

2025 제22차 국제연수과정 NHIS UHC GLOBAL ACADEMY

Building a Sustainable Healthcare System through Digital Transformation and AI Governance

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for Responsible AI in Health**



Content

- **Transformative Applications of AI in Healthcare**
- **The Importance of AI Governance and Regulation in Health**
- **Operationalizing AI Ethical Principles and Guidelines**
- **HealthAI – Who we are?**

Can AI transform our healthcare systems?

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AI cancer diagnosis 'might have saved my life'

11 December 2024

Cash Boyle
BBC News, South East

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Updated: JUL 22, 2025 9:07 PM CET

AI Helps Prevent Medical Errors in Real-World Clinics

HEALTH

AI



by Alice Park
SENIOR CORRESPONDENT



A health worker at a Penda Health Clinic in Nairobi during the COVID-19 pandemic in 2020. PATRICK MEINHARDT/AFP—Getty Images

nature

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NATURE BRIEFING | 07 May 2024

AI & robotics briefing: 'Risk-of-death' AI save lives in hospital trial

An algorithm trained on electrocardiograms reduced deaths among high-risk patients by 31%. Plus, an AI transcription tool seems to hallucinate harmful text and a robot that efficiently combines bouncing and flying.

By Katrina Krämer



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AUG 13, 2025 11:45 AM CET

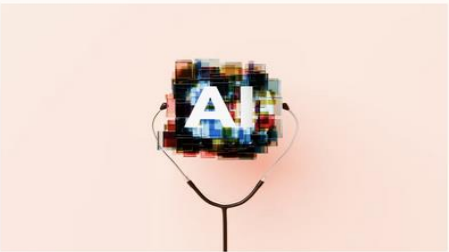
New Study Suggests Using AI Made Doctors Less Skilled at Spotting Cancer

HEALTH

AI



by Miranda Jevaretnam
REPORTER



Getty Images

Illustrative use cases of AI in healthcare

RADIOLOGY



AI Application:

Deep learning for image interpretation

Example /Outcome:

Automated detection of lung nodules in chest X-rays or CT scans

PATHOLOGY



AI Application:

Image-based pattern recognition for biopsy analysis

Example /Outcome:

Detection of cancer cell patterns in digitized slides

OPHTHALMOLOGY



AI Application:

Screening algorithms for diabetic retinopathy

Example /Outcome:

AI-powered retinal image classification tools used in remote clinics

Clinical care pathways

AI can:

-  Reduce both time pressure and address **low doctor-patient ratio**.
-  Support **surgical procedures** with decision support and real-time monitoring of blood loss and supply.
-  Help doctors manage and interpret the growing **volume of medical imaging data** with greater accuracy and efficiency.
-  Identify **high-risk patients** and alert physicians to urgent results, improving clinical decision-making.
-  Analyze **radiological and histopathological images** with high accuracy.

 Microsoft

 Apollo
HOSPITALS
TOUCHING LIVES



 Niramai



Patient facing solutions

AI can:



Engage patients directly through non-clinical solutions such as therapies, chatbots, personalized health advice, and interventions.



Provide patients in areas with low doctor-to-patient ratios or limited specialists **access to medical information**, recommendations, and potential diagnoses.



Help ensure that only those who truly need formal healthcare services use them, allowing health workers to focus on other patients.

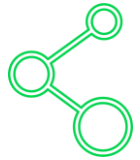


Population health

AI can:



Identify **epidemics**, monitor disease spread, manage populations and risks, and apply predictive analytics to forecast future outbreaks.



Improve population-wide **health outcomes**.



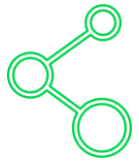
Shape **health determinants** through insights and behavior incentives.

LIME



Optimization of health operations

AI can:



Streamline back-end operations — procurement, logistics, staff scheduling, emergency dispatch, automated note completion, NLP transcription, and patient experience assessments.



Support the strategic deployment of **physical and human resources** to deliver health and care.



MACRO-EYES HEALTH

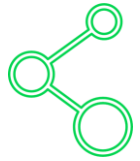


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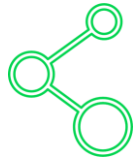


Preclinical research & clinical trials

AI can:



Analyze vast, complex, and unstructured data from multiple sources, including **biomedical and molecular datasets**.



Reduce costs and accelerate **drug development** by streamlining preclinical research.



Improve patient recruitment, feasibility testing, real-time drug monitoring, and disease tracking.

MELLODDY



Benevolent^{AI}



What do you trust more?

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Governing AI in health

Lack of clear governance and regulations in AI for health erodes trust and hinders the widespread adoption of AI technologies that could improve health outcomes globally.



INNOVATORS

- Unclear regulatory pathways to market
- Slow innovation and investment
- Difficulty in gaining trust
- Reputational risks
- Legal liability



HEALTHCARE PROVIDERS

- Uncertainty in liability
- Hesitancy in adoption
- Risk-averse sector: Fear of being early adopters without clear guidelines and protections



CITIZENS (INCL. PATIENTS)

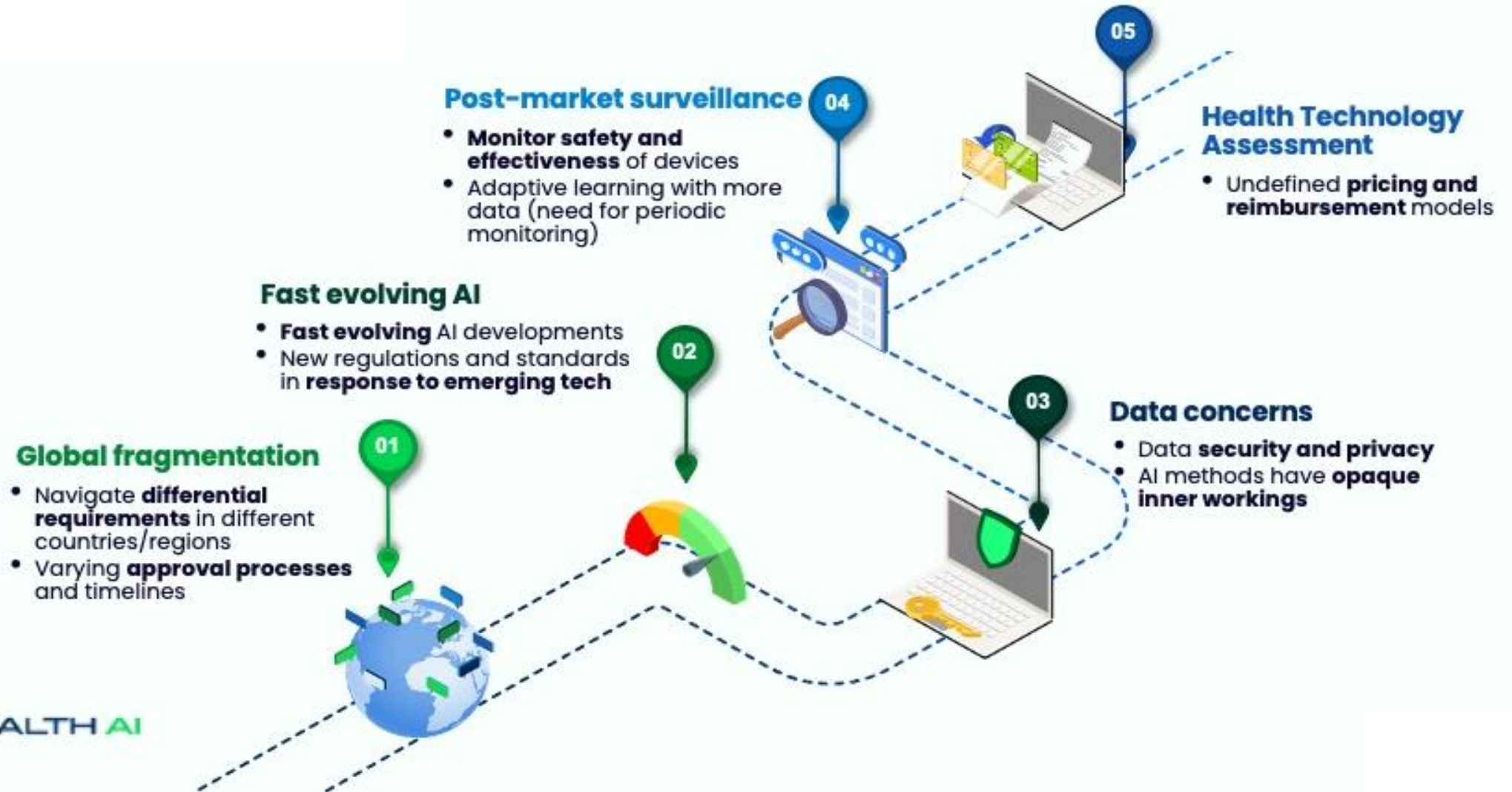
- Increased risk of misdiagnosis and harm from unsafe AI tools
- Inequitable access to AI-driven healthcare solutions
- Erosion of trust in AI-powered medical innovations



GOVERNMENT

- Public distrust in AI-driven healthcare
- Increased legal liabilities from unregulated AI tools
- Missed opportunities for economic growth and global leadership in AI for health

Governance challenges for AI in healthcare



AI governance framework



Strategies and Policy Orientation

Principles of Responsible AI

AI solutions that are ethical, inclusive, rights-respecting, and sustainable.

- Protection of and respect for **human autonomy, agency, and oversight**;
- **Promotion of human well-being and safety**,
- Commitment to “**do no harm**”;
- Technical **robustness and safety**;
- Adherence to **laws** and **ethics**;
- **Transparency, Explainability**, and intelligibility;
- Responsibility and **accountability**;
- **Inclusivity, Fairness** and **equity**;
- **Sustainability**;
- **Societal and environmental well-being**.



Legislative frameworks



EU AI ACT

A comprehensive regulatory framework designed to ensure the safe, ethical, and trustworthy development and use of AI in EU.

EU Artificial Intelligence Act



It adopts a risk-based approach, imposing stricter requirements on high-risk AI systems to safeguard public interest and promote responsible innovation.



Certain AI uses that pose unacceptable risks (e.g., social scoring, real-time remote biometric identification in public) are banned.



It applies to all developers, providers, and users of AI systems that affect people in the EU, whether they are inside or outside the European Union.

Legislative frameworks



BRAZIL'S AI BILL NO. 2338/2023

Guides responsible AI development while protecting rights & democratic values.

BRAZIL'S AI BILL NO. 2338/2023



Risk-based approach, bans excessively risky AI (e.g., social scoring).



Strict governance for high-risk AI (incl. health).



Low-risk AI treated under general law with assumption of good faith.

AI related legislative frameworks

Data Protection Law

Consumers Protection Law

Cybersecurity Law

Medical Laws

Sectoral regulations

IMDRF Definition of SaMD



SOFTWARE AS A MEDICAL DEVICE (SaMD)

Software intended for one or more medical purposes that perform those purposes without being part of a hardware medical device.

SaMD

Can be used for:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease/injury
- Compensation for injury
- Disease mitigation or management
- Provide information to assess compatibility and manage health conditions.
- Aid in diagnosis, screening, monitoring, and assessing health status or risk.

ADOPTION ACROSS COUNTRIES

- IMDRF's SaMD framework has been adopted/adapted by the EU, USA, Canada, Japan, Australia, China, Singapore, South Korea, and others.
- While regulations differ across jurisdictions, IMDRF provides a harmonized reference.

IMDRF SaMD guidance documents



IMDRF SaMD
Working Group



Key Definitions

Risk Framework

Post Market
Management

Quality
Management
System

Clinical Evaluation
& Software
Validation

International standards



Medical Device-Related Standards

ISO Standard	Purpose
ISO 13485: Medical Devices – Quality Management Systems	International standard specifying requirements for a QMS in the medical device industry, focusing on safety, efficacy, and regulatory compliance .
ISO 14971: Medical Devices – Risk Management	International standard for risk management in medical devices, ensuring safety throughout the product lifecycle.
ISO 62304 : Medical Device Software – Software Life Cycle Processes	Structured and standardized framework for the safe design, development, maintenance, and risk management of software used in medical devices.
ISO 14155 : Clinical Investigation Of Medical Devices For Human Subjects	Provides guidelines and requirements for the design, conduct, recording, and reporting of clinical investigations involving human subjects to assess the safety and performance of medical devices

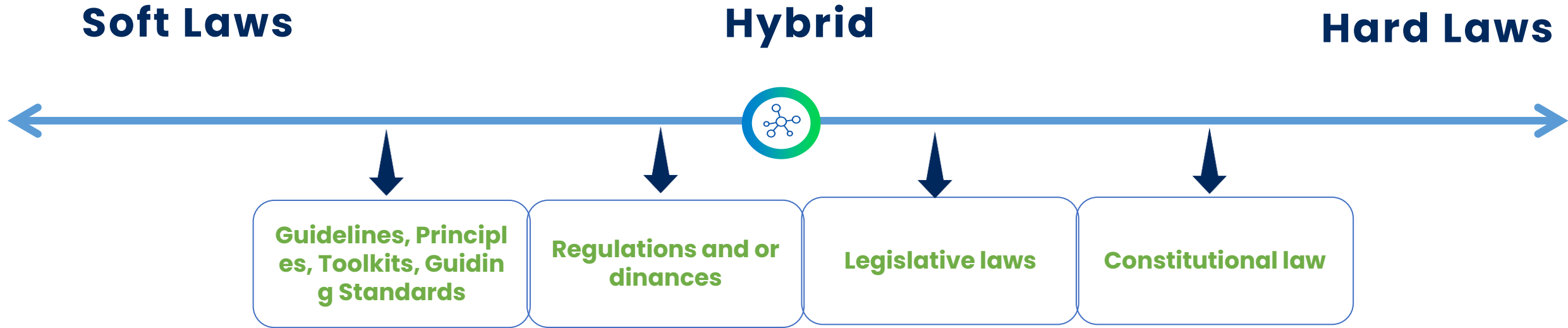
International standards



AI-Related Standards

ISO Standard	Purpose
ISO/IEC 42001:2023 AI Management System	Standard outlining requirements for creating, implementing, maintaining, and improving an Artificial Intelligence Management System (AIMS) in organizations.
ISO/IEC 42005:2025 AI System impact assessment	Offers guidance for organizations to assess how AI systems impact people and society.
ISO/IEC 42006:2025 Requirements for bodies providing audit and certification of AI management systems	Provides additional requirements and guidance for AIMS auditors beyond the standard criteria for management system audits and certification.
ISO/IEC 23894: AI - Guidance on Risk Management	Offers guidance for organizations involved in developing, producing, deploying, or using AI-based products, systems, and services on how to manage risks specific to AI.
ISO/IEC 5338: AI system life cycle processes	Outlines processes and key concepts for describing the life cycle of AI systems , including those based on machine learning and heuristic approaches.

Spectrum of AI governance



What is the impact of these approaches for AI innovation delivery and oversight?

Hard for policymakers to monitor and enforce AI specific because everything is in the grey-zone. Requires a very proactive and trust-based approach

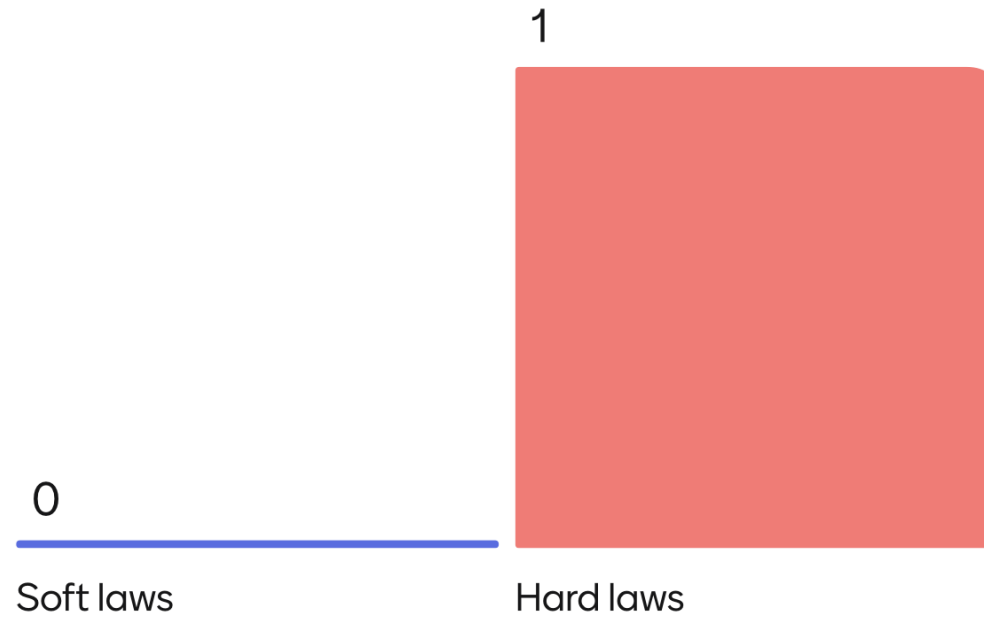
Hard for innovators to adopt, engage, interpret, and comply, especially when the horizontal legislation intersects with sectoral regulations

Your take...

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In your view, should your government prioritise soft laws or hard laws to govern AI in health?



Key takeaways

- **There is a lot of potential for AI and digital technologies to transform our healthcare systems.**
- **AI systems in health have to be developed responsibly in order for the transformation to be sustainable.**
- **We should not forget about strengthening the ecosystem that will enable the Responsible AI systems to thrive**
 - **Digital infrastructure**
 - **Workforce capacity strengthening**
 - **Governance and regulations**

HealthAI – Who are we?

HealthAI serves as a bridge between normative bodies and national and regional regulatory bodies to strengthen capacity and provide qualification of members of our Global Regulatory Network.

Normative Bodies
Set global standards



Promotes recognized Standards and Guidance

HealthAI **DOES NOT** define standards



Regulatory Bodies
Validate AI solutions

Builds Capacity

Qualifies members of our GRN



HealthAI **DOES NOT** validate AI tools for health systems

Facilitates and Stewards

Community of Practice

Global Regulatory Network

Global Public Directory of validated AI solutions for

HealthAI strategy pillars



HealthAI Global Regulatory Network



Develop and strengthen **National & Regional validation mechanisms** on Responsible AI for Health



Qualify Members for our **Global Regulatory Network** for knowledge sharing



Establish a **'Global Early Warning System'** to address all AI adverse events



Create a **Global Public Directory** of validated AI solutions for Health



Deliver Technical Advisory on Policies and Regulations

Technical Acceleration

Community of Practice | HealthAI Portal | Global Governance Forum

HealthAI Community of Practice

Government and regulatory agency leadership group

Invitation-only - safe space for discussions on government structures, laws, approaches, and policies to regulate Responsible AI in health. **33 government institutions as of March 2025**

Wider global health AI community

Invited to Annual HealthAI CoP meeting - **HealthAI Global Governance Forum**



All members

Registration needed

Bi-monthly CoP meetings: to discuss and share experience on key topics + **Working Group bi-monthly meetings:** to advance collaborative work on community objectives

Access to the resources on the **Knowledge Hub and Community Portal**

Join Now << Community of Practice

Thank you!

<https://www.healthai.agency/>

