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Emerging Trends in National Artificial Intelligence Governance for Health: A Multi-Country Comparative Analysis

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ABSTRACT

Artificial intelligence (AI) is rapidly reshaping health systems worldwide, offering unprecedented opportunities but also introducing new risks. Effective governance is therefore essential to ensure that AI in health is safe, trustworthy, and aligned with public interest. This article examines emerging global t`rends in AI governance in health across a diverse set of countries. Three major trends are shaping the global governance landscape. First, national health data resources are increasingly treated as strategic assets, reflecting a shift toward digital sovereignty. Countries are investing in nationally governed health data infrastructures to enable AI development while safeguarding national interests. Second, regulators are coordinating between general AI laws and health-specific regulations, adopting different governance approaches based on the countries' situations. Third, regulatory systems are transitioning from static, pre-market gatekeeping to lifecycle-based oversight. Countries such as the United States, the United Kingdom, Canada, Singapore, and China are pioneering mechanisms to manage adaptive AI systems. Beyond these, emerging themes—including regulatory sandboxes, evolving definitions of AI safety, and the prioritization of equity and digital inclusion—are reshaping national strategies. The analysis highlights the need for interoperable standards, robust data governance, and capacity-building for regulators and health institutions.

1 | Background

The potential of artificial intelligence (AI)-driven health solutions to improve the health and well-being of individuals and communities around the world is immense [1, 2]. However, these technologies also present a unique set of risks and challenges, such as unethical data collection, cybersecurity threats, and bias amplification that must be addressed to safeguard their users. Clear and responsive governance frameworks and

Abbreviations: AI, artificial intelligence; AIaMD, Artificial Intelligence as a Medical Device; AIIMS, All India Institute of Medical Sciences; ASTP, Assistant Secretary for Technology Policy; Bridge2AI, Bridge to Artificial Intelligence; CEN-CENELEC, European Committee for Standardization–European Committee for Electrotechnical Standardization; DATASUS, Department of Information and Informatics of the Unified Health System; DG CNECT, Directorate-General for Communications Networks, Content and Technology; EHDS, European Health Data Space; EMR, electronic medical record; EU, European Union; EU4Health, European Union for Health; FAPESP, Sao Paulo Research Foundation; FDA, United States Food and Drug Administration; FHIR, Fast Healthcare Interoperability Resources; GDPR, General Data Protection Regulation; HHS, Department of Health and Human Services; HL7, Health Level Seven; JTC, Joint Technical Committee; MDR, Medical Device Regulation; MHRA, Medicines and Healthcare Products Regulatory Agency; NICE, National Institute for Health and Care Excellence; NIST, National Institute of Standards and Technology; NITI, National Institution for Transforming India; ONC, Office of the National Coordinator for Health Information Technology; SaMD, Software as a Medical Device; TRUST, Trusted Research and Real-World Data Utilisation and Sharing Tech; UK, United Kingdom; US, United States.

Amanda Leal and Yinting Zheng contributed equally to this study.

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regulations are required to establish the safety and effectiveness of these AI systems before providing them to patients and citizens in need. Without them, governments are hesitant to approve the AI systems; technology developers do not have clear pathways to certification or regulatory approval; and private sector companies are left to develop ethical frameworks without a governmental mandate to protect the public good. In other words, proper AI governance in health can help build trust for long-term acceptability and widespread adoption.

The global governance of AI in health is a multi-layered architecture transitioning from high-level ethical principles to enforceable technical standards and clinical practice. As illustrated in Figure 1, this ecosystem operates across three functional layers: the supranational policy layer, the national regulatory layer, and the implementation ecosystem.

At the apex, international entities, such as the World Health Organization [3], the Organisation for Economic Co-operation and Development [4], and United Nations Educational, Scientific and Cultural Organization [5], provide the policy agenda for development, emphasizing principles such as protecting human autonomy, promoting safety and well-being, and ensuring inclusiveness, transparency, and accountability. These goals are further supported by technical standard-setters that advance metrology for AI systems assessment, such as the International Organization for Standardization [6], and for software as a medical device, such as the International Medical Device Regulators Forum [7]. Below this layer, national stakeholders have to transition from being secondary policy observers to becoming the architects of an active governance system. National regulators translate the global norms into policies through AI councils, health ministries, and data protection authorities (e.g., AI Safety Institute in the United Kingdom [8], the State Council of the People's Republic of China [9], or Ministry of Science, Technology and Innovation in Brazil [10]). At the base level, the implementation layer is conducted either by private or public entities who integrate AI into healthcare institutions' workflows, clinical decision support systems, and data-intensive public health operations.

2 | Methods

The analyses presented in this article build upon the foundational country analyses from the AI Governance in Health: Global Landscape 2025 Report [11], developed by HealthAI—The Global Agency for Responsible AI in Health. This paper uses selected jurisdictions as illustrative comparative cases to identify emerging global governance trajectories. The countries presented cover eight jurisdictions, six of which are part of HealthAI's global regulatory network: Brazil, India, Singapore, Vietnam, the United Kingdom, and Zambia. Given their prowess in the field of AI in health, China and the United States were additionally included due to their major influence on global AI governance and Artificial Intelligence as a Medical Device (AIaMD) regulation. The countries were selected to represent varied legal, regulatory, and governance environments across geographies. They also reflect distinct realities in terms of governance capacity, health system structures, resources, and AI adoption levels, each with its own successes

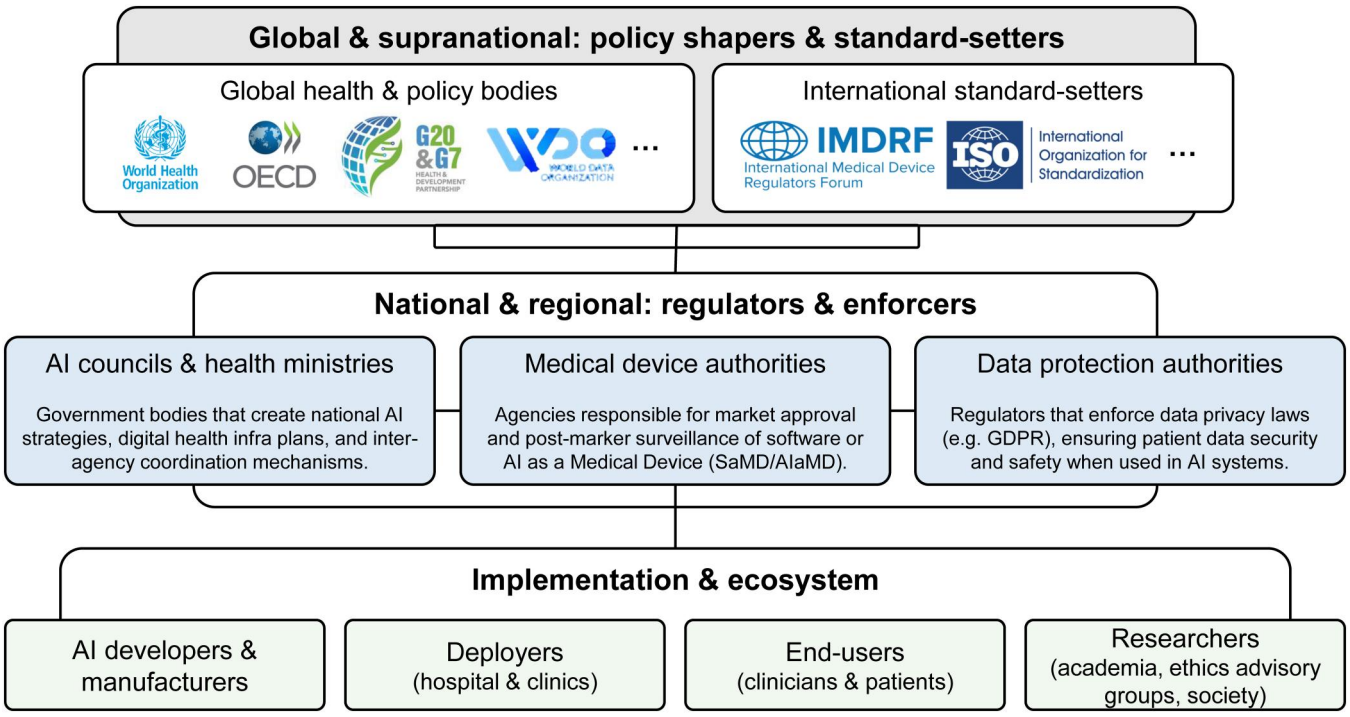


FIGURE 1 | Global AI in health stakeholder architecture. The multi-layered ecosystem governing AI in health, structured across three functional tiers. The global and supranational level sets high-level policy agendas and technical standards. The national and regional level translates global norms into enforceable policies, regulatory pathways, and data governance frameworks. The implementation layer operationalizes AI systems within real-world healthcare settings. AI, artificial intelligence; AIaMD, Artificial Intelligence as a Medical Device; GDPR, General Data Protection Regulation; SaMD, Software as Medical Device.

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and challenges, providing a wide spectrum of experiences and lessons learned.

Data sources included peer-reviewed scientific literature and gray literature with a particular focus on legislative and executive government documents, regulatory guidance, government white papers, and reports from international organizations. Through a purposive comparative analysis approach, this article aims to identify shared patterns, structural differences, and emerging global trends in the governance and regulation of AI in health across the selected group of countries.

3 | Findings

There are three trends that became apparent over the past few years, shaping the current global landscape of AI governance in healthcare.

3.1 | Insight 1: National Health Data Resources as "Digital Sovereignty"

A prominent global trend is the national health data's status as a strategic asset, a phenomenon rooted in a larger trend of "digital sovereignty" [12]. Across jurisdictions, governments are investing in nationally governed health data infrastructures not only to support AI development, but also to strengthen regulatory oversight, reduce dependence on foreign digital platforms, and enhance national control over sensitive population-level data. This orientation is reflected in recent declarations/white papers from organizations such as BRICS [13] and Group of Twenty [14]. Countries are also increasingly investing in nationally governed health data infrastructures, although the specific designs vary by country (Table 1).

Three broad governance models can be observed across countries. China represents a state-led integration model [35], where a four-level (national, provincial, municipal, and county-level) health data platform is organized under the Digital China framework [9]. Brazil and Singapore use more coordinated approaches involving multiple institutions. Brazil employs its National Health Data Network as an interoperability backbone to unify information flows from subnational entities while enforcing its General Personal Data Protection Law to build a rights-based model [15, 36], while Singapore emphasizes secure government-managed research and analytics environments, for example, the Healix and the Trusted Research and Real-World Data Utilisation and Sharing Tech platforms, to foster collaborations to improve patient care [21]. In contrast, India (Ayushman Bharat Digital Mission) [18], the United Kingdom (National Health Service Federated Data Platform) [26, 37], and the United States (Trusted Exchange Framework and Common Agreement) [29] rely more heavily on federated or distributed architectures that prioritize standards, application programming interfaces, and cross-institutional data exchange rather than centralized data repositories. Although each pursues this objective through different approaches, all countries emphasize nationally governed data infrastructures for AI, enabling data exchange among healthcare providers, patients, public health agencies, and payers.

It is worth noting that resource-constrained settings often prioritize foundational digital infrastructure before advanced AI governance mechanisms. Vietnam and Zambia, though very different, share this priority: Vietnam's Medical Digitalization Program (No. 5316/QD-BYT) [32] prioritizes the nationwide rollout of electronic medical records, while Zambia's National Digital Transformation Strategy and Digital Health Strategy focus on foundational enablers like electricity, broadband connectivity, and mobile coverage to support future AI adoption and scaling [34, 38]. These examples suggest that national AI governance pathways are shaped not only by regulatory preferences, but also by broader institutional and infrastructural conditions.

3.2 | Insight 2: The Horizontal–Vertical Regulatory Approaches

Regulators are currently navigating the challenge of how AI in health should be governed: through horizontal AI legislation impacting many sectors at once, or relying on vertical sector-specific regulations such as with medical device regulations and health technology assessment. This tension reflects broader debates over institutional coordination, regulatory capacity, and the appropriate balance between innovation governance and patient safety. We found that across countries, the following regulatory architectures have emerged.

Some jurisdictions have adopted dual-layer governance models that combine horizontal AI legislation with sector-specific medical regulation. In the European Union, for example, AI use in health is covered in the horizontal regulation, the European Union AI Act [22], and falls under the high-risk category. Article 43 (3) of the AI Act clarifies that medical devices that have AI systems as safety components or AI as medical devices must satisfy both the European Union AI Act and the Medical Device Regulation [22]. This approach seeks to ensure consistency across sectors while maintaining health-specific safety oversight, although concerns have emerged about bottlenecks in certification, as notified bodies—already short in capacity—are expected to provide AI assessments in those overlapping cases [39].

Several countries have attempted to clarify the relationship between general AI governance and sector-specific oversight through targeted legislation. Republic of Korea has mitigated this overlap with the Digital Medical Products Act (2025) [40], which explicitly clarifies that "if a requirement is specifically covered by 'the digital health law,' the medical products law takes precedence" over the general AI Basic Act. Vietnam has embedded AI provisions directly within its broad Law on Digital Technology Industry [41], which stipulates that AI systems used for clinical functions influencing patient outcomes will "by default, fall into the 'high-risk' category." Peru's Law No. 31814 [42] positioned AI as a driver of development, but initially lacked sectoral oversight. However, the subsequent Supreme Decree No. 115-2025-PCM [43] mandates formal risk assessments and transparency for high-risk systems in health, gradually expanding from broad innovation-oriented AI legislation toward more operational risk-based oversight mechanisms.

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TABLE 1 | Strategic foundations and national data platforms.

Country/region	Key national/regional strategy	National health data platform (digital sovereignty)	Strategic insight
Brazil	Brazilian Artificial Intelligence Plan 2024–2028 [10]	National Health Data Network [15]	Links AI governance directly to General Personal Data Protection Law privacy safeguards to build a rights-based model
China	Plan for the Overall Layout of the Country's Digital Development [16]	Interconnected 4-level platform (national to county-level) [9]	Treats data as a strategic resource comparable to energy; uses a state-led, top-down integration model [9]
India	IndiaAI Mission [17]	Ayushman Bharat Digital Mission [18]	Uses a federated architecture with open application programming interfaces to position itself as an "AI Garage" for the Global South [19]
Singapore	National AI Strategy 2.0 [20]	Healix (analytics) and TRUST (research) [21]	Infrastructure is designed to provide secure, curated environments that bridge the gap between research and clinical deployment
European Union[a]	European Union AI Act (Regulation EU 2024/1689) [22]; Coordinated Plan on AI [23]	European Health Data Space (Regulation EU 2025/327) [24]	Combines a horizontal, risk-based AI law with a sector-specific health data framework, creating a model that operates above the national level and complements Member States' regulatory systems
United Kingdom	Pro-innovation AI White Paper [25]	National Health Service Federated Data Platform [26]	Focuses on a standards-first architecture (HL7 FHIR) to ensure AI can consume semantically consistent records [27]
United States	HHS AI Strategic Plan [28]	Trusted Exchange Framework and Common Agreement [29]	Relies on functional distribution of authority; focuses on creating representative biomedical datasets (Bridge2AI) [30]
Vietnam	National AI Strategy [31]	MoH Digital Transformation Scheme (Decision 5316) [32]	Digitalization is a phased roadmap, prioritizing the nationwide rollout of EMRs as a prerequisite for AI
Zambia	National AI Strategy 2024–2026 [33]	Digital Health Strategy 2022–2026 [34]	Prioritizes foundational enablers (electricity and broadband) to support AI adoption in rural facilities

Abbreviations: AI, artificial intelligence; Bridge2AI, Bridge to Artificial Intelligence; EMR, electronic medical record; EU, European Union; FHIR, Fast Healthcare Interoperability Resources; HHS, Department of Health and Human Services; HL7, Health Level Seven; TRUST, Trusted Research and Real-World Data Utilisation and Sharing Tech.

[a]The EU is included here given the global influence of the European Union AI Act and European Health Data Space. As a supranational regulatory body, the EU sets binding rules that directly shape AI in health governance across its Member States and operates independently from the United Kingdom following Brexit. This table was compiled by the authors based on HealthAI's AI Governance in Health Global Landscape 2025 Report [11] and supplementary policy documents.

Other jurisdictions prefer sector-led models that rely on existing regulatory agencies rather than comprehensive national AI legislation. The United States and the United Kingdom have empowered specialized government agencies such as the Food and Drug Administration and Medicines and Healthcare Products Regulatory Agency to apply principles-based AI governance tailored to their remit. The United States Food and Drug Administration's Artificial Intelligence/Machine Learning-Based Software as a Medical Device Action Plan [44] emphasizes "a total product lifecycle approach" to regulatory oversight. In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency applies five cross-sectoral principles [25]: "safety, security and robustness; appropriate transparency and explainability; fairness; accountability and governance; and contestability and redress." This distribution of authority is further detailed in Table 2.

These contrasting approaches reflect broader differences in state capacity, legal traditions, institutional design, and regulatory philosophy in these countries.

3.3 | Insight 3: From Static Gatekeeping to Lifecycle Oversight

Another global trend concerns the fast-evolving nature of AI technologies. A primary challenge is that the existing medical device regulatory systems, largely designed for static devices, struggle to accommodate adaptive AI systems and

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TABLE 2 | National key stakeholders in AI governance for health.

Country/ region	Strategic and science leadership	Health policy and administration	Medical device and AI regulation	Data protection and privacy oversight	Research and specialized implementation
Brazil[a]	Ministry of Science, Technology and Innovation	Ministry of Health	National Health Surveillance Agency	National Data Protection Authority	DATASUS (data processing); FAPESP (research funding)
China[b]	The State Council of the People's Republic of China; Ministry of Science and Technology of the People's Republic of China	National Health Commission	National Medical Products Administration	National Data Administration; Cyberspace Administration of China	National Healthcare Security Administration; National Standardization Administration of the People's Republic of China
India	Ministry of Electronics and Information Technology	Ministry of Health and Family Welfare; National Health Authority	Central Drugs Standard Control Organisation	Data Protection Board of India (proposed)	NITI Aayog (think tank); Wadhwani AI; AIIMS
Singapore	AI Verify Foundation; Smart Nation Group	Ministry of Health	Health Sciences Authority	Personal Data Protection Commission	Synapxe (health-tech agency); Singapore AI Safety Institute
European Union	European Commission (DG CNECT-AI policy); European AI Office; European AI Board	Directorate-General for Health and Food Safety; EHDS Board	European Medicines Agency; Medical Device Coordination Group; Notified Bodies (member state level) [45]	European Data Protection Board; European Data Protection Supervisor under GDPR framework [46]	CEN-CENELEC JTC 21 (AI standards) [47]; Joint Research Centre; EU4Health Programme [48]
United Kingdom	Department for Science, Innovation and Technology	Department of Health and Social Care	Medicines and Healthcare Products Regulatory Agency	Information Commissioner's Office; National Data Guardian	National Health Service England; Alan Turing Institute; NICE
United States	NIST (standards); Federal Trade Commission	Department of Health and Human Services	United States Food and Drug Administration	Office for Civil Rights—Health Insurance Portability and Accountability Act (enforcement) [49]	National Institutes of Health; ASTP/ONC
Vietnam	Ministry of Science and Technology	Ministry of Health	Infrastructure and Medical Device Administration	National Health Information Center	Administration of Science, Tech, and Training
Zambia	Ministry of Technology and Science	Ministry of Health	Zambia Medicines Regulatory Authority	Zambia Information and Communications Technology Authority; Smart Zambia Institute	Centre for Infectious Disease Research in Zambia

Note: This table was compiled by the authors based on HealthAI's AI Governance in Health Global Landscape 2025 Report [11] and supplementary policy documents.

Abbreviations: AI, artificial intelligence; AIIMS, All India Institute of Medical Sciences; ASTP, Assistant Secretary for Technology Policy; CEN-CENELEC, European Committee for Standardization–European Committee for Electrotechnical Standardization; DATASUS, Department of Information and Informatics of the Unified Health System; DG CNECT, Directorate-General for Communications Networks, Content and Technology; EHDS, European Health Data Space; EU4Health, European Union for Health; FAPESP, Sao Paulo Research Foundation; GDPR, General Data Protection Regulation; JTC, Joint Technical Committee; NICE, National Institute for Health and Care Excellence; NIST, National Institute of Standards and Technology; NITI, National Institution for Transforming India; ONC, Office of the National Coordinator for Health Information Technology.

[a]Brazil, in slight contrast, represents a state-coordinated but horizontally grounded approach, where health AI is governed primarily through cross-sector legal frameworks—most notably the General Personal Data Protection Law, while horizontal AI laws have been proposed in Parliament but not yet approved, such as the Draft Bill No. 2338/2023 [50]—and sector-specific legislation, normatives, and policies.

[b]China represents a vertically state-led model, in which health AI governance is embedded within sector-specific regulatory hierarchies and national data strategies. Authority flows top-down from the State Council of the People's Republic of China, with clinical governance led by the National Health Commission, safety and market approval enforced by the National Medical Products Administration, and data integration centrally coordinated by the National Data Administration under Data Security Law of the People's Republic of China [51] and Personal Information Protection Law of the People's Republic of China [52].

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post-deployment algorithm changes. Regulators are thus seeking to, as the World Health Organization identifies, shift from a one-time gatekeeping event at market entry to a continuous cycle of monitoring and management that "facilitates continuous AI learning and product improvement while providing effective safeguards." [53].

Several higher-capacity regulatory systems have begun developing formal mechanisms to manage post-deployment algorithm changes. The United States Food and Drug Administration, the United Kingdom Medicines and Healthcare Products Regulatory Agency, and Health Canada have pioneered Predetermined Change Control Plans. These plans allow developers to pre-authorize modifications—such as periodic retraining—without triggering a full new regulatory submission [54]. Singapore adopted a similar Change Management Program in December 2024, providing guidelines on managing post-market changes efficiently while ensuring continued compliance with safety standards [55].

While some countries emphasize procedural flexibility through change in management pathways, China is transitioning from principled guidance to "quantifiable, implementable technical standards" through its Artificial Intelligence Medical Device—Quality Requirements and Evaluation (YY/T 1833.1—2022) [56]. This series covers critical issues like terminology, data annotation, and synthetic data requirements, aiming to adopt a total product lifecycle approach to constructing a quality evaluation framework.

Despite these advancements, a significant maturity gap remains; jurisdictions with limited resources still operate primarily under general medical device rules that lack specific pathways for continuously updating AI technologies. In Zambia, for example, the Zambia Medicines Regulatory Authority regulates software as an active medical device under general rules adapted from International Medical Device Regulators Forum [57], while specific guidance for AIaMD is still pending. Similarly, in India, while the Medical Devices Rules, 2017 [58] establish a four-tier risk classification, they do not yet provide specific criteria for categorizing AI-enabled adaptive devices.

These differences illustrate an emerging global regulatory maturity gap in AI total product lifecycle governance. Figure 2 illustrates how countries differ in both governance scope and regulatory adaptability, ranging from static oversight to a more integrated total product lifecycle approach to governance.

4 | Moving Forward: Emerging Trends in Safety, Ethics, and the Digital Divide

Beyond laws and policies, several emerging trends are reshaping the AI governance in health landscape.

The global governance architecture is an open and evolving ecosystem. As the digital economy expands and cross-border data flows intensify, new actors are entering this space. A recent example is the World Data Organization [59], positioned as a non-governmental,

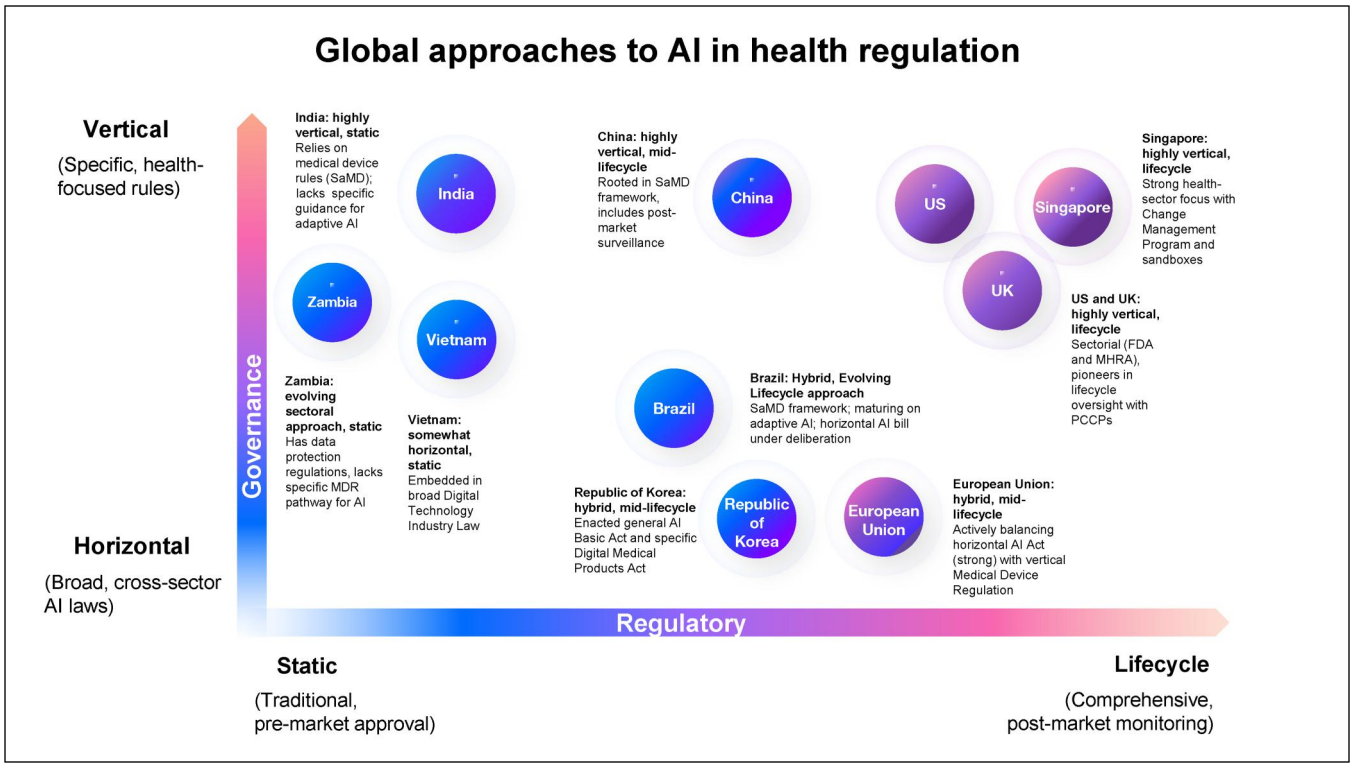


FIGURE 2 | Global approaches to AI in health regulation. The horizontal axis represents the regulatory approach, ranging from static pre-market approval to a total product lifecycle approach to oversight including post-market monitoring, while the vertical axis captures governance scope, from horizontal cross-sector AI laws to vertical, health-specific regulation. National positions reflect dominant regulatory orientation for AI oversight in healthcare. AI, artificial intelligence; FDA, United States Food and Drug Administration; MDR, Medical Device Regulation; MHRA, Medicines and Healthcare Products Regulatory Agency; SaMD, Software as Medical Device; UK, United Kingdom; US, United States.

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non-profit platform emphasizing bridging the data divide and supporting the Global South. It reflects a broader trend toward pluralizing the institutional infrastructure for global data and AI governance. Similar new platforms may emerge in the coming years, particularly in response to the rapid expansion of AI in health and the widening capacity gap between high-income and lower-resource jurisdictions. Recognizing this dynamism is essential for interpreting the trends identified in this study, and for anticipating future shifts in the global governance landscape.

Regulatory sandboxes—controlled environments for real-world testing—have become essential pragmatic bridges for innovation. Examples include the United Kingdom's AI Airlock [60], Singapore's Licensing Experimentation and Adaptation Programme [61], and India's Ayushman Bharat Digital Mission Sandbox [18]. These tools allow regulators to better understand innovative products and services by partnering early with industry and other ministries while generating the real-world evidence needed to inform future standards.

The definition of AI safety is also broadening to encompass equity and ethics in some countries. China's national frameworks emphasize a "people-centered" and "fair and inclusive" approach [62]. In the United States, the Bridge to Artificial Intelligence program focuses on creating ethically sourced, representative datasets to mitigate algorithmic bias. However, a reverse tendency has been noted in the United Kingdom where broad safety mandates have occasionally shrunk to focus more narrowly on technical security and standard-setting, resulting in name changes that emphasize "security" over broader social dimensions [8, 63].

Finally, addressing the digital divide has become a central success metric [64]. Brazil, India and Zambia explicitly integrate equity into their national strategies, focusing on ensuring that AI benefits reach remote regions and Indigenous communities rather than remaining concentrated in urban centers [65]. Moreover, as AI tools proliferate, the expanding gray zone of wellness and general applications that fall outside traditional classification but have considerable public health impacts must be urgently addressed by policymakers. The ultimate goal, for all nations, is to ensure that AI translates into measurable improvements in health outcomes for humanity.

Author Contributions

Amanda Leal: methodology, writing – original draft. **Yinting Zheng:** writing – original draft, investigation. **Muxue Liang:** writing – review and editing, investigation. **Peiling Yap:** conceptualization, methodology, writing – review and editing. **You Wu:** conceptualization, visualization, formal analysis, writing – review and editing.

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Consent

The authors have nothing to report.

Conflicts of Interest

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Data sharing is not applicable to this article as no datasets were generated or analyzed in the current article.

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