Universal de Saúde" (SUS).

Meu SUS Digital is a citizen-facing portal and mobile application, evolved from the original Conecte SUS interface in 2023, that provides access to individual health records, including vaccination history, prescriptions, and clinical encounters. It serves as an interface for patients and health professionals, facilitating digital inclusion and care coordination. The system is integrated into the broader RNDS, which functions as the national interoperability backbone. The RNDS enables the standardized exchange of clinical and administrative data between public and private actors.

DATASUS, the Department of Information and Informatics at the Ministry of Health, plays a critical role in backend data processing and computational support for those initiatives. It is responsible for the secure processing and management of large-scale health data flows within the SUS infrastructure, including the operation of data warehouses and analytic services that can support population health monitoring and algorithm training.

Together, these platforms create an integrated digital ecosystem capable of supporting AI deployment in health, particularly for machine learning systems that rely on structured, high-quality, real-world data.

The Digital Health Strategy explicitly calls for technology to adapt to the Brazilian context, including the need to support underserved and remote regions, Indigenous communities, and populations with limited access to specialist care. By anchoring AI implementation in nationally governed digital health infrastructure, Brazil can ensure that AI tools deployed in health respect local norms, population needs, and equity goals. An important lever for further governance frameworks focused on AI in health could be the draft bill for a horizontal AI legislation 2338/2023, which was approved in the Senate in December 2024 and is now under review in the Chamber of Deputies [14].

4. Brazil's rising status in AI research, funding, and innovation versus gaps in digital access

HIGHLIGHT:

Brazil has established a prominent role in AI research and development in Latin America, particularly in health. In parallel, the country is advancing in closing social and regional inequality gaps in rural and remote regions.

The UNESCO Readiness Assessment Report on Artificial Intelligence for Brazil (2025) highlights that Brazil still needs to address persistent inequality in access to STEM education to improve its AI workforce and tackle urban-rural disparities. In the socio-cultural dimension, studies show no gender difference in internet access, but a persistent, albeit narrower, urban-rural gap: 85% of urban households have internet access versus 74% in rural areas, an improvement from 33% in 2016 [15]. The CETIC.br surveys on infrastructure and connectivity in Brazil reveal that, while mobile phone ownership is widespread, with almost nine out of ten people having access to at least one device, digital access continues to be uneven across the country [16].

Despite those challenges, Brazil stands out in the region for funding AI innovation in healthcare, with multiple dedicated initiatives, including the FAPESP-UKRI (MRC) AI in Health Funding of over R$40 million and the Grand Challenges Brazil Program for LLMs in public health of R$4.5 million. With a total investment of over R$20 billion in AI research since 2021, Brazil seeks to achieve global competitiveness in this area [17].

Brazil has presented steady progress in the scientific, structural, and governance dimensions of AI in the Latin American Artificial Intelligence Index (ILIA) 2025, ranking second regionally in the overall index, behind Chile.

The strongest results were achieved in the R&D+A (Research, Development, and Adoption) dimension, where Brazil scored 59.2 points, above the regional average of 38.8. Those results were driven by high scores in open-source productivity, patents, and industry adoption of high-technology manufacturing.

When it comes to AI research units by sector in Brazil, healthcare has the second highest number, with 25 units, behind 30 units dedicated to AI for industry and manufacturing [18].

These findings illustrate how Brazil is experiencing notable advances in AI capacity despite remaining barriers. Progress in research and infrastructure coexist with persistent, though narrowing, territorial and social inequalities [19].

5. Data protection steers the generative AI conversation

HIGHLIGHT:

Brazil's data protection authority (ANPD) is proactively shaping the national debate on generative AI by linking AI governance to privacy safeguards and setting boundaries for data use to protect fundamental rights. Its landmark study on generative AI and the LGPD calls for transparency, data minimization, and ethical training practices, explicitly warning against web scraping as a threat to fundamental rights.

Brazil's National Data Protection Authority (ANPD) has become a central actor in shaping the national debate on generative AI by explicitly linking AI governance to the principles of the General Personal Data Protection Law (LGPD).

In 2024, ANPD published its Technology Radar on generative AI, a landmark study that mapped the risks and opportunities of this technology. In that document, ANPD emphasized that the LGPD principles, such as transparency, minimization, necessity, and good faith, apply directly to the development and use of generative AI systems, even when models are trained on publicly available data. The report also warned against the widespread practice of web scraping, stressing that indiscriminate collection of online content can expose individuals to privacy violations and threaten fundamental rights [20].

Moreover, the ANPD noted that responsible use of training datasets requires pre-processing measures, such as

anonymization and pseudonymization, to reduce the risk of re-identification and misuse of personal data. It also calls for ethical and legal training practices to ensure that data protection obligations are built into AI development from the outset [21].

Through these actions, the ANPD is not only interpreting how the LGPD applies to generative AI but also setting clear boundaries for ethical and lawful development across sectors, including healthcare.

By linking AI governance directly to privacy safeguards, the authority is moving towards a rights-based model, establishing Brazil as an early mover in embedding data protection principles into the regulation of AI systems.

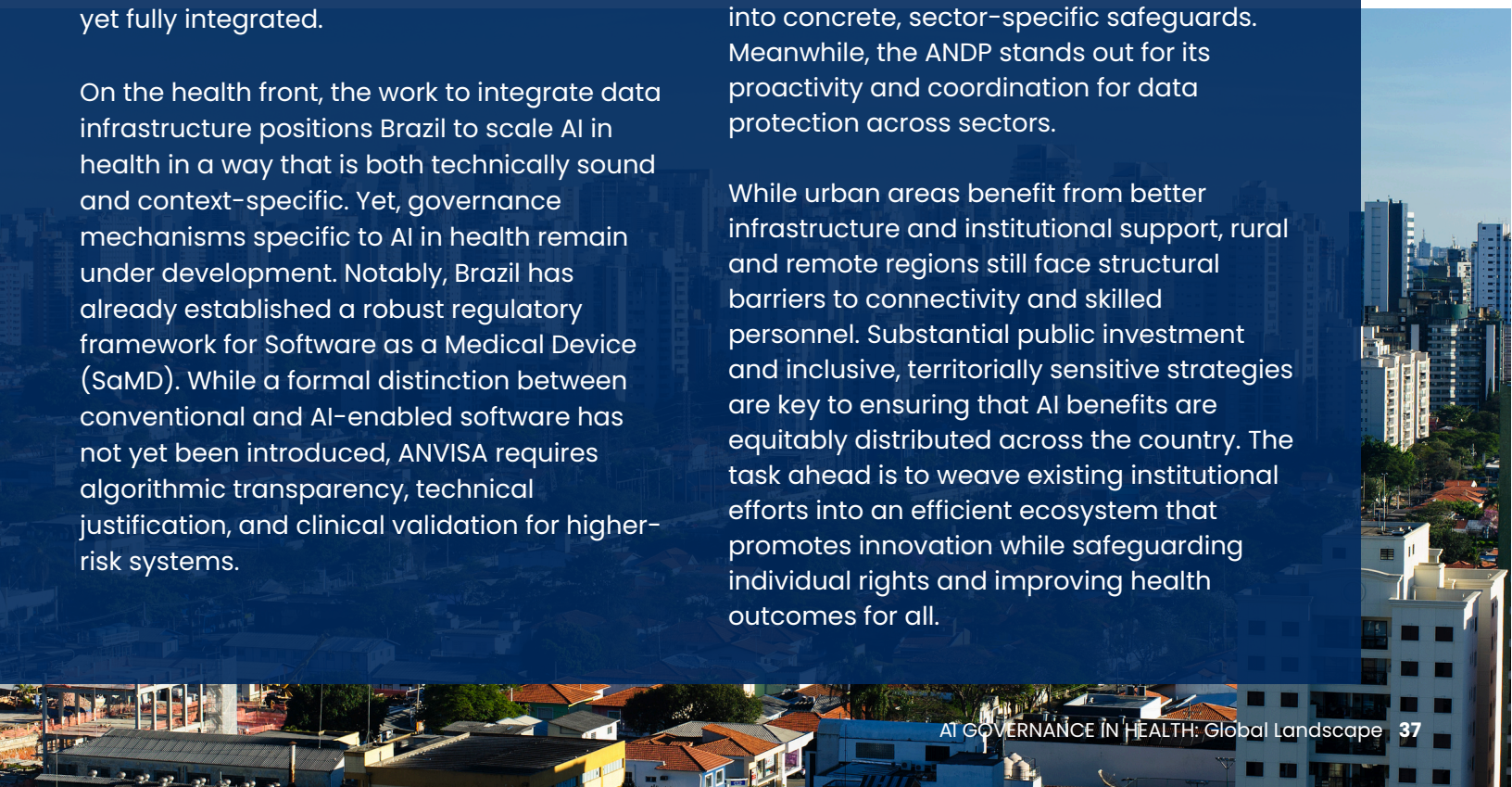
Bringing the Threads Together: Brazil's governance strategy for AI in health

Brazil's regulatory trajectory for AI in health reflects a layered but still maturing architecture, where promising components are being developed in parallel, though not yet fully integrated.

On the health front, the work to integrate data infrastructure positions Brazil to scale AI in health in a way that is both technically sound and context-specific. Yet, governance mechanisms specific to AI in health remain under development. Notably, Brazil has already established a robust regulatory framework for Software as a Medical Device (SaMD). While a formal distinction between conventional and AI-enabled software has not yet been introduced, ANVISA requires algorithmic transparency, technical justification, and clinical validation for higher-risk systems.

ANVISA's initiatives to update norms and engage with global regulatory fora position the agency as a key technical actor in translating global governance principles into concrete, sector-specific safeguards. Meanwhile, the ANDP stands out for its proactivity and coordination for data protection across sectors.

While urban areas benefit from better infrastructure and institutional support, rural and remote regions still face structural barriers to connectivity and skilled personnel. Substantial public investment and inclusive, territorially sensitive strategies are key to ensuring that AI benefits are equitably distributed across the country. The task ahead is to weave existing institutional efforts into an efficient ecosystem that promotes innovation while safeguarding individual rights and improving health outcomes for all.



References

[1] Ministério de Ciência, Tecnologia e Inovações. Portaria MCTI nº 4.617: Estratégia Brasileira de Inteligência Artificial (Brazilian Strategy for Artificial Intelligence) [Internet]. Government of Brazil; 2021. Available from: https://antigo.mctic.gov.br/mctic/opencms/legislacao/portarias/Portaria_MCTI_n_4617_de_06042021.html

[2] Uechi CAS, Moraes TG. OECD.AI Policy Observatory. 2023 [cited 2025 Nov 18]. Brazil's path to responsible AI. Available from: https://oecd.ai/en/wonk/brazils-path-to-responsible-ai

[3] Agência Senado. CCT debaterá estratégia de inteligência artificial. Senado Notícias [Internet]. 2025 Aug 21 [cited 2025 Nov 18]; Available from: https://www12.senado.leg.br/noticias/materias/2025/08/21/cct-debatera-estrategia-de-inteligencia-artificial

[4] Governo Federal, Serviço de Comunicação Institucional. Laboratório Nacional de Computação Científica - LNCC. 2024 [cited 2025 Nov 18]. Plano Brasileiro de Inteligência Artificial (PBIA) 2024-2028. Available from: https://www.gov.br/lncc/pt-br/assuntos/noticias/ultimas-noticias-1/plano-brasileiro-de-inteligencia-artificial-pbia-2024-2028

[5] Brazil, Ministry of Health. Brazilian National Digital Health Strategy 2020-2028 [Internet]. Government of Brazil; 2020 [cited 2025 Nov 10]. Available from: https://bvsms.saude.gov.br/bvs/publicacoes/estrategia_saude_digital_Brasil.pdf

[6] Ministry of Health of Brazil. Meu SUS Digital. [cited 2025 Nov 18]. Meu SUS Digital. Available from: https://meususdigital.saude.gov.br/login

[7] RNDS [Internet]. [cited 2025 Nov 18]. Rede Nacional de Dados em Saúde. Available from: https://rnds-guia.saude.gov.br/

[8] Sen. Pacheco R. Senado Federal do Brasil. 2023 [cited 2025 Nov 18]. PL 2338/2023. Available from: https://www25.senado.leg.br/web/atividade/materias/-/materia/157233

[9] Brazilian Health Regulatory Agency. COLLEGIATE BOARD RESOLUTION – RDC No. 751 OF 15 SEPTEMBER 2022 [Internet]. 2022. Available from: https://www.gov.br/anvisa/pt-br/assuntos/produtosparasaude/temas-em-destaque/arquivos/2024/rdc-751-2022-en.pdf

[10] Brazilian Health Regulatory Agency. COLLEGIATE BOARD RESOLUTION – RDC NO. 657 OF 24 MARCH 2022 [Internet]. 2022. Available from: https://www.gov.br/anvisa/pt-br/assuntos/produtosparasaude/temas-em-destaque/arquivos/2024/rdc-657-2022-en.pdf

[11] Brazilian Health Regulatory Agency. Perguntas & Respostas: RDC Nº 657, de 24 de março de 2022 Regularização de software como dispositivo médico (Software as a Medical Device - SaMD). Brasília, Brazil: ANVISA; 2022 Sept.

[12] Jambor DG. Avaliação regulatória de software como dispositivo médico com foco na inclusão e equidade nas aplicações da inteligência artificial em saúde. Revista de Direito Sanitário. 2025 Sept 25;25(1):e0017.

[13] Levy L, Sanada P, Loh E. Emergo by UL. [cited 2025 Nov 18]. Brazil ANVISA Announces Priorities for the 2024-2025 Year. Available from: https://www.emergobyul.com/news/brazil-anvisa-announces-priorities-2024-2025-year

[14] Ministry of Culture of Brazil. Ministério da Cultura. 2024 [cited 2025 Nov 18]. Senado Federal aprova marco regulatório da inteligência artificial. Available from: https://www.gov.br/cultura/pt-br/assuntos/noticias/senado-federal-aprova-marco-regulatorio-da-inteligencia-artificial

[15] UNESCO. Brazil: readiness assessment report on artificial intelligence [Internet]. 2025 [cited 2025 Nov 18]. Report No.: SHS/BIO/AI-RAM/2025/BRA. Available from: https://unesdoc.unesco.org/ark:/48223/pf0000393091

[16] Brazilian Internet Steering Committee. ICT Households: Survey on the use of information and communication tehcnologies in Brazilian households [Internet]. São Paulo; 2024. Available from: https://cetic.br/media/docs/publicacoes/2/en-us/20251031080012/e-book_ict_households_2024b.pdf

[17] Center for Strategic Studies and Management (CGEE). The Brazilian Landscape of Science, Technology and Innovation in Artificial Intelligence [Internet]. Brasília: Center for Strategic Studies and Management (CGEE); 2025. Available from: https://www.cgee.org.br/w/the-brazilian-landscape-of-science-technology-and-innovation-in-artificial-intelligence

[18] Soto Á, Duran R, Moreno A, Adasme S, Rovira S, Jordán V, et al. Índice Latinoamericano de Inteligencia Artificial [Internet]. Comisión Económica para América Latina y el Caribe y Centro Nacional de Inteligencia Artificial; 2025. Report No.: ILC/TS.2025/68. Available from: https://indicelatam.cl/wp-content/uploads/2025/10/Documento_ILIA_2025.pdf

[19] Vieceli L, Cucolo E. Income Inequality Drops Again and Hits Lowest Level on Record in Brazil. Folha de SPaulo [Internet]. 2025 May 8 [cited 2025 Nov 19]; Available from: https://www1.folha.uol.com.br/internacional/en/business/2025/05/income-inequality-drops-again-and-hits-lowest-level-on-record-in-brazil.shtml

[20] Autoridade Nacional de Proteção de Dados. Radar Tecnológico: Inteligência Artificial Generativa [Internet]. Brasília; 2024. Available from: https://www.gov.br/anpd/pt-br/centrais-de-conteudo/documentos-tecnicos-orientativos/radar_tecnologico_ia_generativa_anpd.pdf

[21] Furtado TN. What Brazil's ANPD expects from companies using generative AI | IAPP [Internet]. IAPP. 2025 [cited 2025 Nov 19]. Available from: https://iapp.org/news/a/what-brazil-s-anpd-expects-from-companies-using-generative-ai

CHINA

1. China's state-led digital transformation: a centralized architecture and strategic coordination

HIGHLIGHT:

In China, the development of AI in health is part of a state-led digital transformation agenda. With data as a strategic resource and digital infrastructure as a core development pillar, China positions AI as a critical enabler of national goals across health, governance, and economic development.

In China, AI in health is part of an ambitious state-led digital transformation agenda. The government's top-down approach and centralized vision of modernizing the country through technology is evidenced by the national strategy "Plan for the Overall Layout of Building a Digital China" of 2022. The cross-cutting strategy aims to build a digital-first society and position China as a global leader in digital development by 2035. In healthcare, it proposes leveraging AI to improve the efficiency, accessibility, and precision of health services, with specific calls to standardize the development of Internet-based diagnostics. Moreover, it recognizes digital infrastructure and data resource systems as strategic assets comparable to transportation and energy [1].

Complementing this vision, the government seeks to promote the digital transformation of government agencies, with the goal of establishing by 2025 a "new paradigm of digital and intelligent government operations" [2]. Within this overarching framework, the health sector is a priority area for AI development and application, enabling core objectives such as improving public welfare and strengthening national competitiveness.

To further strengthen the integration of AI into health and related sectors, China's State Council—the executive branch's chief administrative authority—issued a new policy in August 2025 promoting the application of AI-assisted diagnosis and treatment, health management, and medical insurance services across the healthcare system [3].

In addition, the "Implementation Plan for the Digital and Smart Transformation of the Pharmaceutical Industry (2025–2030)" [4] released in April 2025 elevates AI as a national strategic priority and supports the establishment of large pharmaceutical model innovation platforms. It aims to pilot "AI across the entire pharmaceutical industry chain," covering drug R&D, production monitoring, and traditional Chinese medicine data, while promoting standardized cross-border data transfer and smart regulation.

Supporting this vision, the National Data Administration [1] (NDA) was established to promote data empowerment and large-scale circulation of data resources, playing a pivotal role in strategic coordination.

The NDA coordinates the establishment of foundational data institutions, directs the integration, sharing, and utilization of data resources, and oversees the planning and construction of China's digital economy. This entity serves as a powerful cross-sector coordinator, facilitating data integration across health institutions and government departments to provide higher-quality, more comprehensive datasets for AI model development. The NDA also leads the development of foundational initiatives for data circulation, transaction, and benefit allocation, which is essential for defining the rights and responsibilities of commercial entities leveraging public health data in AI product development. This centralized architecture aims to avoid fragmentation, harmonize regulations, and ensure that public investment is directed toward high-impact projects, such as the deployment of AI in medical diagnostics or public health monitoring systems.

2. Staged digital health policy: from infrastructure development to AI regulation

HIGHLIGHT:

China's digital health policy has evolved from the construction of interoperable platforms to the regulation of specific AI applications and use cases, as well as standards-driven implementation.

As a pioneering field in digital health development, The "Internet Plus Healthcare" is a state-led application of the Internet to healthcare, combining health education and information, electronic health records, electronic prescriptions, remote consultations, and myriad other health services [5]. Its core objective is to utilize digital technologies to optimize the allocation of medical resources and improve the convenience and accessibility of services [6][7]. By December 2024, China had established 3,340 internet hospitals, with the number of online healthcare users reaching 418 million [8]. Among these policies, "Notice on issuing the detailed rules for Internet diagnosis and treatment supervision (trial)", issued by the National Health Commission (NHC), stands as a milestone regulatory document in this field [9]. This document provides detailed provisions for the entire process of internet-based diagnosis and treatment, such as requiring real-name authentication for both patients and physicians to ensure the authenticity and traceability of medical activities. Furthermore, the document explicitly prohibits human personnel or AI from impersonating or replacing a physician in providing medical services. In addition, it strictly prohibits the use of AI or other means to automatically generate prescriptions.

The Chinese government defines and manages health and medical big data as an important national strategic foundation since 2018 [10].

One of the core initiatives of China's "medical big data" strategy is to promote the construction of a unified, authoritative, and interconnected four-level (national, provincial, municipal, and county) population health information platform [11] to integrate data resources from multiple systems, including public health, medical services, health insurance, and drug supply, and enable cross-departmental, cross-regional, and cross-sectoral business coordination and data sharing. This top-down model of data governance reflects China's multi-year, phased strategy in advancing digital health: first, investing heavily to build a robust digital highway (data platforms and governance standards), and then, guiding vehicles (AI applications) to transit efficiently and safely on these roads.

With the data foundation consolidated, recent policies have shifted toward the specific applications and use cases of AI in health, focusing on scenario-based standardization and full life-cycle regulation. In November 2024, NHC jointly with the National Administration of Traditional Chinese Medicine (NATCM) and the National Disease Control and Prevention Administration (NDCPA) released the "Reference Guidelines on Artificial Intelligence Application Cases for the Health Sector" [12], with a comprehensive technical reference framework for AI implementation in health. In October 2025, the NHC, together with National Development and Reform Commission (NDRC), Ministry of Industry and Information Technology (MIIT), NATCM and NDCPA issued the "Implementation Opinions on Promoting and Regulating the Application and Development of 'AI + Healthcare" [13], setting clear goals for 2027 (full coverage of AI-assisted diagnostics in primary care) and 2030 (universal application in secondary and tertiary hospitals).

Finally, to address risks from rapid technological iteration, especially of generative AI, the State Administration for Market Regulation (SAMR) and the National Standardization Administration (NSA) jointly released three key standards in April 2025: "Basic Security Requirements for Generative Artificial Intelligence Service" [14] "Generative Artificial Intelligence Data Annotation Security Specification" [15] and "Security Specification for Generative Artificial Intelligence Pre-training and Fine-tuning Data" [16]. These standards establish unified security baselines for data collection, annotation, and model training in generative AI, regulating medical AI model development and enhancing hospitals' and enterprises' data management capabilities. Additionally, the "Regulations on the Administration of Clinical Research on and Clinical Translational Application of New Biomedical Technologies" [17] issued by the State Council on September 28, 2025, fills the regulatory gap for high-risk technologies such as cutting-edge AI diagnostics, establishing a full-process management system including ethical review and clinical research filing.

3. The medical device framework as the core of AI regulation in health

HIGHLIGHT:

SaMD is a significant component of China's digital health regulations framework, with the National Medical Products Administration (NMPA) issuing dedicated technical guidance for AIaMD covering the full product lifecycle. Recent policy advancements have refined technical standards for datasets, pre-trained models, and synthetic data, aligned with international trends.

China's approach to regulating AI in the health sector is firmly rooted in the SaMD framework, which serves as the primary mechanism for overseeing AI-enabled technologies. The National Medical Products Administration (NMPA), as the regulatory authority, has developed specialized guidelines [18] to address the unique challenges posed by AI in medical applications, classifying such software typically as Class II or Class III medical devices depending on their risk level and intended use [19]. This classification ensures that AI software undergoes rigorous evaluation, with higher-risk products requiring more extensive clinical evidence and oversight.

Central to this framework are documents such as the "Guiding Principles for the Technical Review of Artificial Intelligence Medical Devices," which outline the requirements for registering AI-based products, including detailed provisions for technical review, clinical trials where necessary, and quality management systems [20]. Complementing this, the "Principles for the Classification Defining of AI-Based Medical Software Products" [21], issued in 2021, provides clear criteria for determining the regulatory class of AI software, factoring in aspects like the degree of automation, impact on clinical decision-making, and potential risks to patient safety. These guidelines emphasize lifecycle management, mandating continuous monitoring from pre-market approval through post-market surveillance to address issues like algorithm drift or data biases that could affect performance over time [22].

The NMPA's "Guidelines for the Registration and Review of Artificial Intelligence Medical Devices" [23] further specify technical standards for AIaMD, including robust requirements for algorithm transparency, data quality in training sets, and validation of performance metrics such as accuracy, sensitivity, and specificity. Risk classification is tailored to the software's function. For instance, diagnostic AI tools that influence treatment decisions are subject to greater scrutiny, often requiring randomized controlled trials or real-world evidence to demonstrate safety and efficacy [24]. Post-market surveillance involves mandatory reporting of adverse events, periodic re-evaluations, and updates to the software, ensuring adaptability to evolving technologies while maintaining public health protections.

This balancing act between adaptation and protection also extends to China's strategy for regulating Brain Computer Interface (BCI). To manage the risks of this frontier technology, the National Science and Technology Ethics Committee pre-emptively issued its Ethics Guidelines for BCI Research in 2023 [25], establishing strict ethical review, informed consent, and data protection requirements for BCI studies, particularly distinguishing between "Restorative BCI" (for medical purposes) and "Augmentative BCI" (for enhancement). In addition, the government is already paving the way for market access [26]. A recently published national industrial strategy jointly issued by seven ministries identified BCI as a key future industry and directed the NMPA to provide "priority support" and "increased registration guidance" for high-risk implantable BCI medical devices [27].

To further refine the regulatory system, NMPA has successively released the "Artificial Intelligence Medical Device - Quality Requirements and Evaluation" series since 2022, aiming to construct a full lifecycle quality evaluation framework, with 6 of 8 parts having been published, covering issues from terminology to data annotation and synthetic data requirements [28][29][30][31][32][33]. This series highlights China's transition from principled guidance to quantifiable, implementable technical standards, aligning with international norms such as the EU Medical Device Regulation (EU MDR/IVDR) and the FDA's Good Machine Learning Practice (GMLP) to enhance global product mutual recognition.

In support of industrial innovation, the State Council has issued a policy to establish technical standards-setting organizations for cutting-edge medical devices, including AI and medical robots, AI-enabled devices, brain-computer interface (BCI) devices, and medical imaging equipment in the priority review channel [34]. It advocates for intelligent "penetrating supervision" and "full-chain traceability of Unique Device Identifiers (UDI)," while aligning domestic review requirements with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) rules and IMDRF guidelines to promote synchronous global innovation launches in China.

Embedding AI-specific considerations into the broader medical device regulatory framework enables China to apply standards consistently across traditional and emerging devices.

4. Regulated clinical deployment: from strategic pilots to approved use

HIGHLIGHT:

With over 110 Class III AI-enabled medical devices approved by October 2025, China has transitioned from policy vision to clinical implementation. However, market entry remains constrained to those with high technical and compliance capacity.

China's progression in deploying AI in healthcare has marked a significant shift from conceptual strategies and pilot programs to widespread, regulated clinical use, underscoring the country's commitment to translating national policies into tangible medical advancements. By October 2025, NMPA had approved over 110 Class III AI-enabled medical devices [35], the highest-risk category that includes technologies directly supporting or sustaining life, such as advanced diagnostic tools and interventional systems. This milestone reflects a deliberate transition from early-stage strategic pilots, initiated under frameworks like the "New Generation Artificial Intelligence Development Plan", to full-scale approved applications in clinical settings, where AI enhances precision in areas like imaging analysis, pathology, and surgical assistance [36].

However, entry into this regulated space remains highly selective, limited to entities with substantial technical prowess and compliance capabilities.

The approval pathway involves rigorous pre-market evaluations, including randomized controlled trials or real-world evidence demonstrations, as well as post-market surveillance to monitor ongoing safety and efficacy [37]. In China's competitive environment, domestic firms hold over 90% of approvals, evidencing China's self-reliance in this space [38].

5. Ethical governance and inter-agency collaboration in a complex regulatory landscape

HIGHLIGHT:

While China has established national ethical frameworks for responsible AI, the governance of AI in health involves multiple authorities with distinct mandates and regulatory roles. In the absence of a permanent coordination mechanism, this multi-actor landscape can create challenges for consistent oversight.

China's governance of AI in the health sector is characterized by a multifaceted ethical framework that emphasizes responsible development, while navigating a complex web of inter-agency collaborations [39]. At the national level, the "Global Artificial Intelligence Governance Initiative" [40] provides a strategic foundation, emphasizing "people-centered, safe and controllable, and fair and inclusive" principles that guide the embedding of ethical norms into subsequent AI in health policies. Such emphasis aligns with international frameworks such as UNESCO's Recommendation on the Ethics of AI and the OECD AI Principles, advocating for a human-centered approach to global AI governance.

To translate these ethical principles into actionable standards, the National Technical Committee 260 on Cybersecurity (TC260) released Version 1.0 of the "Artificial Intelligence Security Governance Framework" [41] in September 2024, proposing principles for a risk-oriented and agile governance approach , focused on inclusivity and safety.

Building on this, Version 2.0 [42], led by the National Internet Emergency Center (CNCERT), updates risk classification and prevention measures to keep pace with technological advancements, promoting cross-border, cross-domain, and cross-industry collaborative governance. These frameworks establish national-level standards for algorithmic transparency, data security, model explainability, and ethics in the medical field.

The regulatory landscape involves multiple key authorities, each with distinct mandates that contribute to a layered approach to AI in health governance. The State Council provides top-level legal and policy oversight, filling regulatory gaps for high-risk AI technologies in health. The National Data Administration (NDA) coordinates data integration and sharing. The Ministry of Science and Technology (MOST) drives research and innovation policies, supporting ethical AI development through funding and guidelines for emerging technologies like intelligent diagnostics. The Cyberspace Administration of China (CAC) focuses on data security, algorithmic ethics, and cybersecurity, often issuing rules for

AI labeling and ethical reviews in digital health applications. The National Medical Products Administration (NMPA) primarily handles device approvals and safety evaluations for AI-enabled medical technologies, ensuring compliance with technical and clinical standards. The National Health Commission (NHC) oversees clinical applications and public health implications, issuing reference guidelines for AI applications and uses in healthcare. The National Healthcare Security Administration (NHSA) serves as a critical link between AI in health innovation and sustainable healthcare delivery, focusing on pricing standardization, medical insurance fund security, and value-based access to AI-enabled services. This division of roles fosters specialized expertise but can lead to challenges like overlapping jurisdictions, inconsistent enforcement, and delays in addressing cross-cutting issues such as privacy in data-sharing for AI training.

To address potential coordination challenges, recent policies have strengthened inter-agency collaboration. The "Comprehensively Deepening the Reform of Drug and Medical Device Supervision to Promote High-Quality Development of the Pharmaceutical Industry" proposes establishing specialized technical organizations for AI and medical robots to centralize algorithm standardization.

Bringing the Threads Together: China's governance strategy for AI in health

China's governance model for AI in health exemplifies a centrally orchestrated ecosystem, where technological development, data governance, and ethical oversight are strategically integrated into the broader national project of digital modernization.

The five dimensions analyzed, namely state-led digital transformation, staged digital health policy, SaMD-based regulation, clinical implementation, and ethical governance, reveal a continuum rather than isolated initiatives. Together, they form a governance architecture designed to sustain innovation while seeking sovereign control over data, safety, and strategic direction.

At the systemic level, digital infrastructure and data governance serve as the fertile ground for large-scale medical-AI deployment.

The state's long-term investment in interoperable health data platforms and the establishment of the NDA ensure that data-driven initiatives, such as precision medicine, operate under national standards.

Recent policies have strengthened this foundation by promoting cross-sectoral integration and smart regulation. From this foundation, AI regulation evolves organically through the SaMD framework, embedding emerging technologies into a pre-existing risk-based structure that enforces safety, quality, and accountability across the product lifecycle.

Ethical and inter-agency governance mechanisms illustrate China's effort to govern rapid technological advancement and its overlap with ethical considerations, data security, and social stability. Ultimately, China's ambition for systemic coherence reflects a maturing regulatory trajectory that seeks to balance policy centralization with adaptability.

References

[1] State Council of the People's Republic of China. 《数字中国建设整体布局规划》Plan for the Overall Layout of Building a Digital China [Internet]. Beijing: State Council; 2023 Feb [cited 2025 Nov 15]. Available from: https://www.gov.cn/zhengce/2023-02/27/content_5743484.htm

[2] State Council of the People's Republic of China. 《关于加强数字政府建设的指导意见》Guiding Opinions of the State Council on Strengthening the Building of a Digital Government [Internet]. Beijing: State Council; 2022 June [cited 2025 Nov 15]. Available from: https://www.gov.cn/zhengce/content/2022-06/23/content_5697299.htm

[3] State Council of the People's Republic of China. 《关于深入实施"人工智能+"行动的意见》Opinions of the State Council on Further Implementing the 'AI+' Action [Internet]. Beijing: State Council; 2025 Aug [cited 2025 Nov 15]. Available from: https://www.gov.cn/zhengce/content/202508/content_7037861.htm

[4] Ministry of Industry and Information Technology, Ministry of Commerce, National Health Commission, National Healthcare Security Administration, National Data Administration, National Administration of Traditional Chinese Medicine, et al. 《医药工业数智化转型实施方案（2025—2030年）》Implementation Plan for the Digital and Smart Transformation of the Pharmaceutical Industry (2025–2030) [Internet]. Beijing: Ministry of Industry and Information Technology; 2025 Apr [cited 2025 Nov 15]. Available from: https://www.miit.gov.cn/jgsj/xfpgys/wjfb/art/2025/art_3077bb1835d54962a55ff61b6addf4fa.html%E2%80%9D

[5] Yang F, Shu H, Zhang X. Understanding "Internet Plus Healthcare" in China: Policy Text Analysis. J Med Internet Res. 2021 July 26;23(7):e23779.

[6] General Office of the State Council. 《关于促进"互联网+医疗健康"发展的意见》Opinions on promoting the development of 'Internet Plus Healthcare' [Internet]. Beijing: General Office of the State Council; 2018 Apr [cited 2025 Nov 15]. Report No.: 国办发〔2018〕26号. Available from: https://www.gov.cn/zhengce/content/2018-04/28/content_5286645.htm

[7] National Health Commission. 《关于促进"互联网+医疗健康" 发展的意见》政策解读Policy interpretation of the Opinions on promoting the development of 'Internet Plus Healthcare' [Internet]. Beijing: National Health Commission; 2018 Apr [cited 2025 Nov 15]. Available from: https://www.gov.cn/zhengce/2018-04/28/content_5286786.htm

[8] China Internet Network Information Center. 第55次《中国互联网络发展状况统计报告》The 55th statistical report on China's Internet development [Internet]. Beijing: China Internet Network Information Center; 2025 Jan [cited 2025 Nov 15]. Available from: https://www.100ec.cn/detail--6646318.html

[9] General Office of the National Health Commission, Office of the National Administration of Traditional Chinese Medicine. 《关于印发互联网诊疗监管细则（试行）的通知》Notice on issuing the detailed rules for Internet diagnosis and treatment supervision (trial) [Internet]. Beijing: National Health Commission; 2022 Mar [cited 2025 Nov 15]. Available from: https://www.nhc.gov.cn/yzygj/c100068/202203/2072f0e8988249e59d942e1b2a933916.shtml

[10] Measures for the Administration of National Health and Medical Big Data Standards, Security, and Services (Trial). 《关于印发国家健康医疗大数据标准、安全和服务管理办法（试行）的通知》Measures for the Administration of National Health and Medical Big Data Standards, Security, and Services (Trial) [Internet]. Beijing: National Health Commission; 2018 Sept [cited 2025 Nov 15]. Available from: https://www.nhc.gov.cn/guihuaxxs/c100133/201809/c5e3e58313a24fdeb26d3dc07003d56e.shtml

[11] General Office of the State Council. 《关于促进和规范健康医疗大数据应用发展的指导意见》Guiding opinions on promoting and regulating the application and development of health and medical big data [Internet]. Beijing: General Office of the State Council; 2016 June [cited 2025 Nov 15]. Available from: https://www.gov.cn/gongbao/content/2016/content_5088769.htm

[12] General Office of the National Health Commission, General Office of the National Administration of Traditional Chinese Medicine, General Office of the National Disease Control and Prevention Administration. 《关于印发卫生健康行业人工智能应用场景参考指引的通知》Reference Guidelines on Artificial Intelligence Application Cases for the Health Sector [Internet]. Beijing: National Health Commission; 2024 Nov [cited 2025 Nov 15]. Available from: https://www.nhc.gov.cn/guihuaxxs/c100133/202411/3dee425b8dc34f739d63483c4e5c334c.shtml

[13] General Office of the National Health Commission, General Office of the National Development and Reform Commission, General Office of the Ministry of Industry and Information Technology, General Office of the National Administration of Traditional Chinese Medicine, General Office of the National Disease Control and Prevention Administration. 《关于促进和规范"人工智能+医疗卫生"应用发展的实施意见》Implementation Opinions on Promoting and Regulating the Application and Development of 'AI + Healthcare [Internet]. Beijing: National Health Commission; 2025 Nov [cited 2025 Nov 15]. Available from: https://www.nhc.gov.cn/guihuaxxs/c100133/202511/d1a42ae835c743b9b3e83ac0253c3e9f.shtml

[14] State Administration for Market Regulation, National Standardization Administration. 《网络安全技术 生成式人工智能服务安全基本要求》Cybersecurity technology: basic security requirements for generative artificial intelligence services [Internet]. Beijing: State Administration for Market Regulation; 2025 Apr [cited 2025 Nov 15]. (National Standard of the People's Republic of China). Report No.: GB/T 45654-2025. Available from: https://std.samr.gov.cn/gb/search/gbDetailed?id=33D40F1160BF5D92E06397BE0A0A5B93

[15] State Administration for Market Regulation, National Standardization Administration. 《网络安全技术 生成式人工智能数据标注安全规范》Cybersecurity technology—Generative artificial intelligence data annotation security specification [Internet]. Beijing: State Administration for Market Regulation; 2025 Apr [cited 2025 Nov 15]. (National Standard of the People's Republic of China). Report No.: GB/T 45674—2025. Available from: https://openstd.samr.gov.cn/bzgk/std/newGbInfo?hcno=407584DD0FA2BA19E62E85D3469290B0

[16] State Administration for Market Regulation, National Standardization Administration. 《网络安全技术 生成式人工智能预训练和优化训练数据安全规范》Cybersecurity technology—Security specification for generative artificial intelligence pre-training and fine-tuning data [Internet]. Beijing: State Administration for Market Regulation; 2025 Apr [cited 2025 Nov 15]. (National Standard of the People's Republic of China). Report No.: GB/T 45652—2025. Available from: https://openstd.samr.gov.cn/bzgk/std/newGbInfo?hcno=82710B59110419C285BDC48AB4D7D1F3

[17] State Council of the People's Republic of China. 《生物医学新技术临床研究和临床转化应用管理条例》Regulations on the Administration of Clinical Research on and Clinical Translational Application of New Biomedical Technologies [Internet]. State Council Decree No. 818 Sept 28, 2025. Available from: https://www.gov.cn/zhengce/content/202510/content_7043790.htm

[18] The State Council of the People's Republic of China. China issues guideline to accelerate 'AI Plus' integration across key sectors. 2025 Aug 27 [cited 2025 Nov 15]; Available from: https://english.www.gov.cn/policies/latestreleases/202508/27/content_WS68ae7976c6d0868f4e8f51a0.html

[19] State Council of the People's Republic of China. 《医疗器械监督管理条例》Regulations on the supervision and administration of medical devices [Internet]. State Council Decree No. 739 Feb 9, 2021. Available from: https://www.gov.cn/zhengce/content/2021-03/18/content_5593739.htm

[20] Han Y, Ceross A, Bergmann J. Regulatory frameworks for AI-enabled medical device software in China: Comparative analysis and review of implications for global manufacturer. JMIR AI. 2024 July 29;3:e46871.

[21] National Medical Products Administration. 《人工智能医用软件产品分类界定指导原则》Principles for the Classification Defining of AI-Based Medical Software Products [Internet]. Beijing: National Medical Products Administration; 2021 July [cited 2025 Nov 15]. Available from: https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.nmpa.gov.cn%2Fdirectory%2Fweb%2Fnmpa%2Fimages%2F1625713895408075422.docx&wdOrigin=BROWSELINK

[22] Emergo by UL. Emergo by UL. [cited 2025 Nov 16]. China medical device approval. Available from: https://www.emergobyul.com/services/china-medical-device-registration-and-approval

[23] Center for Medical Device Evaluation, National Medical Products Administration. 《关于发布人工智能医疗器械注册审查指导原则的通告（2022年第8号）》Guidelines for the Registration and Review of Artificial Intelligence Medical Devices [Internet]. Beijing: National Medical Products Administration; 2022 Mar [cited 2025 Nov 16]. Available from: https://www.cncsdr.org/ggtz/ggzz/202203/t20220311_304188.html

[24] National Medical Products Administration. National Medical Products Administration. [cited 2025 Nov 15]. National Medical Products Administration. Available from: https://english.nmpa.gov.cn/

[25] National Science and Technology Ethics Committee, Artificial Intelligence Ethics Subcommittee. 《脑机接口研究伦理指引》Ethical guidelines for brain-computer interface research [Internet]. Beijing: Ministry of Science and Technology; 2024 Feb [cited 2025 Nov 15]. Available from: https://www.most.gov.cn/kjbgz/202402/t20240202_189582.html

[26] National Healthcare Security Administration. 《神经系统类医疗服务价格项目立项指南（试行）》Project initiation guidelines for neurological medical service pricing (trial) [Internet]. Beijing: National Healthcare Security Administration; 2025 Mar [cited 2025 Nov 15]. Available from: https://www.nhsa.gov.cn/art/2025/3/12/art_14_15946.html

[27] Ministry of Industry and Information Technology, National Development and Reform Commission, Ministry of Education, National Health Commission, State-owned Assets Supervision and Administration Commission, Chinese Academy of Sciences, et al. 《关于推动脑机接口产业创新发展的实施意见》Implementation opinions on promoting innovative development of the brain-computer interface industry [Internet]. Ministry of Industry and Information Technology; 2025 July [cited 2025 Nov 15]. Available from: https://www.miit.gov.cn/jgsj/kjs/wjfb/art/2025/art_438e059801414869abc50abdb06eeac6.html

[28] National Medical Products Administration. 《人工智能医疗器械 质量要求和评价 第1部分：术语》Artificial intelligence medical device— Quality requirements and evaluation—Part 1: Terminology [Internet]. Beijing: National Medical Products Administration; 2022 July [cited 2025 Nov 15]. (Medical Device Industry Standard of the People's Republic of China). Report No.: YY/T 1833.1-2022. Available from: https://app.nifdc.org.cn/biaogzx/dataGkZqyj.do?formAction=viewZqyj&id=2c9048d88e991dc6018e9cab5ed70fa8

[29] National Medical Products Administration. 《人工智能医疗器械 质量要求和评价 第2部分：数据集通用要求》Artificial intelligence medical device: quality requirements and evaluation, Part 2: General requirements for datasets [Internet]. Beijing: National Medical Products Administration; 2022 July [cited 2025 Nov 15]. Report No.: YY/T 1833.2—2022. Available from: https://std.samr.gov.cn/hb/search/stdHBDetailed?id=E538DE5AEECF3527E05397BE0A0AF2A4

[30] National Medical Products Administration. 《人工智能医疗器械 质量要求和评价 第3部分：数据标注通用要求》Artificial intelligence medical device: quality requirements and evaluation, Part 3: General requirements for data annotation [Internet]. Beijing: National Medical Products Administration; 2022 Aug [cited 2025 Nov 15]. (Medical Device Industry Standard of the People's Republic of China). Report No.: YY/T 1833.3—2022. Available from: https://std.samr.gov.cn/hb/search/stdHBDetailed?id=E92817BCAF87FFFFE05397BE0A0A6860

[31] National Medical Products Administration. 《人工智能医疗器械 质量要求和评价 第4部分：可追溯性》Artificial intelligence medical device—Quality requirements and evaluation—Part 4: Traceability [Internet]. Beijing: National Medical Products Administration; 2023 Sept [cited 2025 Nov 15]. (Medical Device Industry Standard of the People's Republic of China). Report No.: YY/T 1833.4-2023. Available from: https://app.nifdc.org.cn/biaogzx/dataGkZqyj.do?formAction=viewZqyj&id=2c9048d8956b6a1601957f1cc5613c3f

[32] National Medical Products Administration. 《人工智能医疗器械 质量要求和评价 第5部分：预训练模型》Artificial intelligence medical device: quality requirements and evaluation, Part 5: Pre-trained models [Internet]. Beijing: National Medical Products Administration; 2024 Sept [cited 2025 Nov 15]. (Medical Device Industry Standard of the People's Republic of China). Report No.: YY/T 1833.5—2024. Available from: https://std.samr.gov.cn/hb/search/stdHBDetailed?id=259650B6B8A05193E06397BE0A0A3791

[33] National Medical Products Administration. 《人工智能医疗器械 质量要求和评价 第6部分：合成数据》Artificial Intelligence Medical Devices Quality Requirements and evaluation—Part 6: synthetic data [Internet]. Beijing: National Medical Products Administration; 2025 Oct [cited 2025 Nov 15]. (Medical Device Industry Standard of the People's Republic of China). Available from: https://std.samr.gov.cn/gb/search/gbDetailed?id=2E65C6BFCFFA1C32E06397BE0A0AC23B

[34] General Office of the State Council. 《关于全面深化药品医疗器械监管改革促进医药产业高质量发展的意见》 Comprehensively Deepening the Reform of Drug and Medical Device Supervision to Promote High-Quality Development of the Pharmaceutical Industry [Internet]. Beijing: General Office of the State Council; 2024 Dec [cited 2025 Nov 16]. Available from: https://www.gov.cn/zhengce/content/202501/content_6996115.htm

[35] National Medical Products Administration. National Medical Products Administration. 2025 [cited 2025 Nov 16]. 《对十四届全国人大三次会议第3816号建议的答复》Reply to Proposal No. 3816 of the Third Session of the 14th National People's Congress. Available from: https://www.nmpa.gov.cn/zwgk/jyta/rdjy/20251014091946151.html

[36] Sina Finance [Internet]. 2025 [cited 2025 Nov 16]. 《Ai影像诊断：技术赋能与资本热浪》AI imaging diagnosis: technological empowerment and capital boom. Available from: https://finance.sina.com.cn/wm/2025-01-27/doc-inehkazi9767922.shtml

[37] ProRegulations. ProRegulations. [cited 2025 Nov 16]. China medical device registration and device classification-proregulations. Available from: https://www.proregulations.com/china-medical-device-registration-and-device-classification.html

[38] Liu Y, Yu W, Dillon T. Regulatory responses and approval status of artificial intelligence medical devices with a focus on China. Npj Digit Med. 2024 Sept 18;7(1):255.

[39] National New Generation Artificial Intelligence Governance Expert Committee. Ministry of Science and Technology. 2019 [cited 2025 Nov 16]. 《发展负责任的人工智能：新一代人工智能治理原则发布 》Governance principles for the new generation of artificial intelligence: developing responsible artificial intelligence. Available from: https://www.most.gov.cn/kjbgz/201906/t20190617_147107.html

[40] Ministry of Foreign Affairs of the People's Republic of China. 《全球人工智能治理倡议》Global artificial intelligence governance initiative [Internet]. Beijing: Ministry of Foreign Affairs; 2023 Oct [cited 2025 Nov 16]. Available from: https://www.mfa.gov.cn/web/ziliao_674904/1179_674909/202310/t20231020_11164831.shtml

[41] National Information Security Standardization Technical Committee. 《人工智能安全治理框架》1.0版 Artificial intelligence security governance framework, version 1.0 [Internet]. Beijing: Cyberspace Administration of China; 2024 Sept [cited 2025 Nov 16]. (AI Security Governance Framework). Available from: https://www.cac.gov.cn/2024-09/09/c_1727567886199789.htm

[42] National Information Security Standardization Technical Committee. 《人工智能安全治理框架》2.0版 Artificial intelligence security governance framework, version 2.0 [Internet]. Beijing: Cyberspace Administration of China; 2025 Sept [cited 2025 Nov 16]. (AI Security Governance Framework). Available from: https://www.cac.gov.cn/2025-09/15/c_1759653448369123.htm

INDIA

1. India's AI governance prioritizes public value alongside sectoral priorities

HIGHLIGHT:

India's AI governance framework reflects a coordinated effort to institutionalize cross-sectoral priorities through national infrastructure and dedicated programs aimed at social impact and wide AI adoption.

India's National Strategy for AI (2018), developed by the governmental think tank NITI Aayog, established a vision for leveraging AI to address structural socio-economic challenges and improve public service delivery [1]. It framed AI as a public good and identified five high-impact areas for government focus: health, agriculture, education, smart cities, and mobility. While this framing reflects India's commitment to socially beneficial AI, operational mechanisms—such as funding instruments, institutional governance, and evaluation frameworks—are under ongoing design and refinement.

Since 2018, India's AI policy has evolved from a strategic vision to implementation. The IndiaAI Mission, approved by the Cabinet in March 2024, builds directly on the 2018 framework by articulating a comprehensive national agenda for operationalizing AI across society [2]. Structured around seven operational pillars (IndiaAI Compute Capacity, Innovation Centre, Datasets Platform, Application Development Initiative, FutureSkills, Startup Financing, and Safe & Trusted AI), the Mission seeks to democratize access to AI resources, promote ethical and trustworthy practices, and support the development of indigenous models and applications with broad socio-economic benefits [3].

Together, the 2018 Strategy and the IndiaAI Mission reinforce India's model of inclusive, equitable, public interest-driven AI to address systemic gaps and support human development [4].

By leveraging public investments coupled with private innovation and partnerships, India seeks to brand itself as an "AI Garage", a hub for developing and testing AI solutions suited to emerging economies in the Global South and shaping AI in ways that reflect its diverse sociocultural and linguistic landscape [1]. In parallel, India is also deepening its international engagement on AI governance and regulation in health [5].

2. Integration of AI into the medical device regulatory framework in India

HIGHLIGHT:

India's medical device regulations formally recognize software as a medical device (SaMD) subject to a risk-based classification framework aligned with IMDRF principles. While this allows for AI systems to be evaluated as SaMD, specific regulatory guidance for AI is still under development.

In India, the Medical Device Rules of 2017 were amended by subsequent notifications in 2020 and 2022 to include SaMD in the regulatory scope, with the Central Drugs Standard Control Organization (CDSCO) as the national regulatory authority for those devices [6].

While the 2017 Medical Device Rules establish a four-tier risk classification system, ranging from low-risk Class A (e.g., data visualization) to high-risk Class D (e.g., AI for critical diagnostics), they do not yet provide specific criteria for categorizing AI-enabled devices.

In September 2021, the CDSCO issued a set of IMDRF-aligned guidelines that provide regulatory pathways for SaMDs in India. these guidelines support structured procedures for pre-market approvals, manufacturing licenses, and import controls, ensuring that AI tools in areas such as diagnosis, patient monitoring, and treatment planning are evaluated for safety and efficacy before deployment [7].

This framework has already been applied in practice to AI: In September 2024, the CDSCO approved Remidio Medios DR AI, a portable, AI-enabled device for detecting diabetic retinopathy that operates fully offline, a crucial feature for low-connectivity environments [8]. The approval was based on a risk-based SaMD evaluation and demonstrated compliance with global data protection and cybersecurity standards, including GDPR, HIPAA, and ISMS [9].

While the SaMD foundation enables the regulation of narrow AI systems, India has yet to issue specific guidance for adaptive or continuously learning AI. Addressing this gap will require greater clarity on dynamic risk classification, updated protocols that avoid unnecessary re-approval, and robust post-market surveillance mechanisms to monitor real-world performance and adverse events [10].

Recent developments signal progress in this direction. In 2025, CDSCO released draft amendments related to risk categorization for certain device types to enhance the existing framework with more precise classifications and guidance [11]. Given India's aim to establish itself as a hub for AI in health innovation, refining regulatory mechanisms will be crucial to achieving international leadership, ensuring patient safety, and enabling scalable AI deployment.

3. Digital health infrastructure as an enabler for AI deployment

HIGHLIGHT:

India's federated digital health architecture provides a technical and policy foundation for scalable and privacy-aware AI integration. However, the full deployment of responsible AI in health still depends on advancing legal harmonization, workforce development, and nationwide uptake.

India has built a digital health ecosystem focused on interoperability, security, and accessibility, with the Ayushman Bharat Digital Mission at its core [12]. Launched in 2021, this mission connects various actors, patients, providers, professionals, and insurers through open-standard public digital goods and APIs, intending to set efficient and secure clinical data flows [13]. Its key components include the Health Facility Registry, Healthcare Professional Registry, and the Ayushman Bharat Health Account, all designed to support longitudinal patient records accessible in real time [14].

The federated infrastructure, built on open APIs and interoperable digital layers, is a crucial step towards responsible AI, structured clinical data, data integrity, and privacy standards. One illustrative example of India's digital readiness is the large-scale digitization of personal health records achieved through platforms integrated with the Ayushman Bharat Digital Mission [15]. These systems have enabled the creation of millions of longitudinal patient records and supported wide user adoption across states. This demonstrates the transformative potential of India's federated digital infrastructure to support AI-enabled health solutions, particularly by facilitating real-time data availability, patient identification, and interoperability at scale.

However, implementation varies widely across states. Some states demonstrate high digital maturity and robust infrastructure, while others face challenges in connectivity, workforce capacity, and digital literacy. This creates uneven readiness for deploying AI-enabled tools and services nationwide. Moreover, there is no unified regulatory framework guiding how AI tools, particularly adaptive or continuously learning systems, should interoperate with regulator-backed technical standards or be evaluated for safety and efficacy in this digital environment [16]. However, progress includes consultations for the "Report on AI Governance Guidelines Development" [17] and initiatives such as IIT Kanpur's MoU with the National Health Authority (NHA) for AI benchmarking using Ayushman Bharat Digital Mission data [2].

According to the WHO Global Digital Health Monitor, India has achieved Phase 4 maturity in Infrastructure and Leadership & Governance, demonstrating strong technical capacity and national coordination mechanisms for digital health. However, the country remains at Phase 3 across key areas such as Overall Readiness, Legislation, Policy & Compliance, Strategy & Investment, Standards & Interoperability, and Services & Applications, indicating a digital ecosystem that is still maturing and uneven across its regulatory and implementation layers.

Notably, Workforce Readiness is rated at Phase 2, highlighting a critical gap in the availability of trained professionals to sustain and scale up digital health and AI-based solutions [18].

While India's foundational architecture and governance capacity are essential enablers, the full deployment of AI in health still depends on advancing legal harmonization, workforce development, and nationwide uptake across subnational entities.

WHO Global Digital Health Monitor:
India's Maturity Levels

PHASE 4 (High Maturity)
- Infrastructure
- Leadership & Governance

PHASE 3 (Mid Maturity)
- Overall Readiness
- Legislation, Policy & Compliance
- Strategy & Investment
- Standards & Interoperability
- Services & Applications

PHASE 2 (Critical Gap)
- Workforce Readiness

4. New data protection law and privacy safeguards

HIGHLIGHT:

India's newly enacted Digital Personal Data Protection Act (DPDP Act) 2023 establishes enforceable obligations and creates the Data Protection Board of India to oversee compliance.

India's Digital Personal Data Protection Act (DPDP Act), enacted in 2023, marks a significant milestone by introducing a statutory data governance framework applicable to AI systems, including those used in healthcare [19]. The Act governs the processing of digital personal data. It establishes enforceable obligations for "Data Fiduciaries," including obtaining valid consent, limiting data processing to lawful purposes, ensuring data accuracy, implementing reasonable security safeguards, and enabling data principals to exercise rights such as access, correction, and redress. It also proposes establishing the Data Protection Board of India, tasked with adjudicating non-compliance and ensuring accountability.

Although not health-specific, the Act applies to digital health data and AI-powered applications, and it offers a foundational legal framework for trustworthy AI deployment in the sector. However, it lacks provisions on sensitive data categories and does not explicitly regulate automated decision-making.

In September 2025, the Ministry of Electronics and Information Technology (MeitY) released the Draft Digital Personal Data Protection Rules 2025, which introduces operational details such as mechanisms for consent managers, particularly relevant for handling health data in AI-driven systems like diagnostics and patient monitoring [20]. These draft rules aimed to address regulatory ambiguities by offering clearer guidance on consent processes, data fiduciary responsibilities, and compliance enforcement.

5. Public–private ecosystems for scalable AI innovation in health

HIGHLIGHT:

India is fostering a public–private ecosystem focused on co-developing AI tools for health. Aligning innovation with regulatory oversight through sandboxes or staged certification pathways will be key to ensuring the safe and sustainable scaling of AI in public health.

India has cultivated a vibrant public–private ecosystem for health-focused AI innovation, where collaborations among government, academia, and non-profits are driving scalable solutions to pressing health challenges. Institutions like Wadhwani AI, the All India Institute of Medical Sciences (AIIMS), and IIT Delhi are at the forefront, developing AI tools to tackle issues such as tuberculosis (TB), maternal health, and rural clinical decision-making.

While these initiatives reflect a dynamic innovation landscape, many tools are still in pilot or research stages and currently operate without full regulatory approval from the Central Drugs Standard Control Organisation (CDSCO) [5]. This underscores the need to align innovation pathways with regulatory oversight to ensure safety, scalability, and sustained impact.

For example, one AI-powered screening tool, deployed in partnership with India's national tuberculosis program, analyzes cough sounds and assists in interpreting drug resistance test results [21]. Integrated into mobile outreach activities across districts, it has contributed to earlier detection of TB and improved access to diagnostics in underserved communities [22].

Other AI-driven tools include a smartphone-based application for non-invasive anemia detection and a fetal risk stratification system, both of which are currently being piloted in public hospitals and state-led maternal health programs [23][24]. These solutions are designed to operate on low-cost smartphones and cloud platforms, extending services to rural populations.

To support a safe transition from pilots to large-scale implementation, India has also embraced regulatory sandboxes to test and refine AI health solutions in real-world conditions. The Ayushman Bharat Digital Mission Sandbox provides a structured, time-bound environment for developers to integrate and validate AI-enabled applications such as secure electronic health records, telemedicine platforms, and patient consent management tools. Under temporary regulatory flexibilities, participants can generate empirical evidence on safety, performance, and ethical compliance [25]. This process helps bridge the gap between experimentation and formal regulatory approval, aligning with India's broader strategy for ethical and scalable AI in public health.

Bringing the Threads Together: India's governance strategy for AI in health

India presents a unique and evolving strategy for regulating AI in health. The Indian model aims to create a thriving AI ecosystem for health by articulating a strategic vision, building digital infrastructure, and promoting institutional coordination.

These foundations further support an active community of universities, public hospitals, and technical institutes developing pilot projects. It is an ecosystem that does not wait for perfect conditions, moving forward with large-scale deployment of AI tools in health, even in the absence of unified frameworks or full regulatory clarity. While this strategy may accelerate innovation, it may also increase ethical risks, particularly if AI is deployed in underserved or vulnerable communities without established safeguards. Responsible AI governance is key to mitigate such risks.

Regulatory progress remains uneven across sectors and geographical regions. The personal data protection framework still requires clearer operational rules for complex scenarios like automated decision-making, and adaptive AI models remain outside formal regulatory oversight. India has the advantage of a national roadmap and policy tools that could steer the country towards a stronger regulatory path, such as proposed regulatory sandboxes or staged certification mechanisms. The challenge ahead is effectively implementing them to sustain trust and quality over time.

India's AI governance in health is ultimately rooted in real-world capabilities, committed to scaling, and willing to embrace complexity as a starting point. It seeks to gradually build regulatory frameworks from context, with a focus on public good, and a readiness to learn along the way.

References

[[1] NITI Aayog. National Strategy for Artificial Intelligence [Internet]. Government of India; 2018 June. Available from: https://www.niti.gov.in/sites/default/files/2023-03/National-Strategy-for-Artificial-Intelligence.pdf

[2] PIB Delhi. Government of India Press Information Bureau. 2024 [cited 2025 Nov 12]. Cabinet Approves Ambitious IndiaAI Mission to Strengthen the AI Innovation Ecosystem. Available from: https://www.pib.gov.in/www.pib.gov.in/Pressreleaseshare.aspx?PRID=2012355

[3] IndiaAI [Internet]. [cited 2025 Nov 12]. INDIAai. Available from: https://indiaai.gov.in/

[4] Verma S. TICE News. 2025 [cited 2025 Nov 12]. The IndiaAI Mission: What is the 7-Pillar Strategy for National AI Leadership? Available from: https://www.tice.news/tice-trending/the-indiaai-mission-what-is-the-7-pillar-strategy-for-national-ai-leadership-9528402

[5] Dupré S. India Joins HealthAI's Global Regulatory Network, Pioneering Safe AI in Health — HealthAI [Internet]. HealthAI - The Global Agency for Responsible AI in Health. 2025 [cited 2025 Nov 12]. Available from: https://healthai.agency/india-joins-healthai-grn/

[6] Central Drugs Standard Control Organisation. Medical Device Rules [Internet]. Ministry of Health and Family Welfare, Government of India; 2017. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf

[7] Central Drugs Standard Control Organization. Medical Devices Frequently Asked Questions (FAQ) [Internet]. CDSCO; 2025. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/Addendum02faqmd.pdf

[8] Sarthe A. Digital Health News. 2025 [cited 2025 Nov 12]. Remidio Receives Regulatory Approval in Karnataka for AI-Based Eye Care Tools. Available from: https://www.digitalhealthnews.com/remidio-receives-regulatory-approval-in-karnataka-for-ai-based-eye-care-tools

[9] Chakraborty A. CDSCO approves ophthalmic AI software Remidio Medios DR AI [Internet]. Practical Patient Care. 2024 [cited 2025 Nov 12]. Available from: https://www.practical-patient-care.com/news/indias-cdsco-approves-ophthalmic-ai-software-remidio-medios-dr-ai/

[10] Ong AY, Taribagil P, Sevgi M, Kale AU, Dow ER, Macdonald T, et al. A scoping review of artificial intelligence as a medical device for ophthalmic image analysis in Europe, Australia and America. NPJ Digit Med. 2025 May 29;8(1):323.

[11] Taylor NP. Regulatory Focus, Regulatory Affairs Professionals Society. 2025 [cited 2025 Nov 13]. Asia-Pacific Roundup: India's CDSCO seeks feedback on medical device software regulation. Available from: https://www.raps.org/news-and-articles/news-articles/2025/10/asia-pacific-roundup-india-s-cdsco-seeks-feedback

[12] Ayushman Bharat Digital Mission (ABDM). ABDM. India: National Health Authority, Ministry of Health & Family Welfare. Available from: https://abdm.gov.in/

[13] Narayan A, Bhushan I, Schulman K. India's evolving digital health strategy. npj Digit Med. 2024 Oct 16;7(1):284.

[14] National Digital Health Mission. Government of India. 2025. ABHA – Ayushman Bharat Health Account. Available from: https://services.india.gov.in/service/detail/abha-ayushman-bharat-health-account

[15] ET Online. AI and ABHA: How Eka Care digitised 110 million health records. Economic Times [Internet]. 2025 Aug 8 [cited 2025 Oct 28]; Available from: https://economictimes.indiatimes.com/small-biz/entrepreneurship/ai-and-abha-how-eka-care-digitised-110-million-health-records/articleshow/123181234.cms?from=mdr

[16] Bureau EN. Revolutionising Indian healthcare through responsible AI integration [Internet]. Express Healthcare. 2025 [cited 2025 Nov 13]. Available from: https://www.expresshealthcare.in/news/revolutionising-indian-healthcare-through-responsible-ai-integration/447607/

[17] IndiaAI. Report on AI Governance Guidelines Development [Internet]. Ministry of Electronics & Information Technology (MeitY), Government of India; 2024 Dec. Available from: https://indiaai.s3.ap-south-1.amazonaws.com/docs/subcommittee-report-dec26.pdf

[18] Global Digital Health Monitor [Internet]. [cited 2025 Nov 13]. Global Digital Health Monitor Map. Available from: https://monitor.digitalhealthmonitor.org/map

[19] Parliament of India. The Digital Personal Data Protection Act [Internet]. Aug 11, 2023. Available from: https://www.meity.gov.in/static/uploads/2024/06/2bf1f0e9f04e6fb4f8fef35e82c42aa5.pdf

[20] Press Information Bureau (PIB). MeitY releases Draft Digital Personal Data Protection Rules, 2025 for public consultation; Feedback/comments sought from public by 18th February, 2025 [Internet]. Government of India; 2025 [cited 2025 Nov 13]. Available from: https://www.pib.gov.in/www.pib.gov.in/Pressreleaseshare.aspx?PRID=2090048

[21] Stop TB Partnership. Wadhwani AI - Cough sound analysis - TB Innovation Sandbox [Internet]. 2025 [cited 2025 Nov 13]. Available from: https://sandbox.stoptb.org/articles/wadhwani-ai-cough-sound-analysis

[22] Singh UB, Rade K, Rao R, Kumar N, Mattoo SK, Nair S, et al. Lessons and updates from India's National TB Elimination Program – bold decisions and innovative ways of fast-tracking progress towards ending TB. IJID Regions [Internet]. 2025 Feb 5 [cited 2025 Nov 13];0(0). Available from: https://regions.ijidonline.org/article/S2772-7076(25)00034-7/fulltext

[23] Das S, Ahamed F, Das A, Das D, Nandi J, Banerjee K. NiADA (Non-invasive Anemia Detection App), a Smartphone-Based Application With Artificial Intelligence to Measure Blood Hemoglobin in Real-Time: A Clinical Validation. Cureus. 2024 July;16(7):e65442.

[24] 2025 Global Health Challenge: Pregnancy Risk Stratification [Internet]. Solve MIT. 2025 [cited 2025 Nov 13]. Available from: https://solve.mit.edu/solutions/101861

[25] Chase India. Regulatory Sandbox for Responsible AI [Internet]. Chase India; Available from: https://www.chase-advisors.com/media/sljmxav/chase-india_regulatory-sandbox-for-responsible-ai.pdf

SINGAPORE

1. Singapore's adaptive approach to AI governance and international collaboration

HIGHLIGHT:

Singapore adopts a practical and risk-based approach to AI governance, building upon a foundation of frameworks focused on driving innovation and adoption. Recent policies address distinct challenges and risks posed by novel AI technologies such as generative AI, including in healthcare contexts.

Singapore was one of the first countries to launch a National AI Strategy in 2019 (updated in 2023) [1][2]. It was also an early mover in developing industry guidance to support the trustworthy development and use of AI through the Model AI Governance Framework (MGF) (updated in 2020) [3].

With the advent of generative AI, Singapore has adopted a holistic and systematic approach, looking at nine dimensions: accountability, data, trusted development and deployment, incident reporting, testing and assurance, security, content provenance, safety and alignment R&D, and AI for Public Good. This is outlined in the 2024 Model AI Governance Framework for Generative AI (MGF-GenAI) [4]. Dimensions like trusted development and deployment, and incident reporting are particularly relevant for AI deployment in clinical settings.

Beyond frameworks, Singapore develops practical tools to help the industry implement responsible AI.

In 2022, it launched a software testing toolkit, AI Verify, to help companies objectively demonstrate the safety of their AI and build credibility and trust with end users. Singapore has open-sourced the AI Verify toolkit and set up the AI Verify Foundation (AIVF), focused on improving AI testing [5]. Singapore's AI testing tools also cover generative AI through Project Moonshot – an evaluation toolkit for LLMs [6].

Regarding the trustworthiness of generative AI applications, in 2025, Singapore launched a Starter Kit for Safety Testing of LLM-Based Applications, to present best practices and testing methodologies [7]. In February 2025, it also launched a Global AI Assurance Sandbox focused on AI systems that comprise large language or multi-modal model. The sandbox provides a technical testing ground for industry and supports the growth of the AI assurance market [8].

Seeking to remain ahead of the curve in international AI governance developments, Singapore has established the Singapore AI Safety Institute to build its AI safety research ecosystem and advance global research on safety and evaluation through international collaborations [9]. With this effort, Singapore joined the international AI safety network comprising the UK, Japan, the US, Canada, EU, and France [10].

Moreover, Singapore has sought alignment with international frameworks, such as harmonization efforts between the AI Verify Testing Framework and the National Institute of Science and Technology (NIST)'s AI Risk Management Framework. The country also contributes to global standards development through forums such as ISO/IEC JTC1/SC 42 on AI [11][12][13][14].

2. Singapore's approach to AI Governance in the health sector

HIGHLIGHT:

Singapore sets clear standards and guidelines to foster trust and reliability in AI healthcare solutions, enhancing patient care and advancing health innovation.

Singapore recognises that good governance is crucial, as AI technologies develop and adoption advances in the healthcare sector. While AI can transform the way care is delivered, it also raises important questions about safety, accountability, and trust.

In 2021, the Ministry of Health (MOH), Health Sciences Authority (HSA), and Synapxe (the national health-tech agency) published the AI in Healthcare Guidelines, establishing good practices for AI developers (e.g., manufacturers or companies) and AI implementers (e.g., healthcare institutions – hospitals, clinics, laboratories), on safe and responsible AI [15]. The guidelines are a

non-legislative instrument that aims to complement the existing regulatory framework and integrate guidance across four domains—products, services, professionals, and data.

As AI technologies mature, Singapore is working on strengthening safeguards to ensure that AI innovation continues to serve patients and healthcare professionals. Singapore has announced it will release the updated AI in Healthcare Guidelines 2.0 in 2026, with comprehensive, practical guidance for the safe and effective use of AI across the healthcare ecosystem. The updated guidelines are expected to reinforce accountability across all stakeholder groups—developers, deployers, and healthcare professionals—with greater emphasis on transparency at every stage of the AI lifecycle. These safeguards aim to support responsible AI innovation, enhance care delivery, and improve patient outcomes.

3. Singapore's approach to AI regulations in the health sector

HIGHLIGHT:

Singapore has developed a suite of regulatory instruments, technical toolkits, and innovation platforms to support the responsible development, testing, safety, security, and deployment of AI systems in health.

Singapore's regulatory framework for AI in healthcare integrates governance across four critical pillars: products, services, professionals, and data. It recognizes that mitigating AI risks involves looking upstream to data sources and downstream to implementers and users, rather than focusing solely on the technology itself. The Health Sciences Authority (HSA) is the national regulator for medical devices, and regulates AIaMD within an existing medical device registration process under the Health Products Act (HPA), setting quality and safety standards that products must meet before entering the healthcare system [16].

In 2018, Singapore's MOH rolled out the Licensing Experimentation and Adaptation Programme (LEAP), a Regulatory Sandbox initiative to better understand new, innovative services by partnering early with industry. This effort led to other initiatives aimed at fostering innovation in a controlled manner. That same year, Singapore launched the Telemedicine sandbox, which is now licensed under the Healthcare Services Act (HCSA) as a Remote Mode of Service Delivery [17].

A recent initiative to facilitate iterative updates of rapidly evolving technology is the launch of the Change Management Program (CMP) for AI/ML-enabled SaMDs in December 2024, which provides guidelines on managing post-market changes, such as algorithm retraining or software updates [18]. It allows developers to implement improvements efficiently while ensuring continued compliance with safety and performance standards. Similar to the Pre-determined Change Control Plan adopted in the US, the UK, and Canada, the CMP allows pre-authorised modifications to approved algorithms, such as retraining or version updates, without requiring full re-registration. To qualify, manufacturers must submit a list of pre-specified changes, performance validation plans, and annual implementation reports.

In parallel to efforts related to AI, Singapore also sought to strengthen the cybersecurity of medical devices with the Cybersecurity Labelling Scheme for Medical Devices—CLS(MD)—launched in October 2024, becoming the first country to do so globally [19]. Jointly developed by the Cyber Security Agency of Singapore (CSA), the Ministry of Health (MOH), HSA, and Synapxe, the scheme rates medical devices based on their levels of cybersecurity provisions. It provides a standardised framework to incentivise manufacturers to adopt a security-by-design approach while empowering healthcare providers and consumers to make informed decisions about the medical devices they use.

The framework covers secure software design, vulnerability management, and data protection. The CLS(MD) certification seeks to demonstrate a manufacturer's commitment to safeguarding patient protection and medical device integrity against cybersecurity threats.

4. International partnerships to accelerate medical device approvals and foster global collaboration

HIGHLIGHT:

Singapore leverages regulatory reliance to expedite medical device approvals and collaborate with international regulators to pilot fast-track initiatives.

HSA employs a regulatory reliance approach for medical devices, including Software as a Medical Device (SaMD), to enhance efficiency, reduce duplication of efforts, and expedite patient access to innovative technologies by leveraging assessments from trusted international regulators. This strategy involves abridged and expedited evaluation pathways for Class B, C, and D devices that have obtained prior approvals from reference authorities such as Australia's Therapeutic Goods Administration (TGA), the United States Food and Drug Administration (U.S. FDA), Japan's Ministry of Health, Labour and Welfare (MHLW), Health Canada, and European Union Notified Bodies, allowing for streamlined registrations in Singapore and reciprocal recognition where applicable to facilitate market entry in partner jurisdictions [20].

In parallel, HSA partners with other key regulators, such as Thailand's Food and Drug Administration (Thai FDA), Hong Kong's Medical Device Division (MDD), and the Philippines Food and Drug Administration (FDA), by sharing regulatory approaches, best practices, and technical expertise to build trust and encourage their recognition of HSA approvals, thereby expanding access to innovative devices in those markets without HSA necessarily relying on their assessments. In addition, Singapore and Malaysia signed a Memorandum of Understanding in August 2025 to pilot expedited regulatory approvals for medical devices, including SaMD, by leveraging mutual recognition and abridged assessments [21]. This six-month pilot aims to reduce regulatory review timelines by up to 50% and to support future regional regulatory convergence in Southeast Asia.

Furthermore, at the international level, HSA actively participates in the IMDRF, collaborating with the AIMD Working Group to harmonize AI/ML-enabled SaMD principles, including risk classification, lifecycle management, and post-market surveillance. It has also adopted definitions and risk classification criteria from IMDRF to determine when software, including AI-enabled systems, qualifies as a medical device [22].

5. Health data protection and governance

HIGHLIGHT:

Singapore has an integrated health data infrastructure with the potential to support large-scale AI applications. The Personal Data Protection Act (PDPA) serves as the foundational legal framework to govern health data.

Health data is governed by Singapore's Personal Data Protection Act (PDPA), which mandates consent, data security, and breach reporting, establishing baseline standards for personal data protection [23]. The PDPA requires organizations to obtain informed consent before collecting, using, or disclosing personal data and mandates appropriate security measures to prevent unauthorized access or disclosure. Amendments to the PDPA in 2020 introduced mandatory breach notifications, an expanded consent framework, higher penalties for non-compliance, the right to data portability, and conditions under which data may be processed without consent.

Cross-border transfers of identifiable health data are only permitted when the receiving party provides a level of data protection comparable to Singaporean law, typically enforced through binding contractual terms, according to the PDPA's Advisory Guidelines for the Health Sector [24]. Complementing those efforts, Singapore launched the Global Cross-Border Privacy Rules (CBPR) Certification in 2025, allowing organizations to demonstrate alignment with internationally recognized data protection standards [25].

Data Platforms such as HEALIX and TRUST serve as foundational enablers for Singapore's ecosystem for AI in health. They provide secure, standardised, and trusted environments that accelerate AI development and innovation. HEALIX delivers unified analytics, strong governance, and curated datasets to support AI model deployment in the health system. It works hand in hand with TRUST which provides a secure data framework and analytics platform to enable health research with anonymised real-world and research data [26][27].

Together, HEALIX and TRUST form the national backbone for scalable, validated and operational AI solutions across healthcare and research ecosystems.

Bringing the Threads Together: Singapore's governance strategy for AI in health

Singapore's AI in health governance strategy has evolved into a multi-layered ecosystem comprising principled frameworks, sectoral regulation, innovation projects, and international cooperation.

Singapore deploys a range of regulatory tools to address emerging challenges, including legislation, regulatory sandboxes, guidelines, and stakeholder education. However, further developments will be needed as technology and data practices evolve.

Singapore's trajectory in AI governance in health demonstrates how dynamic, adaptive regulation can keep pace with technological innovation while ensuring safeguards are met. As AI capabilities continue to evolve rapidly, Singapore's experience indicates that leveraging shared learning, collaborative oversight, and adaptive frameworks can help harness AI's transformative potential in healthcare systems.

References

[1] National AI Strategy. Republic of Singapore; 2019. Available from: https://file.go.gov.sg/nais2019.pdf

[2] National AI Strategy. Republic of Singapore; 2023. Available from: https://file.go.gov.sg/nais2023.pdf

[3] Infocomm Media Development Authority, Personal Data Protection Commission. Model Artificial Intelligence Governance Framework – Second Edition [Internet]. Singapore: IMDA; 2020. Available from: https://s899a9742c3d83292.jimcontent.com/download/version/1658166641/module/8292101563/name/AISCI-2020-Singapore.pdf

[4] Infocomm Media Development Authority, AI Verify Foundation. Model AI Governance Framework for Generative AI: Fostering a Trusted Ecosystem [Internet]. Singapore: IMDA; 2024 May. Available from: https://aiverifyfoundation.sg/wp-content/uploads/2024/05/Model-AI-Governance-Framework-for-Generative-AI-May-2024-1-1.pdf

[5] AI Verify Foundation. AI Verify Toolkit [Internet]. 2025. Available from: https://aiverifyfoundation.sg/what-is-ai-verify/toolkit/

[6] AI Verify Foundation. Project Moonshot – An LLM Evaluation Toolkit [Internet]. 2025. Available from: https://aiverifyfoundation.sg/project-moonshot/

[7] Infocomm Media Development Authority. Starter Kit for Safety Testing of LLM-Based Applications. Singapore; 2024. Available from: https://www.imda.gov.sg/-/media/imda/files/about/emerging-tech-and-research/artificial-intelligence/large-language-model-starter-kit.pdf

[8] AI Verify Foundation. Global AI Assurance Sandbox. [Internet]. 2025. Available from: https://aiverifyfoundation.sg/ai-assurance/

[9] Singapore AI Safety Institute [Internet]. 2025. Available from: https://www.sgaisi.sg/

[10] 1. Araujo R. Understanding the First Wave of AI Safety Institutes: Characteristics, Functions, and Challenges [Internet]. Institute for AI Policy and Strategy; 2024 Oct [cited 2025 Nov 23]. Available from: https://www.iaps.ai/research/understanding-aisis

[11] National Institute of Standards and Technology. Artificial Intelligence Risk Management Framework (AI RMF 1.0) [Internet]. Gaithersburg, MD: NIST; 2023. Available from: https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.100-1.pdf

[12] Infocomm Media Development Authority. Joint mapping exercise between Singapore IMDA and the US NIST. IMDA [Internet]. 2023; Available from: https://www.imda.gov.sg/resources/press-releases-factsheets-and-speeches/press-releases/2023/nist-imda-joint-mapping-exercise

[13] Infocomm Media Development Authority. Singapore's MERaLION, Southeast Asia's empathetic Large Language Model, Breaks New Ground with Multilingual Processing and Emotional Intelligence [Internet]. 2025 Available from: https://www.imda.gov.sg/resources/press-releases-factsheets-and-speeches/press-releases/2025/sg-meralion-sea-empathetic-large-language-model

[14] International Organization for Standardization. ISO/IEC JTC 1/SC 42 – Artificial intelligence [Internet]. 2017. Available from: https://www.iso.org/committee/6794475.html

[15] Ministry of Health Singapore. Artificial Intelligence in Healthcare Guidelines (AIHGLE) [Internet]. Singapore: Ministry of Health Singapore; 2021. Available from: https://isomer-user-content.by.gov.sg/3/9c0db09d-104c-48af-87c9-17e01695c67c/1-0-artificial-in-healthcare-guidelines-(aihgle)_publishedoct21.pdf

[16] Singapore. Health Products Act [Internet]. Singapore: Singapore Statutes Online; 2007. Available from: https://sso.agc.gov.sg/Act/HPA2007

[17] Ministry of Health Singapore. MOH Launches First Regulatory Sandbox to Support Development of Telemedicine [Internet]. Singapore: Ministry of Health Singapore; 2018. Available from: https://www.moh.gov.sg/newsroom/moh-launches-first-regulatory-sandbox-to-support-development-of-telemedicine/

[18] Health Sciences Authority. GN-37: Change Management Program (CMP) for SaMD, including machine-learning enabled SaMD [Internet]. Singapore: HSA; 2024. Available from: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gn-37-r1-guidance-on-change-management-program-(cmp)-for-samd-including-machine-learning-enabled-samd.pdf?sfvrsn=143fb54a_1

[19] Cyber Security Agency of Singapore. Cybersecurity Labelling Scheme for Medical Devices [Internet]. Singapore: CSA; 2024. Available from: https://www.csa.gov.sg/our-programmes/certification-and-labelling-schemes/cls-md/about/

[20] Jiuang WW. HSA's Regulatory Journey & Regulatory Reliance: Singapore Experience [Internet]. Slides presented at: International Medical Device Regulators Forum; 2024 [cited 2025 Nov 26]; United States of America. Available from: https://www.imdrf.org/sites/default/files/2024-03/05%20-%20WJ%20Wong%20%28HSA%29.pdf

[21] Health Sciences Authority. 2025. Malaysia and Singapore Sign Memorandum of Understanding and Launch Medical Device Regulatory Reliance Pilot to Fast Track Medical Device Market Access. Available from: https://www.hsa.gov.sg/announcements/press-release/HSA-MDAsignMOU

[22] Sethuraman R. Regulatory Updates: Health Sciences Authority, Singapore [Internet]. International Medical Device Regulators Forum; 2022 Sept [cited 2025 Oct 28]; online. Available from: https://www.imdrf.org/sites/default/files/2022-09/Singapore.pdf

[23] Republic of Singapore. Personal Data Protection Act [Internet]. 2012. Available from: https://sso.agc.gov.sg/Act/PDPA2012

[24] Personal Data Protection Commission. Advisory Guidelines for the Healthcare Sector [Internet]. Singapore; 2014 Sept. Available from: https://www.pdpc.gov.sg/-/media/files/pdpc/pdf-files/advisory-guidelines/advisory-guidelines-for-the-healthcare-sector-sep-2023.pdf

[25] Infocomm Media Development Authority [Internet]. [cited 2025 Oct 28]. Global Cross Border Privacy Rules (Global CBPR) Certification. Available from: https://www.imda.gov.sg/how-we-can-help/globalcbpr

[26] Synapxe. Healix [Internet]. Singapore: Synapxe; Available from: https://www.synapxe.sg/healthtech/health-ai/healix

[27] Ministry of Health Singapore. Transforming Healthcare Through Technology [Internet]. Singapore: Ministry of Health Singapore; 2024. Available from: https://www.moh.gov.sg/newsroom/transforming-healthcare-through-technology/

UNITED KINGDOM

1. The UK's flexible, principles-based approach to AI regulation

HIGHLIGHT:

The UK's regulatory strategy has focused on principles and executive branch policies across sectors, avoiding horizontal AI legislation routes. The move seeks to empower sectoral regulators to apply tailored strategies and frameworks and relies on international and cross-sectoral dialogue—for instance, with MHRA's National Commission into the Regulation of AI in Healthcare.

The UK has established a principles-based and context-specific AI governance framework, designed to be "pro-innovation," adaptable, and collaborative. Regulators are expected to follow five cross-sectoral principles: safety, security and robustness; appropriate transparency and explainability; fairness; accountability and governance; contestability and redress [1].

Rather than creating a single AI regulator, the UK empowers specialized agencies to devise programs and apply AI governance principles within their mandates. This was key in the healthcare context, where the stack of existing regulations required tailored strategies and flexibility to adapt regulatory oversight. In October 2023, the Medicines and Healthcare products Regulatory Agency (MHRA) announced the creation of its AI-Airlock [2], a key part of its Software and AI as a medical device change program roadmap [3]. In February 2024, when the government asked regulators to publish an update outlining their strategic approach to AI, the MHRA was able to respond by publishing its approach to address the AI's impact on the regulation of medical devices (see further details in section 2 below) [4].

The UK's "proportionate, flexible regulatory approach" was reiterated in the January 2025 AI Opportunities Action Plan and related documents such as the AI Playbook, which focus on how the government can leverage AI to boost productivity and implement a "pro-innovation" framework to regulate it [5] [6].

Prior to the AI Action Plan, The Department of Health and Social Care and the Prime Minister's Office had launched the 10 Year Health Plan, which includes plans to leverage AI to move toward a prevention-focused system and sets ambitions such as having all hospitals fully AI-enabled within the plan's time span [7].

Furthermore, the MHRA launched the National Commission into the Regulation of AI in Healthcare in September 2025, a non-statutory advisory body of thirteen international experts from academia, civil society, and the healthcare sector tasked with providing recommendations on new regulatory frameworks to support the responsible uptake of AI in healthcare [8].

Although the July 2024 King's Speech included the announcement of a potential forthcoming AI Bill focused on statutory requirements for developers of "the most powerful AI models," the proposal has been delayed until at least Summer 2026 [9] [10]. In parallel, the UK has reaffirmed its pro-innovation stance by advancing policies aligned with the US-UK Technology Prosperity Deal (September 2025), which mirrors the United States' enabling approach and responds to calls for greater global interoperability [11]. While the government leverages expert input on regulation and holds consultations on safety and pre-release testing of frontier models, it remains cautious about the risk of additional regulatory requirements overburdening the national industry.

2. Health regulators advance adaptive oversight, flexible governance, and international alignment

HIGHLIGHT:

The MHRA is modernizing medical device oversight to accommodate adaptive AI systems, introducing streamlined regulatory pathways and clear requirements for managing algorithm changes in clinical settings.

As explored above, the MHRA plays a central role in translating cross-cutting AI principles into concrete regulatory processes tailored to the challenges of adaptive AI in health. This includes ongoing reforms to the medical device regulatory framework that aim to expedite regulatory pathways—for instance, through international recognition of medical devices [12]—and an additional mechanism for managing algorithm updates post-deployment.

This mechanism is the Predetermined Change Control Plans (PCCPs) adopted via principles by the MHRA in collaboration with the FDA and Health Canada [13]. PCCPs seek to enable pre-approved iterative changes to AI algorithms without static reauthorization cycles, ensuring innovation evolves while maintaining safety.

The AI Airlock regulatory sandbox is a crucial element of the UK's hands-on approach in helping actors navigate the transition into the AI age [14]. It provides a controlled environment for real-world testing of AIaMD and refinement, typically prior to deployment, but at any point of the product lifecycle. It serves as a bridge between innovation and patient safety, enabling evaluation of evolving AI systems under regulatory and technical safeguards. The AI Airlock thus promotes multistakeholder engagement, allowing policymakers, regulators, the NHS, and industry actors to co-develop oversight approaches for AI systems in healthcare settings.

On the international cooperation front, the MHRA and the U.S. FDA announced, in October 2025, a renewed strategic collaboration to strengthen regulatory alignment, accelerate patient access to innovative medical technologies, and reduce transatlantic market barriers [15]. This includes the planned introduction of international reliance routes that will allow UK access to devices already approved by the FDA under the 510(k), De Novo, and PMA pathways. These initiatives deepen the UK's adaptive oversight strategy and enhance interoperability among trusted international partners.

3. Strengthening data protection and governance for AI in health

HIGHLIGHT:

The UK's integration of robust data protection and governance principles into AI health regulation ensures compliance with the UK GDPR, safeguards patient privacy, and builds trust in the use of sensitive health information. It promotes early engagement between sectoral and data regulators to embed privacy-by-design, data minimization, and security-by-design into AI systems.

Data protection and governance are positioned as foundational pillars in the UK's AI in health ecosystem, ensuring that technological advances are grounded in strong legal and ethical safeguards. The UK GDPR and the Data Protection Act 2018 provide the statutory backbone for handling personal health data [16] [17]. Moreover, a recent data reform culminated in the adoption of the Data (Use and Access) Act in June 2025.

The UK data protection frameworks mandate that AI systems used in health incorporate privacy-by-design and data minimization from the earliest stages of development (see art. 5(1)9c and 25), aligning technical architecture with legal requirements rather than treating compliance as an afterthought.

The Information Commissioner's Office (ICO) is the national data protection authority responsible for enforcing those regulations. In addition, the National Data Guardian oversees the handling of confidential health and social care data [18]. The MHRA works with the ICO and the National Data Guardian to ensure that AI-based medical devices and digital health tools meet both safety and privacy standards before NHS deployment.

This cross-institutional coordination extends to assessing whether AI models are trained on appropriately collected and lawfully processed datasets, whether data anonymization and pseudonymization techniques are effectively implemented, and whether governance mechanisms can monitor ongoing compliance in adaptive or continuously learning systems.

The UK's approach to data governance and protection in health seeks to balance innovation with the protection of individual rights, fostering a regulatory environment that enables trustworthy and ethically grounded AI adoption.

4. Advancing interoperability and digital infrastructure readiness

HIGHLIGHT:

The UK couples investments in interoperable health IT systems and digital infrastructure along with technical standards alignment for electronic health records—for instance, through the NHS Federated Data Platform.

At the core of the UK's approach is a standards-first architecture anchored in HL7 FHIR and the UK Core profiles, which provide common data models and API patterns for exchanging clinical information across care settings. This creates predictable interfaces for AI services that depend on timely, structured data [19]. When it comes to national standards for health and care records, the Professional Record Standards Body (PRSB) defines standards for what data should be captured and shared, reducing ambiguity and ultimately helping AI applications consume semantically consistent records [20]. These standards are designed for use within IT systems and map to FHIR artefacts, supporting safe, efficient information flow that AI models can rely on.

To operationalize the standards at scale, the NHS Federated Data Platform (FDP) provides a secure software environment that connects operational data, previously siloed, to give clinicians and managers a unified, governed view [21]. By streamlining access in "one safe and secure environment," the FDP underpins AI use cases that require integrated, near real-time data while maintaining robust controls over access and purpose of access [22].

With the appropriate standards (FHIR UK Core), content criteria (PRSB), and a secure federated platform (FDP) in place, the UK is building the plumbing that AI needs to be safe, explainable, and effective inside NHS pathways. A solid data infrastructure that embeds security and governance in its design reduces integration friction for developers and sustains public trust from the outset.

5. Building public trust through societal engagement in AI in health governance

HIGHLIGHT:

The UK has strengthened a culture of public trust by operationalizing transparency, explainability, and bias mitigation across the AI lifecycle in health. In addition, patient and public involvement is increasingly treated as a core element of AI design, development, and adoption, rather than an add-on.

When it comes to transparency and explainability, the ICO-Alan Turing Institute handbook sets practical steps to explain AI-assisted decisions to affected people, helping organizations meet UK GDPR duties and build legitimacy [23]. In parallel, the Algorithmic Transparency Recording Standard (ATRS), requires public bodies to publish clear information on how and why algorithmic tools are used, raising visibility and accountability [24].

On fairness and bias mitigation, the Department for Science, Innovation and Technology provides guidance on responsible access to demographic data so developers and deployers can detect and mitigate bias in practice, recognizing legal, ethical and practical barriers and proposing workable approaches [25]. To support implementers and developers with regulatory pathways and best practices across those domains, NHS operates the AI & Digital Regulations Service (AIDRS) and the AI Knowledge Repository with guidance and case materials for responsible adoption across the NHS [26].

Moreover, the UK seeks to track evolving public attitudes to data and AI to align policies with societal values and expectations. Through nationally representative surveys, the government has monitored levels of awareness, trust, perceived benefits and risks, and preferences for oversight related to data and AI [27].

Bringing the Threads Together: The UK's governance strategy for AI in health

The UK's approach to AI governance in health combines soft law instruments—such as cross-cutting AI principles and regulatory guidance—with consolidated legal frameworks.

This hybrid structure supports innovation and experimentation while safeguarding patient rights, safety, and democratic oversight. When it comes to oversight, rather than adopting a single, horizontal AI law or creating a centralized AI regulator, the UK empowers dedicated agencies such as the Medicines and Healthcare products Regulatory Agency (MHRA), to apply AI principles within their domains.

The UK's regulatory approach is also deeply integrated with its national digital health agenda. Infrastructure initiatives like the NHS Federated Data Platform and a standards-first architecture enable secure, real-time, interoperable data exchange across the NHS.

These foundations are critical for enabling AI deployment at scale, reducing friction for developers, and enhancing data integrity, reliability, and patient trust in clinical applications. Robust data protection and governance frameworks further underpin this model. The Information Commissioner's Office, the National Data Guardian, and the MHRA work in coordination to ensure that AI systems align with privacy-by-design, data minimization, and lawful data processing requirements. Finally, trust and legitimacy are treated not as aspirational goals, but as operational priorities. Through patient and public involvement, explainability standards, and transparency tools, the UK seeks to embed societal alignment directly into its AI governance lifecycle.

Together, these interlocking components form a coherent and adaptive ecosystem, positioning the UK as a pragmatic reference point in the global debate on trustworthy and sustainable AI in health.

References

[1] Department for Science, Innovation and Technology, Office for Artificial Intelligence. A pro-innovation approach to AI regulation [Internet]. Government of the United Kingdom; 2023 [cited 2025 Nov 3]. Available from: https://www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach/white-paper

[2] Medicines and Healthcare products Regulatory Agency (MHRA). GOV.UK. 2023 [cited 2025 Nov 3]. MHRA to launch the AI-Airlock, a new regulatory sandbox for AI developers. Available from: https://www.gov.uk/government/news/mhra-to-launch-the-ai-airlock-a-new-regulatory-sandbox-for-ai-developers

[3] Medicines and Healthcare products Regulatory Agency (MHRA). GOV.UK. [cited 2025 Nov 3]. Software and AI as a Medical Device Change Programme roadmap. Available from: https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-change-programme-roadmap

[4] Medicines and Healthcare products Regulatory Agency (MHRA). Impact of AI on the Regulation of Medical Products: Implementing the AI White Paper principles [Internet]. Government of the United Kingdom; 2024 Apr [cited 2025 Nov 3]. Available from: https://assets.publishing.service.gov.uk/media/662fce1e9e82181baa98a988/MHRA_Impact-of-AI-on-the-regulation-of-medical-products.pdf

[5] Department for Science, Innovation and Technology. GOV.UK. 2025 Jan [cited 2025 Nov 3]. AI Opportunities Action Plan: government response. Available from: https://www.gov.uk/government/publications/ai-opportunities-action-plan-government-response/ai-opportunities-action-plan-government-response

[6] Government Digital Service. Artificial Intelligence Playbook for the UK Government [Internet]. Government of the United Kingdom; 2025 Feb [cited 2025 Nov 3]. Available from: https://www.gov.uk/government/publications/ai-playbook-for-the-uk-government

[7] National Health Services (NHS). Fit for the Future: 10 Year Health Plan for England [Internet]. Government of the United Kingdom; 2025 July [cited 2025 Nov 3]. Report No.: CP 1350. Available from: https://www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future

[8] Medicines and Healthcare products Regulatory Agency (MHRA). GOV.UK. 2025 [cited 2025 Nov 3]. New Commission to help accelerate NHS use of AI. Available from: https://www.gov.uk/government/news/new-commission-to-help-accelerate-nhs-use-of-ai

[9] Prime Minister's Office, 10 Downing Street and His Majesty King Charles III. GOV.UK. 2024 [cited 2025 Nov 3]. The King's Speech 2024. Available from: https://www.gov.uk/government/speeches/the-kings-speech-2024

[10] Courea E, Stacey K. UK ministers delay AI regulation amid plans for more 'comprehensive' bill. The Guardian [Internet]. 2025 June 7 [cited 2025 Nov 3]; Available from: https://www.theguardian.com/technology/2025/jun/07/uk-ministers-delay-ai-regulation-amid-plans-for-more-comprehensive-bill

[11] Prime Minister's Office, 10 Downing Street. GOV.UK. 2025 [cited 2025 Nov 3]. Memorandum of Understanding between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland regarding the Technology Prosperity Deal. Available from: https://www.gov.uk/government/news/memorandum-of-understanding-between-the-government-of-the-united-states-of-america-and-the-government-of-the-united-kingdom-of-great-britain-and-north

[12] Medicines and Healthcare products Regulatory Agency (MHRA). GOV.UK. 2025 [cited 2025 Nov 3]. Statement of policy intent: international recognition of medical devices. Available from: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices/statement-of-policy-intent-international-recognition-of-medical-devices

[13] Medicines and Healthcare products Regulatory Agency (MHRA), U.S. Food and Drug Administration, Health Canada. Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices [Internet]. 2023 Oct [cited 2025 Nov 3]. Available from: https://www.gov.uk/government/publications/predetermined-change-control-plans-for-machine-learning-enabled-medical-devices-guiding-principles

[14] Medicines and Healthcare products Regulatory Agency (MHRA). GOV.UK. 2025 [cited 2025 Nov 3]. AI Airlock: the regulatory sandbox for AIaMD. Available from: https://www.gov.uk/government/collections/ai-airlock-the-regulatory-sandbox-for-aiamd

[15] Medicines and Healthcare products Regulatory Agency (MHRA). GOV.UK. 2025 [cited 2025 Nov 3]. Patients to benefit as UK and US regulators forge new collaboration on medical technologies and AI. Available from: https://www.gov.uk/government/news/patients-to-benefit-as-uk-and-us-regulators-forge-new-collaboration-on-medical-technologies-and-ai

[16] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (United Kingdom General Data Protection Regulation) [Internet]. King's Printer of Acts of Parliament; May 27, 2016. Available from: https://www.legislation.gov.uk/eur/2016/679/contents

[17] Data Protection Act 2018 (c. 12) [Internet]. United Kingdom. May 23, 2018. Available from: https://www.legislation.gov.uk/ukpga/2018/12/notes/division/1/index.htm

[18] National Data Guardian. GOV.UK. 2024 [cited 2025 Nov 3]. National Data Guardian for health and social care. Available from: https://www.gov.uk/government/organisations/national-data-guardian

[19] NHS England Digital [Internet]. [cited 2025 Nov 3]. FHIR UK Core. Available from: https://digital.nhs.uk/services/fhir-uk-core

[20] Professional Record Standards Body [Internet]. PRSB. [cited 2025 Nov 3]. Available from: https://theprsb.org/

[21] NHS England. NHS England. [cited 2025 Nov 3]. NHS Federated Data Platform. Available from: https://www.england.nhs.uk/digitaltechnology/nhs-federated-data-platform/

[22] Department of Health and Social Care. GOV.UK. 2022 [cited 2025 Nov 3]. Secure data environment for NHS health and social care data - policy guidelines. Available from: https://www.gov.uk/government/publications/secure-data-environment-policy-guidelines/secure-data-environment-for-nhs-health-and-social-care-data-policy-guidelines

[23] Information Commissioner's Office, Alan Turing Institute. Explaining Decisions Made with AI [Internet]. ICO; 2025 [cited 2025 Nov 3]. Available from: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/artificial-intelligence/explaining-decisions-made-with-artificial-intelligence/

[24] Government Digital Service. GOV.UK. 2025 [cited 2025 Nov 3]. Algorithmic Transparency Recording Standard Hub. Available from: https://www.gov.uk/government/collections/algorithmic-transparency-recording-standard-hub

[25] Department for Science, Innovation and Technology. Report: Enabling responsible access to demographic data to make AI systems fairer [Internet]. Government of the United Kingdom; 2023 June [cited 2025 Nov 3]. Available from: https://www.gov.uk/government/publications/enabling-responsible-access-to-demographic-data-to-make-ai-systems-fairer/report-enabling-responsible-access-to-demographic-data-to-make-ai-systems-fairer

[26] National Health Service. AI and Digital Regulations Service for health and social care. [cited 2025 Nov 3]. Regulations and Guidance for Developers. Available from: https://digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-developers/

[27] Department for Science, Innovation and Technology. Centre for Data Ethics and Innovation Public Attitudes to Data and AI: Tracker survey [Internet]. Government of the United Kingdom; 2022 Mar [cited 2025 Nov 3]. Available from: https://www.gov.uk/government/publications/public-attitudes-to-data-and-ai-tracker-survey

UNITED STATES

1. The United States' institutional dynamics for AI governance in health: agencies, power structure, and unique landscape

HIGHLIGHT:

The U.S. AI in health landscape is shaped by a decentralized structure and a risk-based approach led by multiple federal agencies. In 2025, this framework saw a significant shift, including internal restructuring, leadership changes, and the growing use of AI tools within agencies.

The United States governance framework for AI in health is defined by a decentralized institutional structure that distributes authority across several federal agencies [1]. The U.S. Food and Drug Administration (FDA), through its Center for Devices and Radiological Health (CDRH), maintains regulatory authority over Software as a Medical Device (SaMD) [2]. The Department of Health and Human Services (HHS), in turn, exercises cross-agency coordination in health information technology through the Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology (ASTP/ONC) [3].

The Federal Trade Commission (FTC) and the Office for Civil Rights (OCR) within HHS complement this ecosystem: The FTC Act prohibits deceptive or unfair practices or acts (Section 5) [4] and the OCR enforces federal civil rights laws and the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules [5]. Finally, the National Institutes of Health (NIH) leads scientific programs such as Bridge2AI [6], which fund the creation of ethically sourced, demographically representative biomedical datasets to address bias in AI model training [7].

This configuration reflects a decentralized yet coordinated governance model that seeks to promote innovation while managing risks through distributed regulatory authority across federal agencies. However, in 2025, the institutional landscape underwent significant administrative and leadership changes [8]. In March 2025, the HHS experienced substantial staff reductions, estimated at around 10,000 positions, across key public health agencies, including the FDA, the Centers for Disease Control and Prevention (CDC), and the NIH [9]. The elimination of several offices and key technology roles has brought uncertainty about regulatory capacity and continuity of the previous structure and governance.

2. Adaptive regulatory evolution of AI-enabled SaMD: FDA's lifecycle approach, SaMD classification, and postmarket challenges

HIGHLIGHT:

The United States has become a key global reference in regulating AI-enabled SaMD, combining a risk-based, total product lifecycle (TPLC) approach with evolving international alignment. Implementation gaps remain around clinical validation, adaptive algorithms, and postmarket oversight.

The FDA, specifically its Center for Devices and Radiological Health (CDRH), regulates many AI-based health applications as Software as a Medical Device (SaMD) that perform medical functions independently of hardware [10]. The FDA adopts a risk-based Total Product Life Cycle (TPLC) approach for AI-enabled device software functions, fostering a comprehensive risk management approach from development through post-market monitoring [11]. AI-enabled SaMD is subject to the same risk-based device classification system (Class I–III) used for all medical devices, with the level of regulatory scrutiny calibrated to their risk level [12]. This national model aligns with the international framework developed by the IMDRF in which the FDA plays a co-leadership role [13].

Over the past several years, the FDA has developed a robust set of guidelines and principles relevant to AI, including through collaboration with Health Canada and the UK's MHRA. This trilateral effort produced foundational documents such as:

- Good Machine Learning Practice (GMLP) principles (2021): A 10-principle framework emphasizing data quality, reproducibility, transparency, and user-centered design [14].
- Predetermined Change Control Plan (PCCP) Guiding Principles (2023): Allowing developers to pre-authorize expected modifications (e.g., periodic retraining) without fully resubmitting regulatory filings, thus better accommodating the iterative nature of machine learning [15].

- Transparency Principles for ML-enabled Medical Devices (2024): Calling for clarity on algorithm performance, limitations, and explainability [16].

The January 2025 draft guidance on AI-enabled SaMD's lifecycle management and market submission introduces comprehensive expectations for design, validation, explainability, cybersecurity, and postmarket monitoring, embedding them into the TPLC framework [17].

Key regulatory innovations in the draft include [18]:

- Encouragement of transparency design considerations, such as developing explainability metrics and visualizations, and validating them via proper testing.
- Suggesting the inclusion of model documentation ("model cards") detailing inputs, outputs, architecture, limitations, and training methodology.
- Clear articulation of risk management strategies, including misuse scenarios, performance degradation, and human factors.
- Integration of UDI (Unique Device Identification) requirements for AI updates, helping track software versions and assess the need for reauthorization.

Despite these advancements, persistent regulatory challenges have emerged. A 2025 cross-sectional study published in JAMA Health Forum reviewed 950 FDA-cleared AI-enabled medical devices and found that 43% of all device recalls occurred within the first year of clearance, double the historical average for all 510(k) devices. Notably, 59% of recalls remained unresolved, and the majority of recalled devices lacked any documented clinical validation, highlighting a critical vulnerability in the premarket review process. Publicly traded companies accounted for 91.8% of all recalls, suggesting that market pressure may incentivize rapid deployment at the expense of safety and effectiveness. The 510(k) pathway, through which most AI-enabled SaMD have received marketing authorization, was not initially designed for such technologies, and its continued use in this context raises concerns of safety and effectiveness [19].

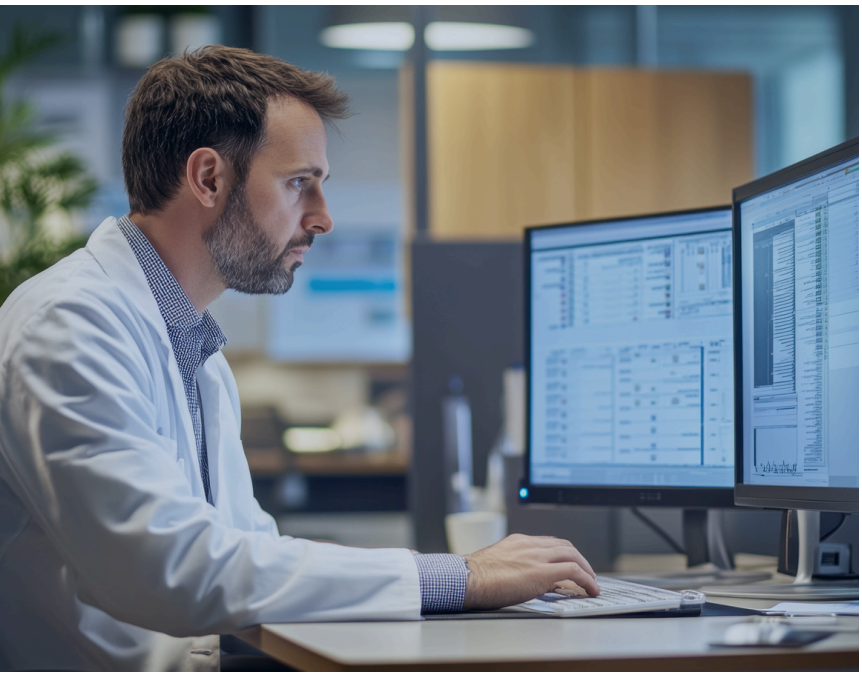
The U.S. regulatory ecosystem for AI-enabled SaMD is evolving towards a more adaptive, flexible, and risk-calibrated model, grounded in international coordination and lifecycle governance. However, significant obstacles remain, including clinical testing, version control, and real-world monitoring, to ensuring that AI in healthcare is safe, effective, and trustworthy throughout its entire lifecycle.

3. Institutional integration of AI in the U.S. FDA's regulatory processes

HIGHLIGHT:

In 2025, the FDA began rapidly integrating AI into its internal regulatory and scientific processes through Elsa, a generative AI tool designed to support agency workflows. This implementation aims to enhance operational efficiency without compromising technical standards, decision traceability, or the role of human oversight.

In May 2025, the FDA announced the completion of a scientific review pilot assisted by generative AI [20]. Based on the agency's internal assessment, this pilot informed a deployment timeline for AI across all FDA centers by June 30, 2025 [21]. The initiative aimed to reduce repetitive workload in technical evaluations and free up expert staff time for higher-value tasks. This institutional precedent informed the formal rollout of *Elsa* under the agency's Chief AI Officer's coordination.



Officially launched in June 2025, *Elsa* is a large language model-based tool developed within a high-security GovCloud environment [21]. The tool is intended to support FDA personnel in tasks such as literature analysis, technical writing, adverse event summarization, and label comparison. According to the FDA, *Elsa* provides a secure platform and is not trained on information submitted by the regulated industry. It is not intended to replace human review or expert decision-making; rather, it is designed to enhance efficiency, accuracy, and consistency under clearly defined oversight and validation protocols ("human-in-the-loop").

Among the initial use cases, *Elsa* has reportedly been applied in pharmacovigilance-related functions, including automated literature screening for safety signals, triage of case reports based on predefined regulatory parameters, and drafting support for regulatory documentation [22]. In mid-June 2025, updates to *Elsa* were announced to address hallucination risks [23].

4. Responsible AI and data challenges in the U.S. federal landscape of AI governance in health

HIGHLIGHT:

Beyond regulatory instruments, the United States navigates structural and ethical considerations in governing AI in health. Unlike other countries with unified privacy laws, the U.S. relies on fragmented, sector-specific, and state-level laws to enhance health data protection.

As AI applications expand across diagnostics, treatment planning, administrative workflows, and public health surveillance, stakeholders and regulators continue to address issues like transparency and accountability alongside safety and effectiveness [24]. They also continue to highlight critical concerns such as fairness, explainability, and societal trust, especially in contexts where AI tools affect diagnosis, triage, or access to care [25][26]. These discussions reflect an ongoing effort to balance rapid innovation with the ethical imperative of doing no harm [27].

Bias and inequity remain core ethical challenges. Algorithms trained on non-representative data may reinforce health disparities unless fairness is built into the entire lifecycle [28]. Transparency and accountability are crucial in addressing those challenges. The National Academy of Medicine (NAM) introduced a Health Care Artificial Intelligence Code of Conduct urging organizations to "center (…) people's needs," "[m]aintain strict oversight," "[d]emonstrate fairness," "[m]ake every stage of AI development and governance open," "[s]hare clear, understandable information about how AI works, performs, and impacts outcomes," and "[d]ocument actions, benefits, and safeguards to ensure responsibility" [29]. Progress continues in translating these high-level principles into concrete audit mechanisms, shared governance mandates, and practical accountability frameworks [30].

However, a critical gap persists in the U.S. governance ecosystem: the lack of a unified, comprehensive federal framework for health data privacy. While HIPAA remains the cornerstone of federal data protection in healthcare, it was not designed to address the complexities of today's digital environment, particularly the proliferation of AI-enabled platforms, health apps, and wearable technologies that operate outside traditional clinical settings [26]. Unlike many countries that have adopted national, cross-sector privacy laws grounded in data-subject rights and consistent enforcement mechanisms, the United States continues to rely on a sector-specific approach at the federal level. Federal bills, such as the American Privacy Rights Act of 2024, were introduced in Congress [31].

However, ultimately, none of them advanced, reflecting the broader complexity of reaching consensus in a federal system where states retain significant authority over privacy matters. As a result, the regulatory landscape has evolved through state-level initiatives, including the passing of comprehensive privacy laws in certain states, designed to address gaps left at the federal level [32]. The lack of a comprehensive federal data privacy law may lead to decreased trust in technology, with growing societal concern over data sharing, commercial uses of health information, and the risk of re-identification, highlighting the need for inclusive and enforceable data governance frameworks that support both technological innovation and individual rights [33].

The AI in health landscape in the United States presents a blend of promise and challenges. The infrastructure provides agility and innovation, with ethical dimensions poised for continued advancement. Bridging the gap between principle and practice will involve inclusive data governance, balanced ethical accountability, and enhanced transparency. Ethical oversight must evolve in parallel with technological progress, not as an afterthought, but as an active force shaping a health system that truly centers human dignity, professional judgment, and equitable outcomes.

5. Translating regulation into practice: implementation pathways, innovation ecosystems, and the rise of regulatory sandboxes

HIGHLIGHT:

The United States is bridging the gap between AI oversight and real-world deployment through collaborative environments, structured data networks, and regulatory sandboxes.

The operationalization of AI governance in the health sector in the United States represents the next frontier beyond regulatory design: the capacity to translate complex guidance into actionable, scalable, and ethically sound practices. At the state level, initiatives akin to regulatory sandbox programs for AI have been created, such as an AI learning laboratory in Utah [34].

In addition, the federal government proposed regulatory sandboxes in its AI Action Plan to bridge the gap between oversight and real-world deployment [35] [36]. These experimental mechanisms are designed to enable the safe testing of AI-enabled health technologies under controlled conditions with regulatory oversight and within defined parameters established by the FDA and other regulators.

The FDA's participation in the Collaborative Communities program has emerged as a strategic priority for stakeholder engagement. It facilitates multi-stakeholder partnerships that can include regulators, healthcare providers, industry developers, and academic experts, helping communities to address healthcare challenges within the medical device ecosystem [37].

In parallel with regulatory innovation, the NIH has advanced the infrastructure required for credible AI validation. Through initiatives like the Bridge2AI program [6], the NIH funds diverse teams to generate representative and AI-ready datasets that support the development of AI-based diagnostics and clinical decision-support systems. The ASTP/ONC furthers interoperability through the Trusted Exchange Framework and Common Agreement (TEFCA), which enables standardized and secure data exchange across health information networks [38].

Within this evolving landscape, regulatory sandboxes, experimental spaces that allow controlled testing of innovative technologies under real-world conditions, are gaining momentum globally as a flexible governance instrument. However, the FDA has not yet implemented a formal sandbox in the legal sense, though the July 2025 AI Action Plan proposed establishing such mechanisms [36]. In addition, the Centers for Medical and Medicaid Services have established reimbursement pathways for specific AI tools, including CPT codes and New Technology Add-on Payments [39].

Bringing the Threads Together: The United States' governance strategy for AI in health

The U.S. regulatory infrastructure introduces a logic of governance through iterative oversight, embracing continuous learning and real-world evidence to support an AI ecosystem in health that is not only effective but also fair and trustworthy.

The U.S. regulatory experience with AI in health demonstrates a living laboratory where governance models are continuously tested amid tensions between agility, fragmentation, innovation, and accountability. In this ecosystem, technical sophistication co-exists with operational gaps, and regulated experimentation aims to fill the voids that traditional legal frameworks have yet to address.

Unlike more centralized or legalistic models, the U.S. approach relies on the functional distribution of regulatory authority, weaving together agencies with distinct mandates that must coordinate to produce coherent responses. This dynamic may also pose risks of diluting regulatory authority, especially for frontier technologies that challenge regulatory structures. The internal deployment of tools like Elsa within federal agencies and the progression of guidance documents without explicit statutory reform are signs of a regulatory system redefining itself through practice more than theory.

Despite normative advances with regulatory guidelines, the proliferation of voluntary frameworks and declarative principles needs to be translated into enforceable obligations to deliver effective governance and protection.

References

[1] Bates BR, Kim J. Artificial intelligence and public health: toward ethical and effective governance. J Health Polit Policy Law [Internet]. 2025 Jan 1 [cited 2025 Nov 17];49(1):57–72. Available from: https://muse.jhu.edu/article/950957

[2] U.S. Food and Drug Administration. Artificial Intelligence in Software as a Medical Device [Internet]. Silver Spring (MD): FDA; 2025 Mar 25 [cited 2025 Nov 17]. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-software-medical-device

[3] Health and Human Services Department. Statement of Organization, Functions, and Delegations of Authority; Office of The National Coordinator for Health Information Technology [Internet]. U.S. Federal Register; 2024 [cited 2025 Nov 28]. Available from: https://www.federalregister.gov/documents/2024/07/29/2024-16571/statement-of-organization-functions-and-delegations-of-authority-office-of-the-national-coordinator

[4] Federal Trade Commission. Federal Trade Commission Act (Incorporating U.S. SAFE WEB Act of 2006) [Internet]. (15) U.S.C. §41 et seq., 109–455 2006. Available from: https://www.ftc.gov/sites/default/files/documents/statutes/federal-trade-commission-act/ftc_act_incorporatingus_safe_web_act.pdf

[5] Department of Health and Human Services. U.S. Department of Human and Health Services. 2008 [cited 2025 Nov 28]. How OCR Enforces the HIPAA Privacy & Security Rules | HHS.gov. Available from: https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/examples/how-ocr-enforces-the-hipaa-privacy-and-security-rules/index.html

[6] National Institutes of Health. National Institutes of Health Office of Strategic Coordination - The Common Fund. 2025 [cited 2025 Nov 28]. Bridge to Artificial Intelligence (Bridge2AI). Available from: https://commonfund.nih.gov/bridge2ai

[7] U.S. Department of Health and Human Services (HHS). Strategic Plan for the Use of Artificial Intelligence in Health, Human Services, and Public Health. Washington D.C.: HHS; January 2025. Available from: https://digitalgovernmenthub.org/examples/u-s-department-of-health-and-human-services-strategic-plan-for-the-use-of-artificial-intelligence-in-health-human-services-and-public-health/

[8] U.S. Department of Health and Human Services. HHS Announces Transformation to Make America Healthy Again [Internet]. Washington (DC): HHS; 2025 Mar 27 [cited 2025 Nov 17]. Available from: https://www.hhs.gov/press-room/hhs-restructuring-doge.html

[9] CNN. RFK Jr. announces major cuts to Department of Health and Human Services [Internet]. 2025 Mar 27 [cited 2025 Nov 17]. Available from: https://edition.cnn.com/2025/03/27/health/hhs-rfk-job-cuts

[10] U.S. Food & Drug Administration. Artificial Intelligence in Software as a Medical Device [Internet]. 2025 Mar 25 [cited 2025 Nov 02]. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-software-medical-device. However, many health-AI-based products fall outside the FDA's regulatory oversight, see, e.g., Gerke, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4404252

[11] Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research. U.S. Food & Drug Administration. FDA; 2025 [cited 2025 Nov 28]. Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing

[12] U.S. Food and Drug Administration. U.S. Food & Drug Administration. FDA; 2025 [cited 2025 Nov 28]. Artificial Intelligence-Enabled Medical Devices. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices

[13] International Medical Device Regulators Forum. IMDRF. [cited 2025 Nov 28]. About IMDRF | International Medical Device Regulators Forum. Available from: https://www.imdrf.org/about

[14] U.S. Food & Drug Administration. Good Machine Learning Practice for Medical Device Development: Guiding Principles [Internet]. Oct 27 2021 [cited 2025 Nov 02]. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

[15] Food and Drug Administration. Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles [Internet]. 2023 Oct 24 [cited 2025 Nov 02]. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles

[16] U.S. Food & Drug Administration. Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles [Internet]. Jun 13 2024 [cited 2025 Nov 02]. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/transparency-machine-learning-enabled-medical-devices-guiding-principles

[17] U.S. Food & Drug Administration. Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations [Internet]. Draft guidance. Jan 06 2025 [cited 2025 Nov 02]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing fda.gov+2federalregister.gov+2

[18] U.S. Food & Drug Administration. Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations [Internet]. Jan 06 2025 [cited 2025 Nov 02]. Available from: https://www.fda.gov/media/184856/download

[19] Lee B, Kramer DB, Sandri MT, et al. Early recalls and clinical validation gaps in artificial intelligence–enabled medical devices. JAMA Health Forum. 2025;6(8):e253172. doi:10.1001/jamahealthforum.2025.3172. Available from: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2837802

[20] U.S. Food & Drug Administration. U.S. Food & Drug Administration. FDA; 2025 [cited 2025 Nov 28]. FDA Announces Completion of First AI-Assisted Scientific Review Pilot and Aggressive Agency-Wide AI Rollout Timeline. Available from: https://www.fda.gov/news-events/press-announcements/fda-announces-completion-first-ai-assisted-scientific-review-pilot-and-aggressive-agency-wide-ai

[21] U.S. Food & Drug Administration. U.S. Food & Drug Administration. FDA; 2025 [cited 2025 Nov 28]. FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People. Available from: https://www.fda.gov/news-events/press-announcements/fda-launches-agency-wide-ai-tool-optimize-performance-american-people

[22]PharmaLex. What Project Elsa means for the FDA's appr oach to AI [Internet]. 24 Jul 2025 [cited 2025 Nov 02]. Available from: https://www.pharmalex.com/thought-leadership/blogs/what-project-elsa-means-for-the-fdas-approach-to-ai/#_edn2

[23] Al-Faruque F. FDA: If used for document libraries, Elsa cannot hallucinate; unlikely to be connected to the Internet [Internet]. Regulatory Focus, Regulatory Affairs Professionals Society. 2025 [cited 2025 Dec 1]. Available from: https://www.raps.org/news-and-articles/news-articles/2025/6/fda-says-elsa-can-t-hallucinate,-unlikely-to-ever

[24] U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology. Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing [Internet]. 2024 Jan 09 [cited 2025 Nov 11]. Available from: https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and

[25] Pham T. Ethical and legal considerations in healthcare AI: innovation and policy for safe and fair use. Royal Society Open Science. 2025 May 14;12(5):241873.

[26] Gerke S, Minssen T, Cohen G. Ethical and legal challenges of artificial intelligence-driven healthcare. Artificial Intelligence in Healthcare. 2020 June 26;295–336.

[27] U.S. Congressional Research Service. Artificial Intelligence (AI) in Health Care. Report No. R48319. Washington, DC: United States Congress; 30 Dec 2024 [cited 2025 Nov 11]. Available from: https://www.congress.gov/crs-product/R48319

[28] Centers for Disease Control and Prevention. Health Equity and Ethical Considerations in Using Artificial Intelligence in Public Health and Medicine. Prev Chronic Dis 2024;21:240245 [Internet]. [cited 2025 Nov 11]. Available from: https://www.cdc.gov/pcd/issues/2024/24_0245.htm

[29] National Academy of Medicine. National Academy of Medicine. 2024 [cited 2025 Nov 28]. Health Care Artificial Intelligence Code of Conduct. Available from: https://nam.edu/our-work/programs/leadership-consortium/health-care-artificial-intelligence-code-of-conduct/

[30] National Academy of Medicine. Health Care Artificial Intelligence Code of Conduct [Internet]. May 2025 [cited 2025 Nov 11]. Available from: https://www.nam.edu/our-work/programs/leadership-consortium/health-care-artificial-intelligence-code-of-conduct/

[31] H.R.8819 – American Privacy Rights Act of 2024 [Internet]. [cited 2025 Nov 17]. Available from: https://www.congress.gov/bill/118th-congress/house-bill/8818/text

[32] Gerke S, Jacoby MB, Cohen IG. Bankruptcy, Genetic Information, and Privacy — Selling Personal Information. New England Journal of Medicine. 2025 Mar 5;392(10):937–9.

[33] Rios G. Digital Diagnosis: Health Data Privacy in the U.S. [Internet]. Stanford Law School; 2025 Feb 26 [cited 2025 Nov 17]. Available from: https://law.stanford.edu/2025/02/26/digital-diagnosis-health-data-privacy-in-the-u-s/

[34] Cullimore KA, Moss J. The Artificial Intelligence Policy Act [Internet]. SB0149 May 1, 2024. Available from: https://le.utah.gov/~2024/bills/static/SB0149.html

[35] Do B, Gray S. Balancing Innovation and Oversight: Regulatory Sandboxes as a Tool for AI Governance - Future of Privacy Forum [Internet]. https://fpf.org/. 2025 [cited 2025 Nov 28]. Available from: https://fpf.org/blog/balancing-innovation-and-oversight-regulatory-sandboxes-as-a-tool-for-ai-governance/

[36] The White House. The White House. 2025 [cited 2025 Nov 28]. White House Unveils America's AI Action Plan. Available from: https://www.whitehouse.gov/articles/2025/07/white-house-unveils-americas-ai-action-plan/

[37] U.S. Food & Drug Administration. Collaborative Communities: Addressing Health Care Challenges Together. [Internet]. Silver Spring (MD): FDA; 2025 Sep 25 [cited 2025 Nov 2]. Available from: https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together#:~:text=Collaborative%20Community%20(CHcc)-,What%20Is%20a%20Collaborative%20Community%3F,achieve%20common%20objectives%20and%20outcomes

[38] Department of Health and Human Services. Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA) [Internet]. Washington (DC): HHS; 2024 Dec 16 [cited 2025 Nov 2]. Available from: https://www.federalregister.gov/documents/2024/12/16/2024-29163/health-data-technology-and-interoperability-trusted-exchange-framework-and-common-agreement-tefca

[39] Parikh RB, Helmchen LA. Paying for artificial intelligence in medicine. npj Digit Med. 2022 May 20;5(1):63.

VIETNAM

1. National AI Strategy and DTI Law lay the foundations for responsible AI

HIGHLIGHT:

Through an alignment between its National AI Strategy and its Digital Technology Industry Law, Vietnam is introducing legal definitions, risk-based oversight, mandatory AI content labeling, regulatory sandboxes, and targeted incentives for AI R&D and deployment.

Vietnam launched its first National AI Strategy in 2021, setting out ambitious goals for research, development, and application of AI, as well as regional leadership by 2030 [1]. More recently, moving from strategy to legislative action, the National Assembly passed the Law on Digital Technology Industry (DTI Law), which will enter into force on January 1, 2026 [2]. The strategy establishes a roadmap for AI research, development, and large-scale application across sectors through 2030 [3]. The DTI Law is Vietnam's first standalone digital technology statute and defines AI as a machine-based system capable of learning from data to generate decisions, predictions, or content that affect physical or digital environments [4].

Moreover, the legal text invokes foundational AI governance principles including transparency, accountability, safety and security, and non-discrimination; mandates that AI systems interacting directly with users or creating digital products bear clear identification marks; institutes a risk-based approach requiring licensing or approval particularly for high-risk AI applications in sensitive sectors; sets substantial incentives, such as tax relief, funding, and support for R&D, AI system development, AI data centers, and semiconductors, and the creation of up to 150,000 digital technology firms by 2030 [5]. Finally, it provides for the establishment of a regulatory sandbox for controlled testing of innovative digital technologies, which is authorized but not yet

formally created or active as of October 2025, pending guiding decrees and the law's full effective date [6].

Vietnam's DTI Law not only marks a national milestone but also positions the country among the early global frontrunners in enacting a standalone statute dedicated to the digital technology industry, with specific, enforceable provisions for AI governance. Looking ahead, this statutory base is expected to evolve further. A draft standalone Law on AI was released for public consultation in September 2025, aiming to refine and potentially consolidate the DTI Law's AI provisions through amendments and expansions [7].

he draft introduces a tiered risk classification (unacceptable, high, medium, low), dedicated rules for general-purpose AI models, and clearer accountability across the AI lifecycle. It also establishes prioritized funding from the National Technology Innovation Fund (NATIF) for AI projects and support for collaborative AI ecosystems, including data centers and talent attraction [8]. In parallel, the Ministry of Science and Technology has announced that an updated National AI Strategy will be issued by the end of 2025 to reinforce AI as part of Vietnam's core digital infrastructure, including plans for enhanced computational resources and data accessibility initiatives [9].

Moreover, in the health sector, Vietnam's approach of embedding AI-related provisions within broader digital technology laws rather than issuing a health-specific AI statute has two major implications. First, AI systems used for clinical diagnosis, treatment support, or any functions influencing patient outcomes will, by default, fall into the "high-risk" category under both the DTI Law and the draft AI Law. This implies tighter licensing, conformity assessment, and post-market oversight requirements compared to low-risk health-adjacent AI tools such as symptom checkers or administrative chatbots.

Second, the combined legal architecture creates regulatory space for sector-specific sandboxes. Health is widely expected to be among the earliest sectors eligible for controlled experimentation, especially for adaptive AI models, multimodal clinical AI (image + text + physiologic data), and general-purpose AI (GPAI) repurposed for clinical decision support.

In this context, the Ministry of Health together with the Infrastructure and Medical Device Administration, the Administration of Science, Technology, and Training, the National Health Information Center, research institutes, and academic partners is positioned to play a leading role in defining which AI categories require sandbox evaluation, designing sector-specific risk benchmarks, and co developing practical pathways for safe, supervised clinical testing of innovative AI systems.

2. Responsible AI guardrails and technical standards led by MoST

HIGHLIGHT:

Vietnam advances from high-level commitments to operational tools as the Ministry of Science & Technology issues Decision 1290/QĐ-BKHCN (2024) with nine Responsible-AI principles and adopts national AI standards, providing a shared ethical and technical baseline for safe, transparent, and accountable AI development.

The Decision No.1290/QĐ-BKHCN issued on 11 June 2024, establishes nine voluntary principles for the research and development of responsible AI systems: cooperation, transparency and explainability, controllability, safety and security, privacy and human rights, accountability and user support, respect for human dignity, innovation, and balancing benefits and risks [10].

In parallel, MoST adopted national AI standards in December 2023, including TCVN13902:2023 (equivalent to ISO/IEC 22989:2022), which defines AI concepts and terminology, and TCVN13903:2023 (equivalent to ISO/IEC TR 24028:2020), which provides an overview of trustworthiness in AI systems [11].

For the health sector, the voluntary principles and TCVN standards are already becoming "soft baselines" for hospitals, medical universities, and health-tech companies. They serve as reference points when designing explainable AI systems for radiology, cardiology, oncology, and physiologic signal analysis (ECG, EEG, ultrasound). They also help structure internal technical files for AI-SaMD submissions, aligning them with both Vietnamese requirements (Decree 98/Decree 04) and international expectations (IMDRF, FDA, MDR).

Importantly, these standards provide a framework for addressing model bias, fairness, and human-rights considerations especially critical in screening programs for tuberculosis, lung cancer, breast cancer, and hypertension.

In practice, early-moving healthcare institutions in Vietnam have begun citing TCVN 13902/13903 in project documentation and procurement criteria, using them as evidence of alignment with global norms for safe and trustworthy AI.

3. SaMD in Vietnam: Risk-based regulation with institutional reform and pending AI-specific guidance

HIGHLIGHT:

Vietnam regulates Software as a Medical Device (SaMD) under a risk-based framework aligned with IMDRF and ASEAN MDD principles.. Although software is clearly included in the legal definition of medical devices, there is no specific guidance for AI-based SaMD, which remain subject to general rules and case-by-case classification.

Vietnam regulates SaMD through a legal and institutional framework designed to align with international standards while strengthening national oversight. The main legal instruments, Decree 98/2021/ND-CP [12] and its amendment Decree 07/2023/ND-CP [13], establish that software qualifies as a medical device when it serves functions such as diagnosis, prevention, monitoring, treatment, or physiological support, if it does not act primarily through pharmacological, immunological, or metabolic means. Standalone software must be registered independently, whereas embedded software may be exempt if the hardware is already authorized.

SaMD in Vietnam is classified into four risk levels, ranging from low to high, depending on the software's potential impact on clinical decisions and patient outcomes [14]. This classification follows principles from IMDRF, though no specific criteria have been issued for AI-based or adaptive SaMD [15]. The existing Circular 05/2022/TT-BYT provides general implementation guidance but leaves room for interpretation in the case of complex or adaptive technologies [16]. In regard to oversight, since January 2025, the regulatory authority for SaMD is the Infrastructure and Medical Device Administration (IMDA), which replaced the Department of Medical Equipment and Construction (DMEC) under the Ministry of Health [17]. This transition also introduced a new online portal to streamline submissions [18]. From July 1, 2025 onwards, all medical devices, including SaMD, must obtain full Marketing Authorization; transitional import licenses were phased out in accordance with Decree 04/2025/NĐ-CP [19].

Promotion and commercialization are also tightly regulated. Marketing claims must align with the approved intended use and receive prior approval from the Ministry of Health. The elimination of transitional licensing in mid-2025 tightened enforcement and marked a new phase in Vietnam's regulatory maturity [20].

Vietnam's regulatory framework for SaMD reflects a strong alignment with international good practices and continues to evolve steadily. Recent reforms have reinforced regulatory oversight and introduced clearer procedures, particularly for higher-risk software.

While the absence of dedicated guidance for AI-based SaMD remains an area for further development, it also represents an opportunity for future updates to enhance clarity and provide more predictable, supportive pathways for innovation in digital health.

4. Legal foundations for data protection in Vietnam

HIGHLIGHT:

Vietnam sought to reinforce cross-sector AI accountability through the Personal Data Protection Decree 13/2023, establishing GDPR-style duties on processing and cross-border data transfers, and the DTI Law, which mandates AI-content labeling and empowers sectoral guidance.

Vietnam's Decree No. 13/2023/ND-CP ("PDPD"), issued on 17 April 2023 and effective from 1 July 2023, establishes foundational data protection obligations across all sectors [21]. It mirrors many elements of the European Union's GDPR by requiring data processors to conform to principles of lawfulness, transparency, purpose limitation, data minimization, accuracy, integrity, confidentiality, and accountability [22]. It mandates informed consent (with narrow exceptions), grants data subject rights (including access, correction, deletion, objection, and withdrawal), imposes requirements for impact assessments on data processing and cross-border transfers, compels entities to appoint data protection officers and adopt adequate security measures, and allows for disciplinary, administrative, or criminal penalties for violations [23].

Together, the legal instruments presented in the first section and Decree 13 establish a shared legal foundation for personal data protection, transparency, and accountability in the use of AI systems in Vietnam. While Decree 13 sets out general privacy principles applicable across all sectors, the DTI Law introduces specific obligations to ensure that AI-based technologies can be clearly identified, understood, and properly monitored. This regulatory combination represents an initial cross-sectoral framework aimed at balancing technological innovation with the protection of fundamental rights, thereby laying the groundwork for a more trustworthy and responsible AI ecosystem.

5. Real-world deployments of AI in health and the national digital health policy

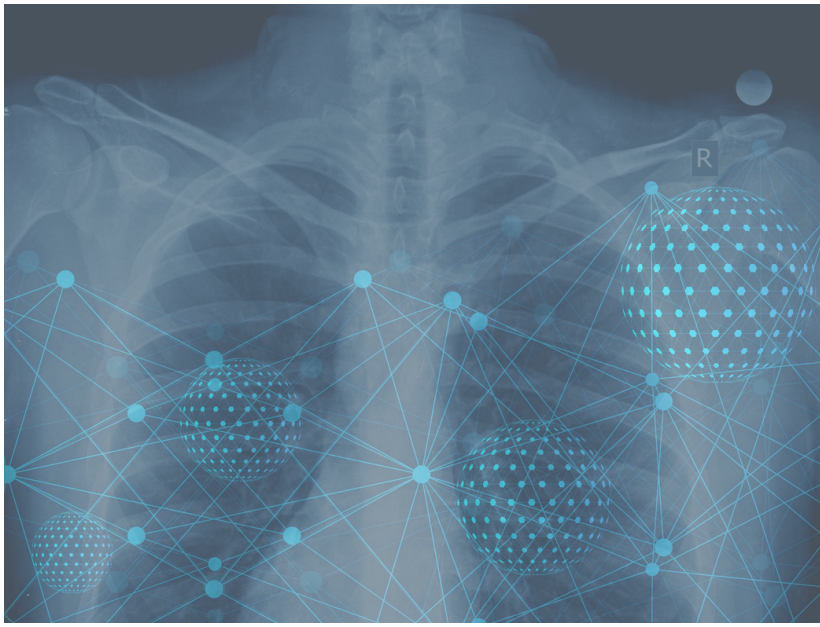
HIGHLIGHT:

Vietnam leverages its national digital health infrastructure, anchored in the MoH Digital Transformation Scheme (Decision 5316/QĐ-BYT, 2020), to enable real-world AI deployments that are clinically validated and aligned with international standards.

The Ministry of Health's Digital Transformation Scheme, issued under Decision No. 5316/QĐ-BYT in December 2020, outlines a comprehensive roadmap for the digitalization of Vietnam's health system [24]. This strategy prioritizes the nationwide rollout of electronic medical records (EMRs), telemedicine services, electronic health data systems, and interoperability between levels of care, laying the groundwork for the adoption of advanced digital tools, including AI. These policy efforts aim to improve healthcare delivery, continuity of care, and data-driven decision-making across public and private sectors [25].

This milestone not only illustrates the country's technical capabilities but also reflects a growing commitment to developing local AI systems that meet international safety and efficacy standards, aligning with Vietnam's broader digital health transformation agenda [27].

A clear example of this real-world AI integration is DrAid™ for Radiology v1, a chest X-ray triage and prioritization tool developed by Vietnamese company VinBrain [26]. The software leverages AI to assist radiologists in identifying abnormalities on chest radiography, enabling faster diagnosis and prioritization of critical cases. Importantly, DrAid became the first Vietnamese AI medical product to receive FDA 510(k) clearance (K221241) in September 2022 as a Class II radiological computer-assisted triage and notification system.



Bringing the Threads Together: Vietnam's governance strategy for AI in health

Vietnam's approach to AI regulation in health is evolving through a layered framework that combines national digital transformation policies, sectoral health strategies, and emerging legal instruments for AI governance.

Instead of enacting health-specific AI laws, Vietnam integrates AI governance into existing structures, such as in its digital health strategy (Decision 5316/QĐ-BYT), SaMD regulation (Decree 98/2021 and Circular 05/2022), and national AI and data governance frameworks, creating a regulatory environment that remains cross-sectoral.

The Digital Technology Industry Law (DTI Law), is set to bring enforceable provisions for AI governance. The provisions are reinforced by Decree 13/2023 on personal data protection, which mirrors the GDPR's principles and imposes duties on lawful processing, consent, cross-border transfers, and accountability. Together, these instruments provide enforceable safeguards for responsible data use and transparency, directly supporting AI adoption in health.

Within the health sector, AI integration builds on the Ministry of Health's Digital Transformation Scheme (Decision 5316/QĐ-BYT, 2020), which prioritizes electronic medical records, telemedicine, interoperable health data systems, and evidence-based decision-making.

In Vietnam, AI applications in health are currently regulated under the pathways for SaMD. Developing dedicated guidance for AI-based devices will require multi-stakeholder participation—including MoH (IMDA, ASTT, NHIC, Legal Affairs), MoST (standards, conformity assessment, digital infrastructure, cybersecurity), academic institutions, medical societies, and experts.

Vietnam's regulatory strategy for AI in health now rests on three interdependent layers: 1) A robust digital health transformation agenda that provides operational readiness; 2) cross-sectoral statutory instruments (DTI Law, Decree 13/2023) that establish cross-sector accountability and transparency; and 3) Ethical and technical frameworks (Decision 1290 and TCVN standards) that anchor responsible and interoperable AI development.

References

[1] Quyết định số 127/QĐ-TTg: Ban hành Chiến lược quốc gia về nghiên cứu, phát triển và ứng dụng Trí tuệ nhân tạo đến năm 2030 [Internet]. Government of Vietnam; 2021. Available from: https://thuvienphapluat.vn/van-ban/Cong-nghe-thong-tin/Quyet-dinh-127-QD-TTg-2021-Chien-luoc-nghien-cuu-phat-trien-va-ung-dung-Tri-tue-nhan-tao-den-2030-463680.aspx

[2] Dung T. Law on Digital Technology Industry approved. Socialist Republic of Viet Nam Government News [Internet]. 2025 June 14 [cited 2025 Nov 10]; Available from: https://en.baochinhphu.vn/law-on-digital-technology-industry-approved-111250614143640329.htm

[3] Quynh Hoa N. Vietnam's AI Sector in 2025: Regulatory Frameworks & Investment Scope [Internet]. Vietnam Briefing News. 2025 [cited 2025 Nov 10]. Available from: https://www.vietnam-briefing.com/news/vietnams-ai-sector-in-2025-regulatory-frameworks-and-opportunities-for-investors.html/

[4] Anh Hoang P, Keil P. Vietnam: Landmark Law on Digital Technology Industry - New Frameworks for AI & Digital Assets [Internet]. DFDL. 2025 [cited 2025 Nov 10]. Available from: https://www.dfdl.com/insights/legal-and-tax-updates/vietnam-landmark-law-on-digital-technology-industry-new-frameworks-for-ai-digital-assets/

[5] Ngoc Bich Nguyen T, Thi Huong Tran G, Minh Vu Q. Vietnam's Digital Tech Industry Law: Building the Future of AI, Chips, and Digital Assets [Internet]. Tilleke & Gibbins. 2025 [cited 2025 Nov 10]. Available from: https://www.tilleke.com/insights/vietnams-digital-tech-industry-law-building-the-future-of-ai-chips-and-digital-assets/

[6] Tran MH, Nguyen HT, Nguyen HM, Nguyen TL. Vietnam: New draft Law on Digital Technology Industry and draft Data Law [Internet]. Global Compliance News. 2024 [cited 2025 Nov 10]. Available from: https://www.globalcompliancenews.com/2024/07/31/https-insightplus-bakermckenzie-com-bm-investigations-compliance-ethics-vietnam-new-draft-law-on-digital-technology-industry-and-draft-data-law_07092024/

[7] Piemwichai W, Thu Bui T. Vietnam's AI Push: Updated National Strategy and First AI Law by End of 2025 [Internet]. Tilleke & Gibbins. 2025 [cited 2025 Nov 10]. Available from: https://www.tilleke.com/insights/vietnams-ai-push-updated-national-strategy-and-first-ai-law-by-end-of-2025/

[8] Tran MH, Nguyen HT, Le TM, Dang MT. Baker Mckenzie. 2025 [cited 2025 Nov 10]. Vietnam: Releasing draft AI Law for comprehensive AI governance framework. Available from: https://insightplus.bakermckenzie.com/bm/data-technology/vietnam-releasing-draft-ai-law-for-comprehensive-ai-governance-framework

[9] VOV.VN. Vietnam to update national AI strategy and law by later 2025. 2025 Sept 20 [cited 2025 Nov 10]; Available from: https://english.vov.vn/en/society/vietnam-to-update-national-ai-strategy-and-law-by-late-2025-post1231516.vov

[10] Tran MH, Nguyen HT, Nguyen HM, Nguyen TL. Baker McKenzie. 2024 [cited 2025 Nov 10]. Vietnam: Balancing AI benefits and risks - Vietnam's approach to responsible AI development through voluntary principles. Available from: https://insightplus.bakermckenzie.com/bm/technology-media-telecommunications_1/vietnam-balancing-ai-benefits-and-risks-vietnams-approach-to-responsible-ai-development-through-voluntary-principles

[11] Baker McKenzie. Artificial Intelligence, Profiling and Automated Decision-Making – Vietnam [Internet]. Baker McKenzie; (Global Data and Cyber Handbook). Available from: https://resourcehub.bakermckenzie.com/api/ExportApi/GenerateWordDoc?resourceid=06838d19-a7cf-4b17-abb9-ee4d974e2a59&jurisdictionid=fdacbb42-0ab9-4df9-aabb-65e74699c092&topicid=8285636f-2c56-40ac-b7b9-4a972930148a

[12] Government of Vietnam. Decree No. 98/2021/ND-CP: Regulation on Medical Device Management [Internet]. Nov 8, 2021. Available from: https://dione.vn/blogs/medical-devices/decree-no-98

[13] Vietnam Amends Decree on Medical Device Management [Internet]. Tilleke & Gibbins. Mar 7, 2023 [cited 2025 Nov 10]. Available from: https://www.tilleke.com/insights/vietnam-amends-decree-on-medical-device-management/

[14] Classification of Medical Devices a b c d [Internet]. Medgate. 2024 [cited 2025 Nov 10]. Available from: https://medgate.vn/en/classification-of-medical-devices-a-b-c-d/

[15] Nishimura, Mima AT, Huong NTT. Lexology. 2023 [cited 2025 Nov 10]. Vietnam: Overview of the national rule for Software of Medical Devices (SaMD). Available from: https://www.lexology.com/library/detail.aspx?g=6ca004df-dd62-4b5f-ac7b-4a9e14b9eac6

[16] Ministry of Health, Vietnam. Circular 05/2022/TT-BYT: Detailing the implementation of a number of articles of Decree No. 98/2021/ND-CP on the management of medical devices [Internet]. Aug 1, 2022. Available from: https://asiaactual.com/wp-content/uploads/2023/09/Circular-05-2022-English-version.pdf

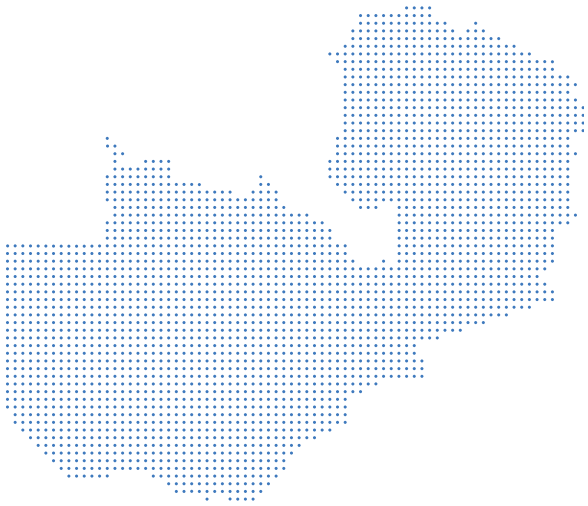
[17] Medical Device Registration in Vietnam Government Authority [Internet]. Asia Actual. [cited 2025 Nov 10]. Available from: https://asiaactual.com/vietnam/medical-device-registration/

[18] Ministry of Health of Vietnam. Infrastructure and Medical Device Administration [Internet]. [cited 2025 Oct 28]. Available from: https://imda.moh.gov.vn

[19] Government of Vietnam. Decree 04/2025/ND-CP amending Decree 98/2021/ND-CP on management of medical equipment, amended and supplemented under Decree 07/2023/ND-CP [Internet]. 2025 [cited 2025 Nov 10]. Available from: https://english.luatvietnam.vn/y-te/decree-04-2025-nd-cp-management-of-medical-equipment-385264-d1.html

[20] Vo D. Vietnam Medical Device Market Access in 2025 [Internet]. Asia Actual. 2025 [cited 2025 Nov 10]. Available from: https://asiaactual.com/blog/vietnam-medical-device-market-access-2025/

ZAMBIA



1. Zambia's foundational National AI Strategy (2024–2026) and AI developments in health

HIGHLIGHT:

Zambia recently adopted the Zambia National Artificial Intelligence Strategy (2024–2026), marking an important milestone in the country's digital transformation. While the strategy highlights healthcare as a strategic sector and includes initiatives like sector-specific working groups and a pilot with Qure.ai, further efforts are needed to develop tailored regulatory guidance and implementation mechanisms for AI in health.

Zambia's National AI Strategy 2024-2026 [1] was launched in late 2024 to harness AI as a catalyst for economic growth, job creation, and improved public services across six priority sectors, including healthcare. The foundational document, spearheaded by the Ministry of Technology and Science [2] outlines a high-level governance roadmap through the establishment of a National AI Council tasked with oversight, ethical guidelines, and coordination of AI initiatives, while emphasizing equitable benefits and responsible deployment to position Zambia as an AI hub in Africa. The strategy explicitly identifies the healthcare domain as a strategic sector ripe for AI applications, such as enhancing diagnostics and disease management, with early momentum evident in pilot projects like the partnership between the Centre for Infectious Disease Research in Zambia (CIDRZ) and Qure.ai, which utilizes AI-powered medical imaging diagnostics for tuberculosis screening across seven hospitals in Zambia [1].

Within the strategy, Technical Working Groups (TWGs) are formally established as an integral part of Zambia's AI governance framework. These groups are created under the authority of the Ministry of Technology and Science and coordinated in alignment with the National AI Council. Rather than being cross-sectoral, each TWG is sector-specific, focusing on domains such as healthcare, education, agriculture, finance, and mining. The TWGs are designed to bring together a diverse range of stakeholders from across the ecosystem, including government officials, academic researchers, private sector practitioners, non-governmental organizations, and technical experts in AI and data science. They are tasked with developing and overseeing the implementation of AI initiatives within their respective sectors, addressing technical challenges, proposing context-relevant solutions, and contributing sector-specific insights to inform broader national AI policies.

This structure not only promotes innovation and collaboration within each sector but also aligns AI implementation with Zambia's broader public service goals, such as equitable service delivery, capacity building, and ethical oversight. By embedding these working groups within the national implementation framework, the strategy enables a more coordinated, participatory, and technically grounded rollout of AI across key areas of national development [1].

To fully realize its health ambitions, the strategy could be further strengthened through the development of more detailed policy and regulatory tools that support implementation at scale. While pilot projects offer a valuable foundation, advancing towards clearer operational frameworks will be important to translate this early momentum into sustainable, system-wide impacts in the health sector.

2. SaMD regulation evolving: Opportunities to clarify pathways for AI-enabled tools

HIGHLIGHT:

Zambia Medicines Regulatory Authority (ZAMRA) plays an important and foundational role in medical device oversight. As the role of AI in clinical applications continues to grow, the development of dedicated pathways for evaluating and certifying AI-enabled Software as a Medical Device (SaMD) represents an area of ongoing progress and future focus.

Zambia's regulatory framework for medical devices is overseen by the Zambia Medicines Regulatory Authority (ZAMRA), established under the Medicines and Allied Substances Act No. 3 of 2013 [3]. Within this act, ZAMRA is responsible for regulating medical devices, including those intended for diagnosis, prevention, monitoring, treatment, or alleviation of disease. The agency ensures that these products meet standards of quality, safety, and efficacy before they are authorized for market access [4].

While Zambia has a global convergence support framework for medical device classification that defines standalone software as an active medical device regulated under its general medical device regulations [5], it has yet to define specific guidance for AI as a Medical Device (AIaMD). SaMD tools are classified [6] under a risk-based system from Class A (low hazard) to Class D (high hazard) and require both clinical evidence as well as technical documentation such as hazard analyses, design documentation, cybersecurity measures, and interoperability assessments. AI-based tools, including those used for clinical decision support or predictive analytics, present unique considerations such as algorithmic transparency, continuous learning, and data dependency, which would benefit from tailored validation approaches. As innovation in this area continues to grow, future efforts to align regulatory pathways with international standards for SaMD and AIaMD could be informed by existing guidance documents, such as those developed by the International Medical Device Regulators Forum (IMDRF). These include the IMDRF's framework for risk categorization of SaMD [7] and its guidance on clinical evaluation [8]. In addition, the principles for machine learning-enabled medical devices [9] (MLMD), developed by the U.S. FDA, Health Canada, and the U.K. MHRA can serve as inspiration as they provide foundational criteria for ensuring safety, effectiveness, and transparency in AI-driven health technologies.

3. Zambia's digital and data governance legislation, coordination, and implementation

HIGHLIGHT:

Zambia has established important digital governance strategies and legal frameworks, such as the 2021 Data Protection Act, that lay a valuable foundation for AI governance. These instruments address key issues related to data protection, digital infrastructure, and ethical use of technology across sectors, forming part of the country's broader efforts in digital transformation. Strengthening coordination across institutions and building enforcement capacity can further support the effective application of these frameworks for AI governance in health.

Zambia has built a legal and policy foundation of digital and data governance through the enactment of pivotal laws and strategies designed to regulate technology and protect information.

The Data Protection Act of 2021

The Data Protection Act of 2021 [10] establishes an effective system for the use and protection of personal data by regulating its collection, transmission, storage, processing, and overall handling to ensure privacy rights and compliance with ethical standards.

The Electronic Communications and Transactions Act of 2009

The Electronic Communications and Transactions Act [11] of 2009 serves as a legal framework for safe electronic data management, imposing penalties for mishandling sensitive information and balancing consumer protection with business interests [12].

The Zambia National AI Strategy for 2024-2026

Further strengthening this basis, the Zambia National AI Strategy for 2024-2026 outlines comprehensive approaches to data governance, including the promotion of secure data infrastructure, ethical data practices, and the establishment of national data repositories to support AI innovation while addressing sovereignty and security concerns, with a proposed National AI Council to oversee ethical compliance and coordinate across stakeholders [1].

The National Digital Health Strategy 2022-2026

In the healthcare context, the National Digital Health Strategy 2022-2026 leverages digital technologies to advance universal health coverage and sustainable development goals, emphasizing governance frameworks for interoperability, cybersecurity, and data privacy to align with national policies [13].

While the legislative and strategic documents provide a solid framework for AI and data governance, its effective implementation remains a work in progress. The involvement of multiple institutions in such initiatives, including the Zambia Information and Communications Technology Authority (ZICTA) [14], the Smart Zambia Institute [15] and the emerging National AI Council, [16] reflects a broad commitment to digital transformation, though coordination mechanisms across these actors are still unfolding.

As the ecosystem matures, efforts to strengthen technical capacity, infrastructure, and inter-agency collaboration will play a key role in supporting the implementation of those frameworks. In the health sector, advancing clarity in data governance and reinforcing accountability structures will be particularly important to enable the safe and effective integration of AI tools that contribute to equitable and innovative healthcare delivery [17].

4. Foundational infrastructure and capacity strengthening: Key enablers for scaling AI in health

HIGHLIGHT:

The adoption of AI in health depends on several enabling factors, including reliable electricity, broadband connectivity, digital infrastructure, and a digitally competent health workforce. Expanding access to digital infrastructure, connectivity, and AI-related training for health professionals represents an important step toward strengthening Zambia's broader environment needed to support the integration of innovative AI solutions across public health systems.

Zambia is laying the groundwork for the integration of AI in the health sector, with important steps underway to expand digital infrastructure and technical capacity [18]. The National Digital Transformation Strategy 2023–2027 [19] reflects a strong national commitment to improving connectivity and digital skills across all sectors, including health. Within this evolving landscape, health facilities in rural areas, are working to improve access to electricity and broadband, both of which are essential to support the use of digital and AI-enabled tools. The 2019 National Health Facility Census highlighted an expanding diversity of power sources in the country, such as solar energy and generators, which demonstrates the country's adaptability and potential to expand off-grid solutions tailored to local needs. Similarly, mobile and broadband coverage continues to grow, which is a prerequisite for real-time digital applications in care delivery [13].

While access to specialized infrastructure such as servers or cloud-based resources is still emerging, the foundation for digital health is gradually taking shape. On the human resources front, capacity strengthening initiatives, like SMART Zambia's digital literacy training [20] are helping health professionals gain confidence in using digital tools.

These efforts, combined with the growing interest in digital health and innovation, signal a promising trajectory for expanding skills in areas such as data management, AI governance, and interoperability. With the progressive alignment of infrastructure, technology, and workforce development, Zambia holds great potential to unlock the benefits of AI for more inclusive and resilient healthcare [21].

5. Pilot initiatives demonstrate AI's promise in health and offer valuable insights for future regulatory development

HIGHLIGHT:

As Zambia continues to explore the use of AI in health, early pilot initiatives, such as the partnership with Qure.ai for tuberculosis screening, are helping to demonstrate the value of AI-powered tools in real-world clinical settings. These experiences not only offer proof of concept, but also contribute to identifying areas where future regulatory development could support broader implementation in a safe and sustainable way.

Zambia, through their Centre for Infectious Disease Research (CIDRZ) [22] implemented a pilot project with the private sector partner Qure.ai to apply AI in the analysis of chest X-rays as part of efforts to improve tuberculosis detection. The software, using qXR, together with the case management platform qTrack, was deployed in seven hospitals across the country, combining both analog and digital radiography equipment with the aim of automating the first stage of screening, reducing pressure on radiologists, and accelerating the referral of patients with suspected tuberculosis [23].

This pilot initiative aligns with Zambia's broader efforts to explore the role of AI in strengthening health service delivery. As outlined in the Zambia National Artificial Intelligence Strategy 2024–2026 [1], regulatory development in sectors such as health is still taking shape, with future work expected in areas like data governance, including privacy and the use of public cloud services for sensitive health information in AI systems, technical standards, and interoperability.

In this context, the experience with Qure.ai also serves as a learning opportunity to inform the development of regulatory and operational frameworks that can support the safe and scalable use of AI to improve diagnosis and health outcomes.

Bringing the Threads Together: Zambia's governance strategy for AI in health

Zambia's path toward governing AI in health reflects a willingness to innovate.

The adoption of the Zambia National Artificial Intelligence Strategy (2024–2026), the recognition of healthcare as a priority sector, and pilot initiatives such as the CIDRZ–Qure.ai project illustrate strong political will and openness to innovation. These efforts build on a broader digital governance framework anchored in the Data Protection Act, the Electronic Communications and Transactions Act, and the Digital Health Strategy 2022–2026, which together establish a foundation for privacy, interoperability, and cybersecurity.

At the same time, Zambia's experience shows that important areas remain to be developed. Electricity and connectivity need expansion, particularly in rural areas where access is still uneven, and the rollout of digital health tools such as electronic health records is progressing gradually. Institutional coordination is also evolving, as multiple bodies, including ZICTA, the Smart Zambia Institute, and the Ministry of Health engage in shaping the digital landscape. Finally, while AIaMD falls under the existing medical device regulations with ZAMRA, further guidance on how to manage the full AIaMD lifecycle could assist the responsible introduction and use of AI in healthcare.

Taken together, Zambia's AI in health governance strategy signals ambition and direction. By building on its current achievements and progressively deepening sector-specific regulations, strengthening participatory mechanisms, and aligning infrastructure development with health priorities, Zambia is well positioned to translate early momentum into sustainable, inclusive, and trustworthy AI applications in health.

References:

[1] Ministry of Technology and Science (MOTS). *Zambia National Artificial Intelligence Strategy 2024–2026* [Internet]. Lusaka: Government of Zambia; 2024 [cited 2025 Oct 16]. Available from: https://www.mots.gov.zm/wp-content/uploads/2025/02/Zambia-Ai-Strategy-Book-option-2.pdf

[2] Ministry of Technology and Science (MOTS). *Official website* [Internet]. Lusaka: Government of Zambia; [cited 2025 Oct 16]. Available from: https://www.mots.gov.zm/

[3] Government of Zambia. *The Medicines and Allied Substances Act.* Act 13 of 2013 [Internet]. Lusaka: Parliament of Zambia; 2013 [cited 2025 Oct 16]. Available from: https://www.zamra.co.zm/wp-content/uploads/2023/05/MASA-No-3-2013.pdf

[4] Zambia Medicines Regulatory Authority. Home [Internet]. Lusaka: ZAMRA; [cited 2025 Oct 16]. Available from: https://www.zamra.co.zm/

[5] Zambia Medicines Regulatory Authority. Guidelines on the Principles of Medical Devices Classifications v1 [Internet]. Lusaka: ZAMRA; 2018 Aug [cited 2025 Oct 16]. Available from: https://www.zamra.co.zm/wp-content/uploads/2023/08/Guidelines-on-the-Principles-of-Medical-Devices-Classifications-v1.pdf

[6] Zambia Medicines Regulatory Authority. Guidelines on Application for Grant of Marketing Authorisation of Non-IVDs [Internet]. Lusaka: ZAMRA; 2024 Jul [cited 2025 Oct 16]. Available from: https://www.zamra.co.zm/wp-content/uploads/2024/07/GUIDELINES-ON-APPLICATION-FOR-GRANT-OF-MARKETING-AUTHORISATION-OF-NON-IVDS.pdf

[7] International Medical Device Regulators Forum. Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations [Internet]. IMDRF; 2014 Oct 13 [cited 2025 Oct 16]. Available from: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.docx

[8] International Medical Device Regulators Forum. Clinical Evaluation [Internet]. IMDRF; 2019 Oct 10 [cited 2025 Oct 16]. Available from: https://www.imdrf.org/documents/clinical-evaluation

[9] U.S. Food and Drug Administration (FDA), Health Canada, United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA). Good Machine Learning Practice for Medical Device Development: Guiding Principles [Internet]. FDA; 2024. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/transparency-machine-learning-enabled-medical-devices-guiding-principles

[10] Zambia. The Data Protection Act [Internet]. N.A.B.No 3 of 2021 Mar 24, 2021. Available from: https://www.parliament.gov.zm/node/8853

[11] Zambia. Electronic Communications and Transactions Act [Internet]. N.A.B.No 4 of 2020 Aug 31, 2009. Available from: https://www.parliament.gov.zm/node/8842

[12] Chikwanda K, Daka S. Analysis on Data Governance Policy in the Health Sector of Zambia: Perspective of Big Data. International Journal of Management Studies and Social Science Research. 2024 Mar 5. Available from: https://www.researchgate.net/publication/378830324_Analysis_on_Data_Governance_Policy_in_the_Health_Sector_of_Zambia_Perspective_of_Big_Data

[13] Zambia Ministry of Health. Digital Health Strategy 2022-2026 [Internet]. 2022. Available from: https://extranet.who.int/countryplanningcycles/planning-cycle-files/digital-health-strategy-2022-2026

[14] Zambia Information and Communications Technology Authority (ZICTA). Homepage [Internet]. Available from: https://www.zicta.zm/

[15] Smart Zambia Institute. Homepage [Internet]; [cited 2025 Oct 16]. Available from: https://www.szi.gov.zm/

[16] Nzuki C. Zambia's National AI Strategy: Balancing Progress with Responsibility [Internet]. Strathmore University Centre for Intellectual Property and Information Technology Law. 2025. [cited 2025 Oct 16]. Available from: https://cipit.org/zambias-national-ai-strategy-balancing-progress-with-responsibility/

[17] Ndembi N, Rammer B, Fokam J, Dinodia U, Tessema SK, Nsengimana JP, et al. Integrating artificial intelligence into African health systems and emergency response: Need for an ethical framework and guidelines. J Public Health Afr. 2025 Mar 31;16(1):876. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC11966719/

[18] Borrowing Agency. Zambia - Improved Rural Connectivity Project : Environmental Project Brief [Internet]. 2020 Jan. Report No.: SFG7253. Available from: http://documents.worldbank.org/curated/en/099030004062222186

[19] Zambia Ministry of Technology and Science. National Digital Transformation Strategy [Internet]. 2023 [cited 2025 Oct 16]. Available from: https://www.mots.gov.zm/wp-content/uploads/2023/10/National-Digital-Transformation-Strategy.pdf

[20] Onyeagoro J. Smart Zambia rolls out digital literacy training for healthcare workers in Mansa. Tech Africa News [Internet]. 2025 July 3 [cited 2025 Oct 17]. Available from: https://techafricanews.com/2025/07/03/smart-zambia-rolls-out-digital-literacy-training-for-healthcare-workers-in-mansa/

[21] Science for Africa Foundation. Governance of Artificial Intelligence for Global Health in Africa: A Review of Policy and Regulatory Frameworks [Internet]. Lusaka: Science for Africa Foundation; 2025 Apr [cited 2025 Oct 16]. Available from: https://scienceforafrica.foundation/sites/default/files/2025-04/Governance%20of%20AI%20for%20Global%20Health%20in%20Africa%20v3.pdf scienceforafrica.foundation

[22] Centre for Infectious Disease Research in Zambia (CIDRZ). Homepage [Internet]. Lusaka: CIDRZ. Available from: https://www.cidrz.org/

[23] Qure.ai. Centre for Infectious Disease Research in Zambia (CIDRZ) partners with Qure.ai for TB screening [Internet]. 2022 [cited 2025 Oct 16]. Available from: https://www.qure.ai/news_press_coverages/centre-for-infectious-disease-research-in-zambia-cidrz-partners-with-qure-ai-for-tb-screening

SECTION 5

CONCLUSION

Across the eight countries examined in this report—Brazil, China, India, Singapore, the United Kingdom, the United States, Vietnam, and Zambia—a noteworthy convergence emerges in how nations are approaching AI governance in health.

Multi-layered architectures combining national AI strategies, data protection legislation, digital health infrastructure, and sector-specific medical device regulations are being leverages to govern AI in health. Notably, countries are aligning with IMDRF-based risk classification frameworks for software as a medical device, reflecting a shared recognition that AI-enabled medical technologies must meet rigorous safety and efficacy standards before reaching patients. At the same time, digital sovereignty emerges as a critical factor in countries' strategies, leading to the adoption of tailored digital health platforms for health data—from Brazil's RNDS and India's Ayushman Bharat Digital Mission to China's four-level population health information platform and Singapore's HEALIX and TRUST.

Although technical challenges are inherent to AI's fast-paced development, such as with the oversight of adaptive systems, broader governance challenges that cut across different government remits are also noteworthy. Multiple agencies hold overlapping mandates, which may create barriers for coordinating oversight. At the international level, the multitude of approaches across jurisdictions complicates the development of baseline international standards and best practices.

Furthermore, despite recent progress in many jurisdictions, infrastructure and connectivity gaps continue to impede equitable AI adoption in areas with uneven access to electricity, broadband, and digital literacy. Across contexts, there is also a considerable distance between high-level policy ambitions and operational enforcement capacity. Many countries have articulated compelling strategic visions but face ongoing work to translate these into enforceable, sector-specific regulations.

Countries are increasingly turning to regulatory sandboxes—such as Singapore's LEAP, and the UK's AI-Airlock—to enable controlled experimentation while generating evidence to inform future regulatory frameworks. International collaboration—including through bilateral agreements, regulatory reliance programs, and harmonization efforts—offers mechanisms for reducing duplication and building trust across borders. In addition to AI governance efforts, ensuring that data governance keeps pace with technological change while enabling secure cross-border data flows will be essential to sustaining momentum.

Ultimately, the countries analyzed demonstrate that while there is no single model for governing AI in health, shared principles—safety, transparency, accountability, and equity—can guide diverse national approaches toward a common objective: ensuring that AI translates into measurable improvements in health outcomes for all.

Moving forward, it is crucial that countries strengthen institutional coordination, expand foundational infrastructure, bridge the gap between innovation and regulatory oversight, and develop a proactive approach to AI governance in health. In addition to the traditional multilateral fora, targeted, AI-focused initiatives among smaller groups of countries may offer a more agile path to achieve those goals and secure a deeper understanding of countries' different contexts.

Participatory processes will also be necessary to reflect diverse voices and increase the likelihood of improving health outcomes for all. Multi stakeholders must be involved in policy-making for AI in health through methodological approaches that deliver evidence-based strategies. Finally, to fully leverage AI development while protecting the population, it will be crucial to adopt proactive risk mitigation strategies, including incident reporting mechanisms and early-warning systems.

HEALTH AI
The Global Agency for Responsible AI in Health

HealthAI is a Swiss-based, globally-oriented nonprofit that champions Responsible AI in health. Its mission is to advance the development and adoption of Responsible AI solutions in health through the collaborative implementation of AI governance, regulatory mechanisms and global standards.

HealthAI – The Global Agency for Responsible AI in Health
Rue de Varembé 7, 1202 Geneva, Switzerland
contact@healthai.agency
www.healthai.agency
+41 (0) 22 552 00 34

Suggested citation
HealthAI – The Global Agency for Responsible AI in Health.
AI Governance in Health: Global Landscape. Geneva, Switzerland; 2025.

© 2025 HealthAI. Some rights reserved.
This publication is licensed under the Creative Commons Attribution–NonCommercial–ShareAlike 3.0 IGO (CC BY-NC-SA 3.0 IGO).