AI Governance in Health: Global Landscape 2025

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Report outline

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Timeline Overview

International convenings and policy instruments launched in the past year

2

Global Analysis

Emerging global regulatory trends, best practices, and persistent gaps in AI and data governance in health

3

Country Analysis

Deep dive into the AI governance and health ecosystem for 8 selected jurisdictions

4

Recommendations

Synthesis of findings into actionable recommendations

Global Trends in AI Governance in Health

Regulation of SaMD at the crux of AI and health regulation

- Regulation of SaMD by default includes AI as a medical device, reflecting a shared recognition that AI-enabled SaMD must be safe and effective before reaching patients and citizens.
- General alignment with IMDRF-based risk classification frameworks for SaMD, but there is still contention with the different specifications and definitions of AI and SaMD.
    - Regulatory grey zone: In-house AIaMD used in hospitals and AI applications that do not fall under the medical device classification.
- Mechanisms to address gaps:
    - Use of model cards and nutrition facts-style labels for AIaMD to increase transparency.
    - Predetermined change control plans (PCCP) to allow certain algorithmic modifications post-approval.
    - Innovation needed for post-market surveillance: expanded authority for total product life cycle monitoring, mandatory reporting of real-world change performance, effective incident-response mechanisms, including retract systems.

Intersection of general AI legislation and health

- Multi-layered governance architecture combining horizontal national AI strategies, data protection legislation, digital health infrastructure, and sector-specific medical device regulations.
- **EU AI Act**:
  - Further clarity needed on whether the same notified body can conduct conformity assessment for both AI Act and MDR; same or separate national regulatory authority for both mandates; guidelines to support enforcement.
- **Peru's AI Law**:
  - Early adoption of an AI law demonstrates commitment to responsible AI but there is a need to increase enforcement capacity to operationalize the law.
- **South Korea AI Basic Act**:
  - AI products entering Korea must get MFDS approval under the Digital Medical Products Act and ensure there is compliance with the governance standards of the AI Basic Act.
- For implementation to take place: Strong institutional coordination within government, training regulators, accrediting assessors, and establishing compliance roadmap for industry.

Emergence of data sovereignty in health

- Digital sovereignty emerges as a critical factor in countries' strategies, leading to the adoption of tailored digital health platforms for health data.
- Data governnace is central to regulating AI in health. Different jurisdictions have varied legal systems.
  - Health-adjacent data, from wearables and consumer applications, often fall outside the scope of traditional health data privacy laws.
- Re-identification becomes increasingly possible through cross-identification from different datasets that may enable reversing or inferring individual characteristics.

EU GDPR

- Sectoral health rules that emphasize data minimization, impact assessments and enforcement of individual rights

EU EHDS Regulation

- Increases individuals' rights and controls, and promotes data interoperability in the EU healthcare system

US HIPPA

- Stricter requirements and expanded scope of act may need to be passed.

Brazil GDP Law

- Creation of national health data spaces and the clarification of lawful bases for secondary uses can provide a more integrated data governance architecture

Country Analysis for Selected Jurisdictions

Country analysis: Key takeaways

Cross-cutting challenges for responsible AI governance in health across 8 countries

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 connectivity and digital literacy between urban and rural regions

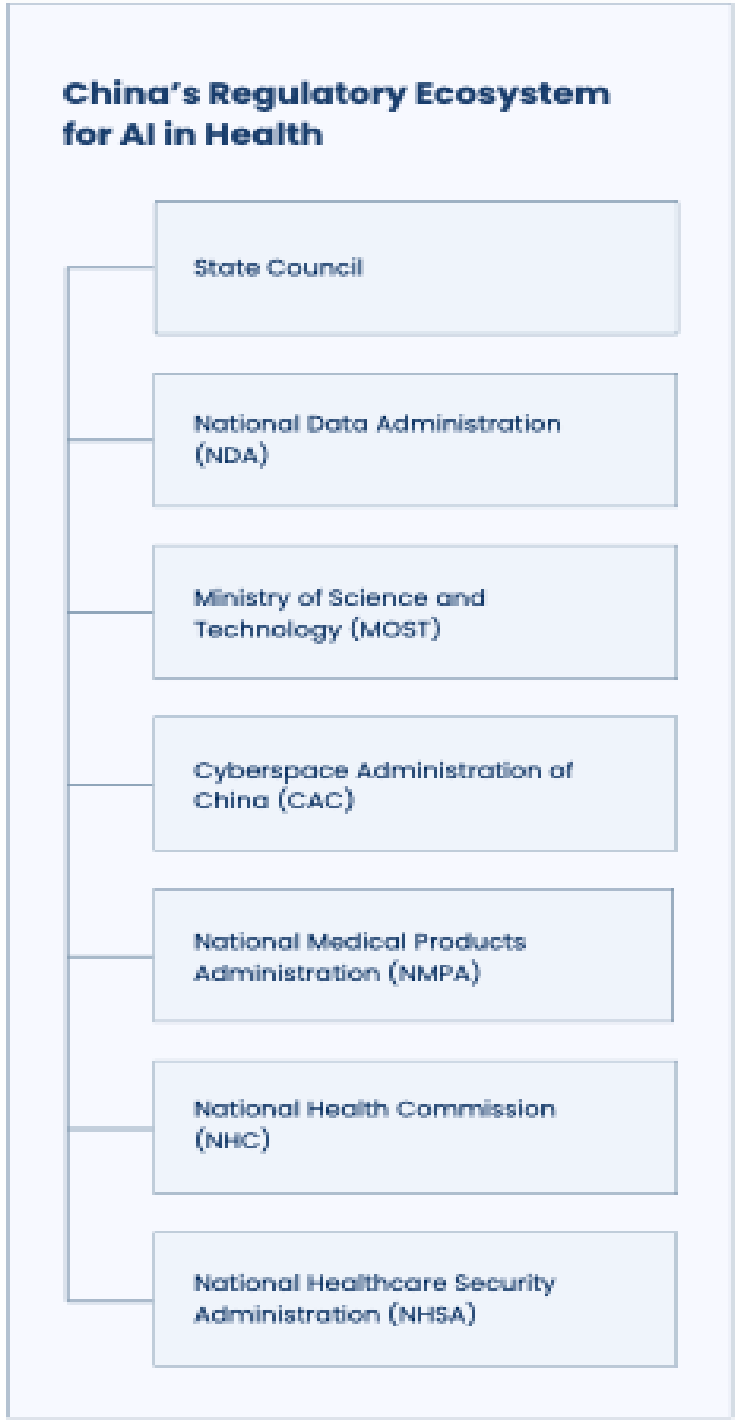
4

Policy and practice divide

Distance between ambitious strategic visions and enforceable regulations with adequate institutional capacity

China's governance strategy for AI in health

- **State council:** Provides top-level legal and policy oversight.
- **NDA:** Coordinates data integration and sharing.
- **MOST:** Drives research and innovation policies and supports ethical AI development.
- **CAC:** Focuses on data security, cybersecurity and issues rules for ethical reviews in digital health applications.
- **NMPA:** Handles approvals and safety evaluations of AI-enabled medical devices.
- **NHC:** Oversees clinical applications of AI in healthcare and issues guidelines.
- **NHSA:** Focuses on pricing standardization, medical insurance and value-based access to AI-enabled health services.



China's governance strategy for AI in health

Building a robust digital highway with data platforms and governance standards

AI in health part of a state-led digital transformation agenda

State council issued new policy in Aug 2025 to promote application of AI across all healthcare services

NDA defines the rights and responsibilities of commercial entities leveraging public health data for AI development

Internet Plus Healthcare – By Dec 2024, 3340 internet hospitals in China – NHC's "Notice on issuing the detailed rules for internet diagnosis and treatment" – *Next stop agentic hospitals?*

NHC leading "**AI Plus Healthcare**" plan sets clear goals for promoting and regulating AI development and use in healthcare with strong focus on primary care by 2027 and secondary and tertiary care by 2030

"**Medical Big Data**" strategy to construct an interconnected 4-level population health information platform

China's governance strategy for AI in health

Guiding vehicles (AI applications) to drive safely and effectively on the highway

Over 110 class III AIaMD approved by Oct 2025 with domestic firms holding over 90% of approvals

NMPA

- Regulation of AI in health firmly rooted in the SaMD framework

Developed specialized guidelines for AIaMD particularly Class II and III

- Risk classification and technical review emphasizing lifecycle management - transparency, data quality, validation of performance metrics
- PMS: Mandatory reporting of adverse events, periodic re-evaluations and updates to the software

Provide **priority support and increased registration guidance for high-risk implantable Brain Computer Interface** medical devices

Alignment with international norms such as EU MDR/IVDR and FDA GMLP to enhance global product mutual recognition

- Aligning domestic review requirements with ICH rules and IMDRF guidelines to promote synchronous global innovation launches in China

Singapore's governance strategy for AI in health

Horizontal AI governance

- Model AI Governance Frameworks for Gen AI (2024) and Agentic AI (2026)
- AI Verify – help companies demonstrate safety of AI products and build trust with end users
  - Starter kit for safety testing of LLM-based applications together with a global AI assurance sandbox

AI governance in health

- AI in Healthcare Guidelines 2.0 (2026)
  - Reinforce accountability across developers, deployers and healthcare professionals
- Emphasizes integrated governance framework across products, services, professionals and data
- Regulatory reliance approach for SaMD with Australia, US, Japan, Canada and EU
- Knowledge sharing with Thailand and the Philippines and recent pilot of expedited regulatory approvals for SaMD with Malaysia

Health data protection and governance

- Data platforms, HEALIX and TRUST
  - Provide secure and standardized environments for AI innovation in health
  - HEALIX delivers unified analytics, strong governance and curated datasets to support AI deployment
  - TRUST provides secure data and analytics platform for health research
- Global Cross-Border Privacy Rules certification launched in 2025 for organizations to demonstrate alignment with international data protection standards

UK's governance strategy for AI in health

Horizontal AI governance

- Five cross sectoral principles:
  - Safety, security and robustness
  - Transparency and explainability
  - Fairness
  - Accountability and governance
  - Contestability and redress
- Focus on empowering sectoral regulators and avoid horizontal legislation routes:
  - AI Opportunities Action Plan and AI Playbook provide a "pro-innovation framework to regulate AI
  - Proposal of an AI Bill during the July 2024 King's Speech delayed until at least summer 2026

AI governance in health

- MHRA launched the National Commission into the Regulation of AI in Healthcare in Sept 2025
  - Provide recommendations on new regulatory frameworks to support responsible uptake of AI in healthcare
- AI Airlock regulatory sandbox provides a controlled environment for real-world testing of AIaMD and refinement, enabling evaluation of evolving AI systems and promoting multistakeholder engagement
- Renew strategic collaboration with US FDA in Oct 2025 to strengthen regulatory alignment and introduce international reliance routes for devices approved under 510(k), De Novo and PMA pathways

Health data protection and governance

- Adoption of the Data (Use and Access) Act in Jun 2025
  - Promotes privacy-by-design, data minimization and security by design into AI systems
- NHS Federated Data Platform provides a secure, unified, governed view of health data
  - HL7 FHIR UK Core enables consistent information flow across the country
  - Reduces integration friction for developers and sustains public trust from the outset

US's governance strategy for AI in health

- Over the past several years, **FDA** has collaborated with Health Canada and UK's MHRA to produce foundational documents such as GMLP, PCCP.
  - Released draft guidance in Jan 2025 on AIaMD's lifecycle management and market submission introducing expectations for design, validation, postmarket monitoring etc within the TPLC framework.

- **NIH** has advanced infrastructure required for AI validation, funding diverse teams to generate representative and AI-ready datasets (Bridge2AI program).

- **ASTP/ONC** enables standardized and secure data exchange across health information networks through the Trusted Exchange Framework and Common Agreement (TEFCA).

- **Centers for Medical and Medicaid Services** have established reimbursement pathways for specific AI tools.

- Decentralized structure distributing authority across several federal agencies. Significant restructuring and leadership changes in 2025 -- uncertainty about the regulatory capacity and continuity of previous structure and governance.

Access the Report

Thank you!

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