Responsible AI for Health: Learnings from the Global Governance Landscape

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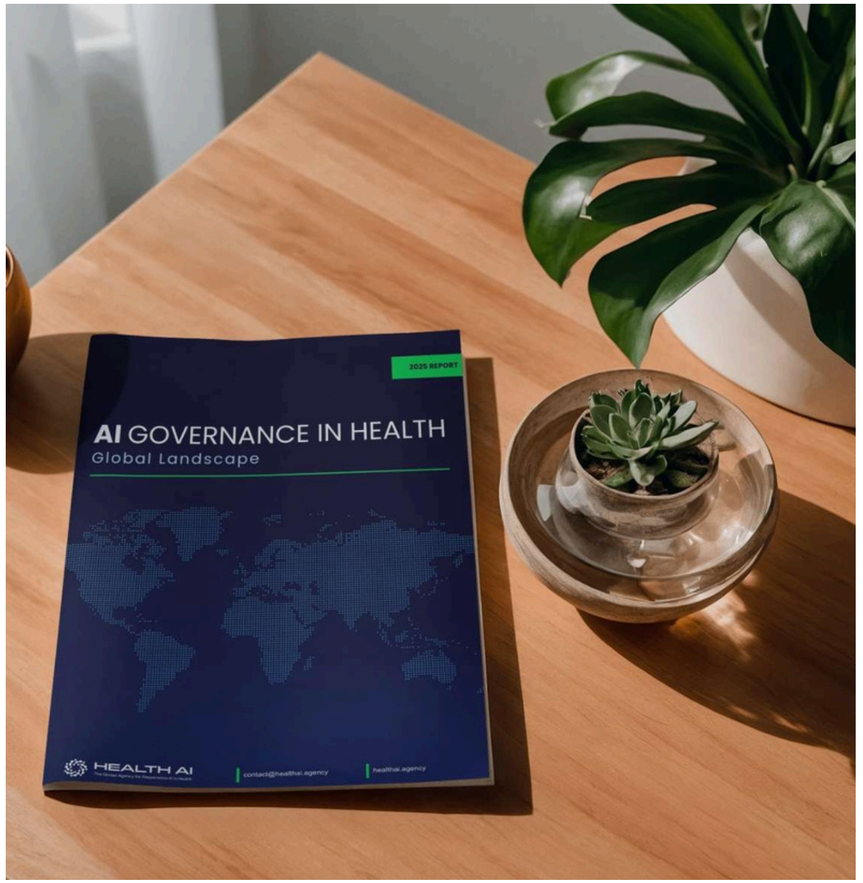
AI Governance in Health: Global Landscape 2025

- Timeline overview of international convenings and policy instruments launched in the past year.
- Analysis of global emerging regulatory frameworks, best practices, and persistent gaps in AI and data governance in health.
- Deep dive into the AI governance and health ecosystem for 8 selected jurisdictions.
- Synthesis of findings into actionable recommendations.



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Global Trends in AI Governance in Health

Regulation of SaMD at the crux of AI and health regulation

- Alignment with IMDRF-based risk classification frameworks for SaMD, reflecting a shared recognition that AI-enabled SaMD must be safe and effective before reaching patients and citizens.

- Regulation of SaMD by default includes AI as a medical device, 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 Direct-to-Consumer 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 regulatory authority for both mandates; guidelines to support enforcement.
  - **Peru 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 South 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 regulatory, accrediting assessors, and establishing compliance roadmap for industry

Emergence of digital sovereignty in health

- Digital sovereignty is a critical factor in countries' strategies, leading to adoption of tailored digital health platforms for health data.

- Data governance is a 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

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

Regulatory fragmentation:

Multiple agencies with overlapping mandates and limited coordination mechanisms.

Adaptive AI governance gaps:

Insufficient frameworks for continuously learning systems that evolve post-deployment.

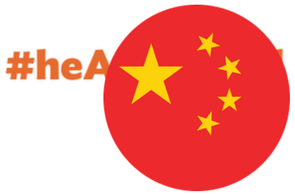
Infrastructure inequity:

Uneven connectivity and digital literacy between urban and rural regions.

Policy and practice divide:

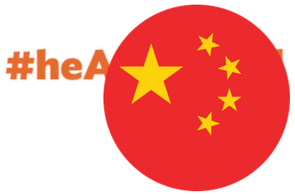
Distance between ambitious strategic visions and enforceable regulations with adequate institutional capacity

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

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

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

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

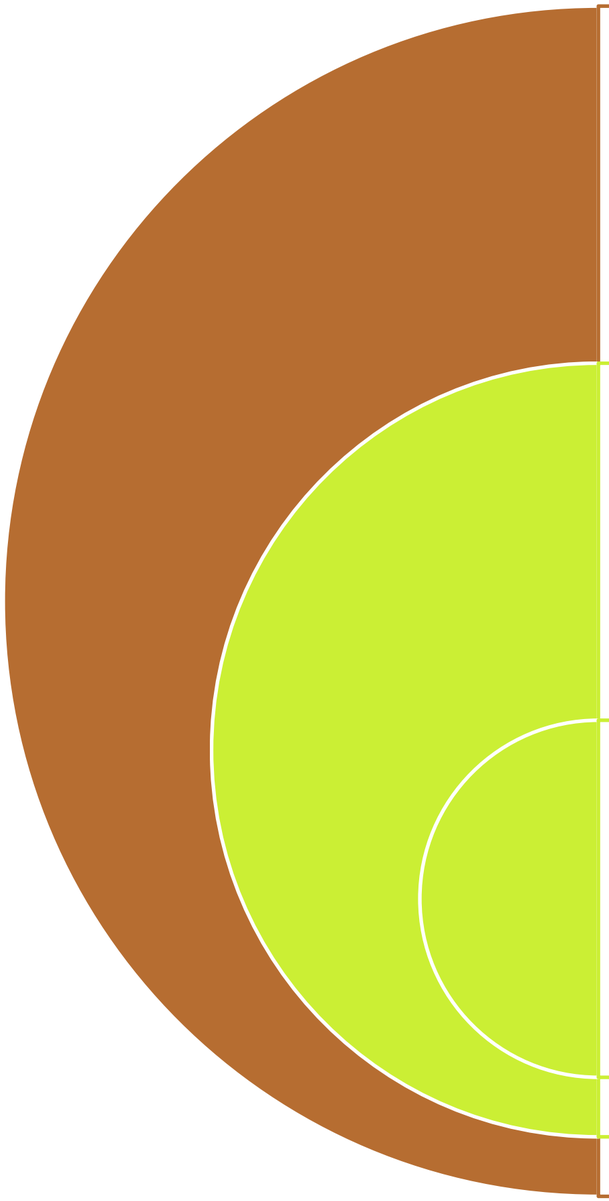
Provide **priority support and increased registration guidance for high-risk implantable Brain Computer Interface** medical devices

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

Global AI Governance Initiative emphasizes ethical principles of “people-centered, safe and controllable, and fair and inclusive”

Vietnam’s governance strategy for AI in health



Legal instruments for AI governance

- Digital Technology Industry Law.
- Decree 13/2023 on personal data protection.

Digital health transformation agenda

- MoH’s Digital Transformation Scheme.
- Prioritizes EMRs, telemed, and interoperable health data systems.

Sectoral health strategies

- AI applications in health are currently regulated under the SaMD pathways.
- Dedicated AIaMD guidance require multi-stakeholder participation.

Recommendations 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-strengthening.

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 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.

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https://www.healthai.agency/