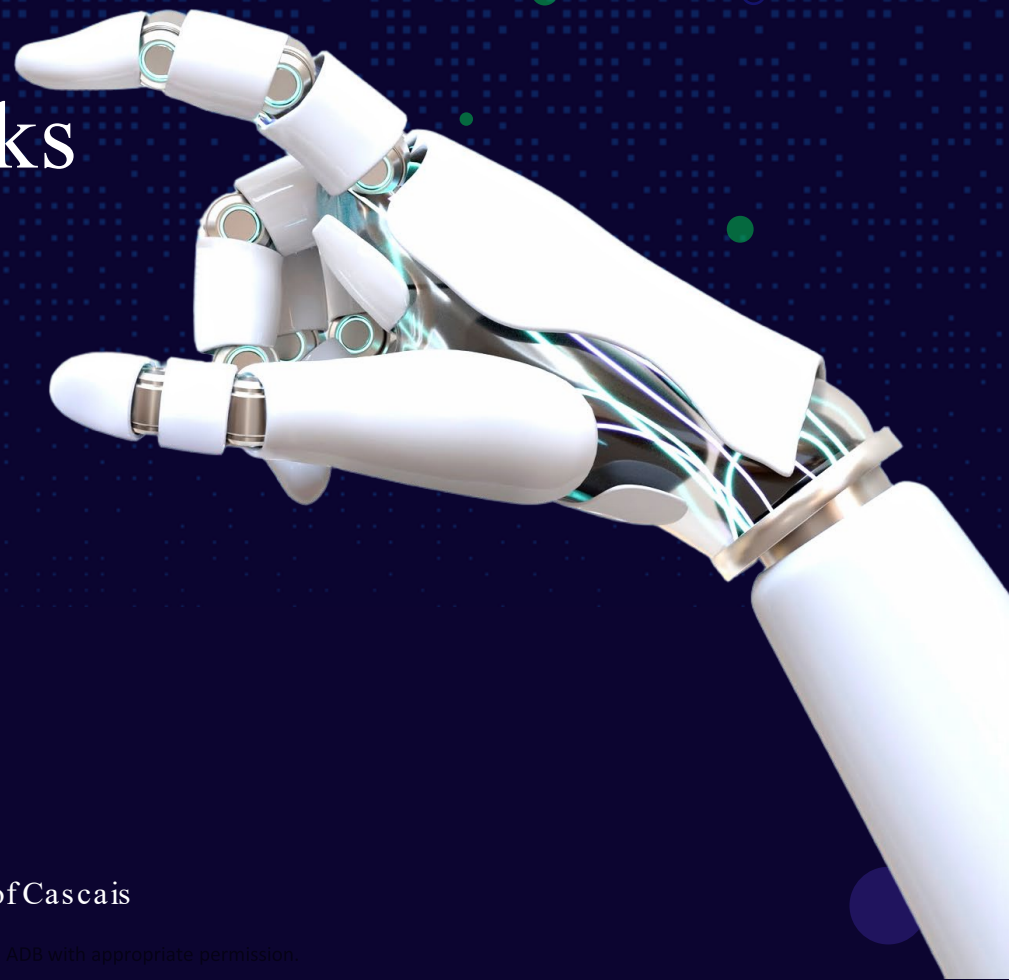
ADB

1ST INSPIRE HEALTH FORUM

# Existing Regulatory Frameworks for AI Systems in Health and Foreseen Gaps

July 2025 | Manila, Philippines



Dr. Ricardo Baptista Leite, M.D.

CEO | HealthAI – The Global Agency for Responsible AI in Health

Founder & President | UNITE Parliamentarians Network for Global Health

Chair | Harvard-Charité Global Health Policy Lab

Chair | NOVA Center for Global Health

City Council of Sintra | Former 4-term Member of Parliament (Portugal) | Former Deputy Mayor of Cascais

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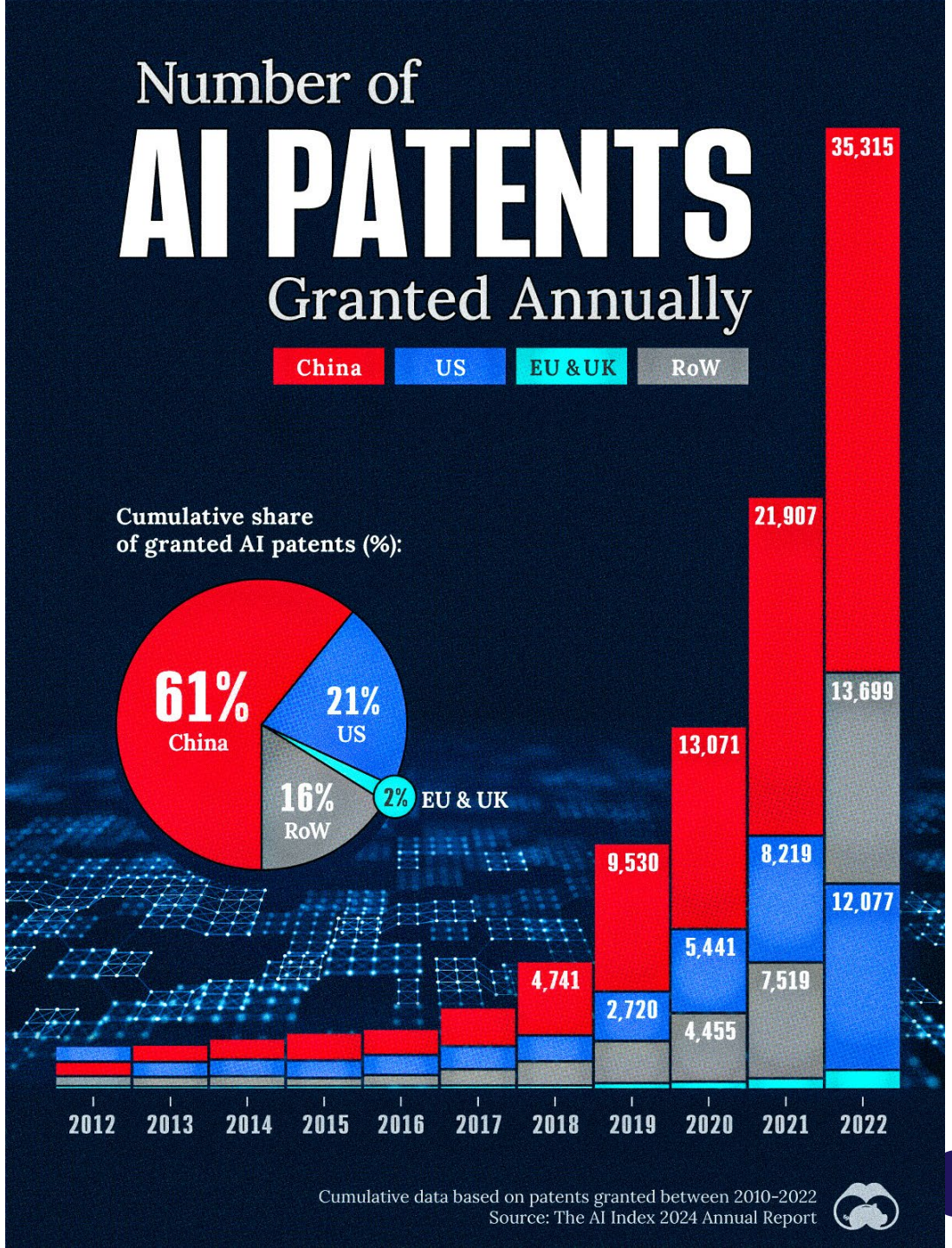
# Insights and Forecasts of Patents for AI and ML

- Total number of published **patents doubled yearly from 2015 to 2022**

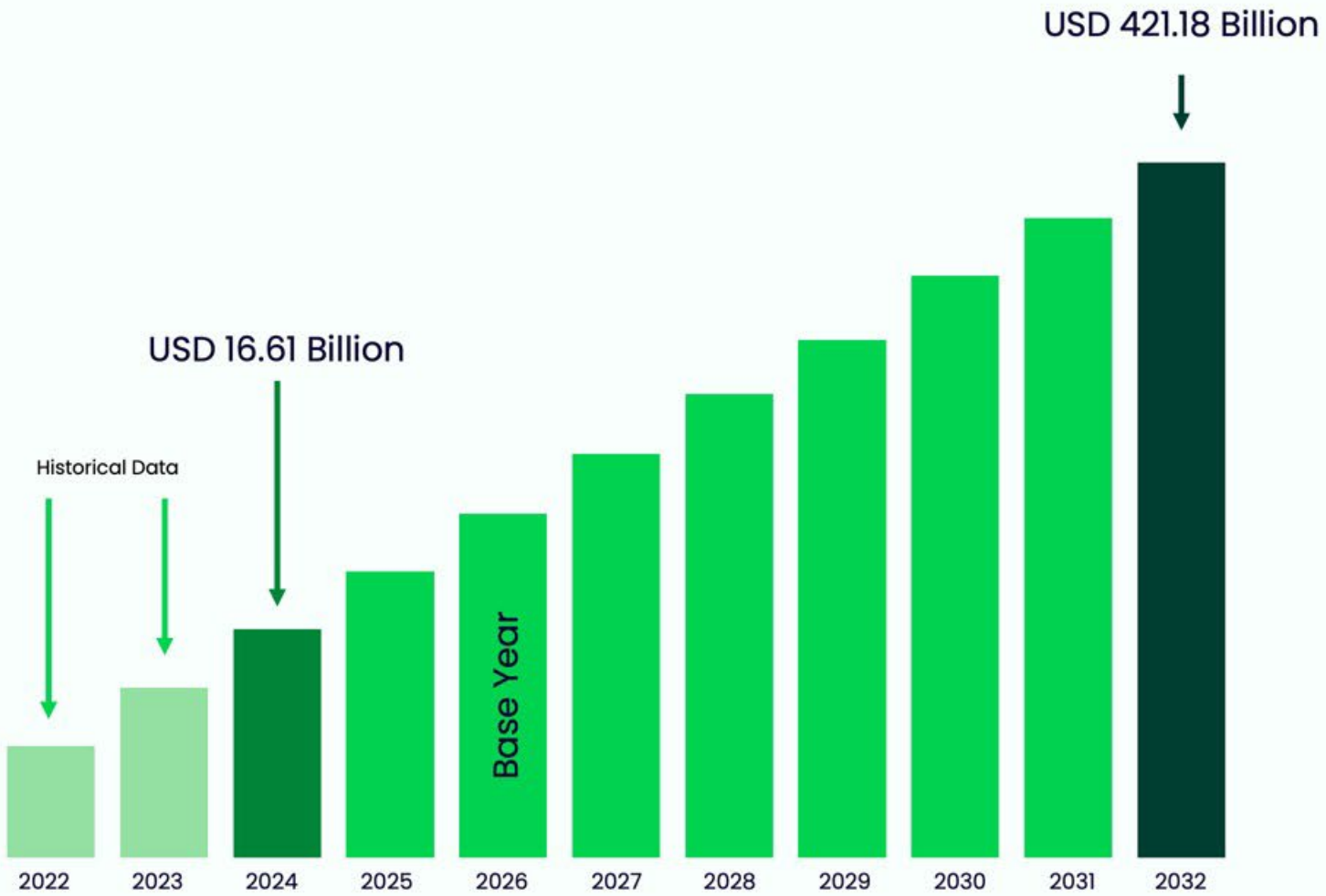
*Source: The AI Index 2024 Annual Report*



# Global Ai in Healthcare Market

49.8%

Global Market CAGR
2024-2032

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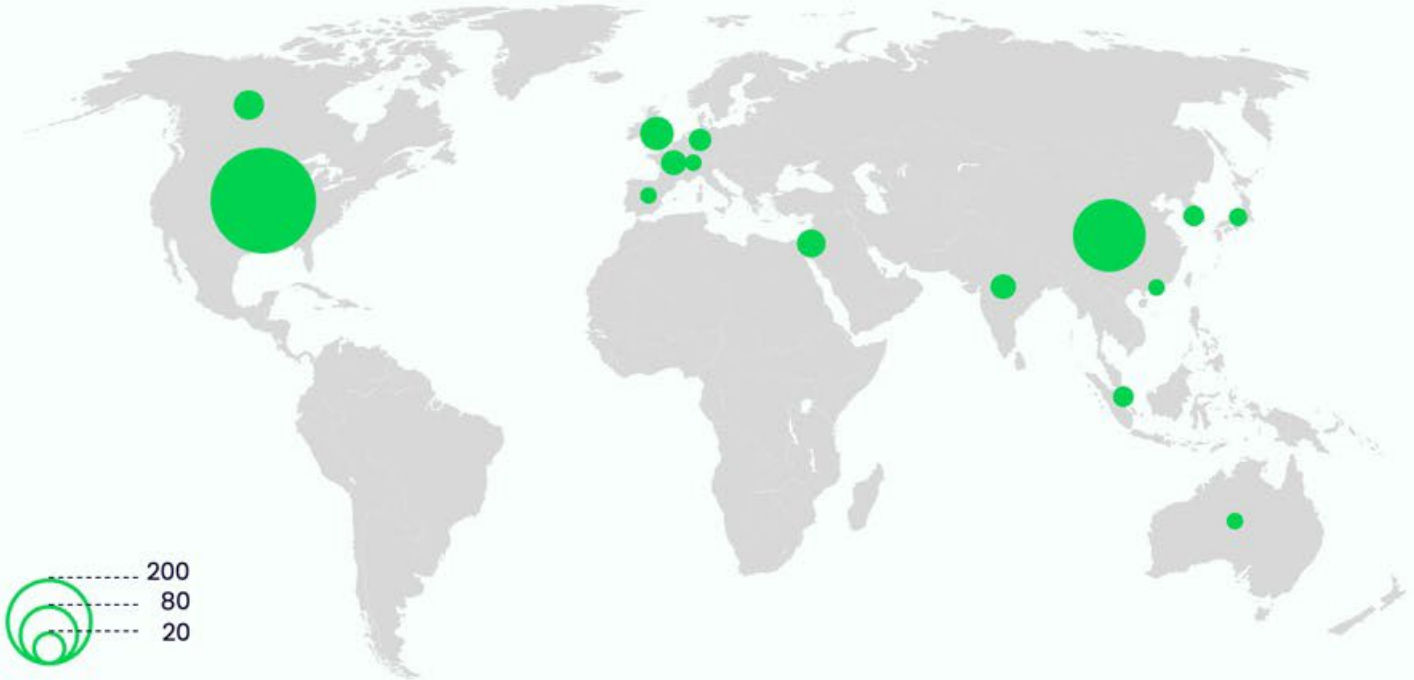
source: Market Data Forecast Analysis

# AI in Healthcare: Market Trends

## Private investment in AI by country

Total for the years 2013 to 2022, in billions of US Dollars




source: Stanford Institute for Human-Centered Artificial Intelligence

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# Why use Artificial Intelligence?





# ‘5 Commandments of Health Management’

If you’re not doing one of the following,

*what are you doing?*

**PREVENT**

**CURE**

**Efficiency**

**MANAGE**

**MINIMIZE**

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**Rising Healthcare Costs and Rising Burden of Disease**

↓

**Risks of Unsustainability**

↓

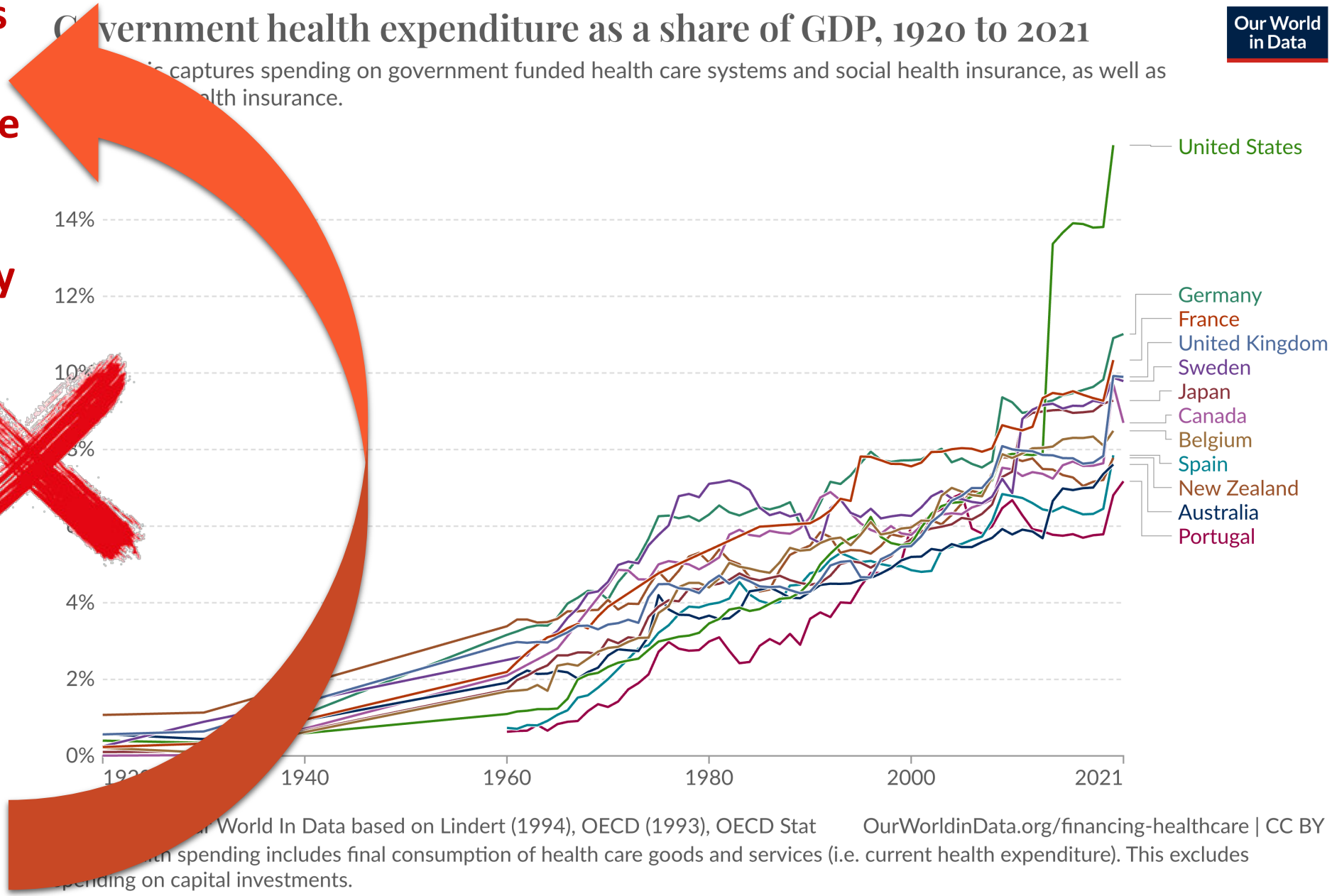
**Universal Health Coverage**

↓

**Worse health - mainly for most vulnerable populations**

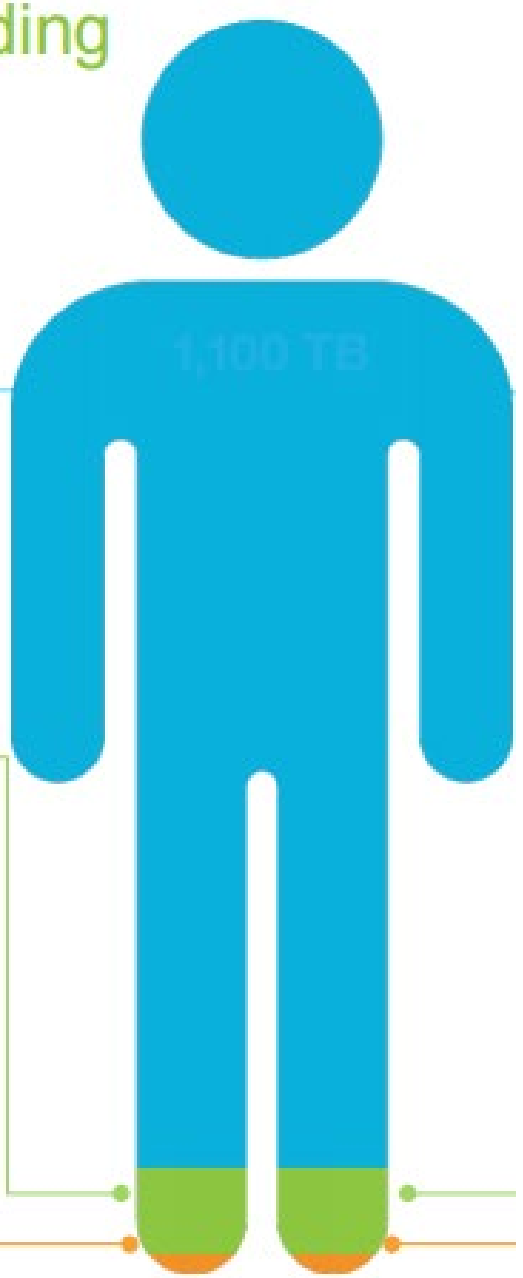
↓

**Rise of inequalities and poverty**



# Personal Data is Exploding

**Impact on a person's health status**




**Exogenous Factors**

**60%**

Environment & Social
Context, Behavior

**Genomic Factors**

**30%**

**Clinical Factors**

**10%**

Don’t *retrofit* AI into your health system …

# AI across the Health Value Chain

## Research & Development

**Drug Discovery:** Accelerates candidate identification

**Clinical Trials:** Optimizes trial design

**Genomic Sequencing:** Speeds analysis of genetic data

**Virtual Patient Simulations:** Reduces need for early-stage human trials

**Systems Medicine:** Designs complex therapies

## Manufacturing & Distribution

**Supply Chain Optimization:** Reduces waste, improves delivery

**Quality Control:** Ensures product safety at scale

**Inventory Management:** Optimizes stock levels

**Autonomous Manufacturing:** Enhances efficiency, reduces error

**Predictive Maintenance for Equipment:** Minimizes downtime

## Population Health & Delivery of Care

**Diagnostic Assistance:** Improves accuracy of diagnostics

**Treatment Personalization:** Tailors treatment plans

**Robotic Surgery:** Aids in precise surgeries

**Remote Surgery:** Expands access to expert surgical care

**Real-Time Population & Patient Monitoring:** Identifies, anticipates and prevents threats, diseases and complications

## Post-Care & Monitoring

**Remote Monitoring:** Monitors patient health remotely

**Rehabilitative AI Tools:** Provides feedback during rehabilitation

**Predictive Risk Modeling:** Aids preventative care efforts

**Personal Health Assistants:** Offers personalized health management

**Mental Health Interventions:** Provides real-time therapy support

## Admin & Info Management

**Billing & Claims Processing:** Automates administrative tasks

**Patient Data Management:** Improves data security and compliance

**Resource Allocation:** Optimizes use of healthcare resources

**AI-driven Policy & Compliance:** Suggests efficiency-improving policies and semi-automates compliance

**Fraud Detection:** Detects and prevents fraudulent activities

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Primary Benefit: better outcomes; cost savings

# The ‘Duality’ of AI in Healthcare

- An **existing** ecosystem of standards and guidelines – and regional regulations

## MD Regulators / IMDRF

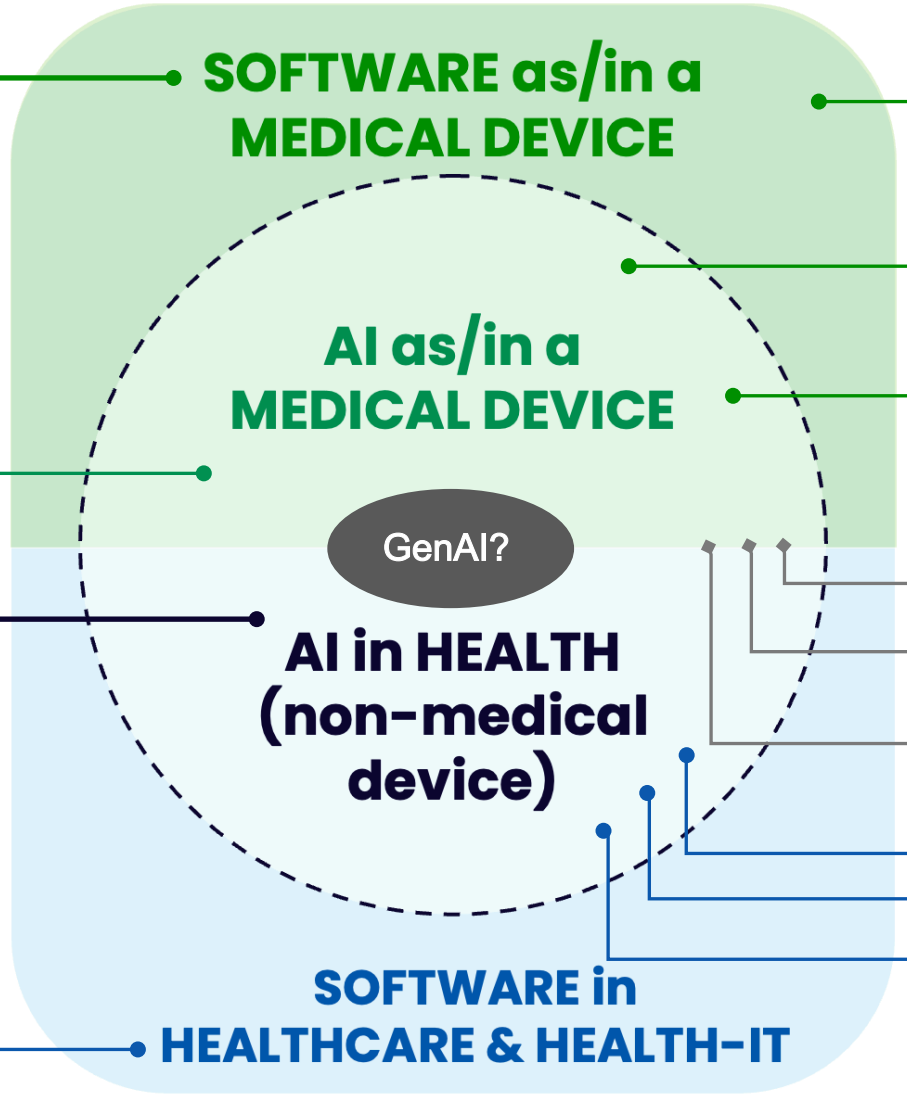
- Standards and Guidance for Medical Devices risk, quality, and product lifecycle management, as well as clinical evaluation

- Standards and Guidance specific to AI-enabled Medical Devices

## OECD/WHO/ITU – AI4H

- ISO & CTA standards dedicated to AI management system, cybersecurity of AI systems, and their use in healthcare

- ISO standards for the general use of software in healthcare; information security, cybersecurity, and protection; and device interoperability




*Dose calculator controlling an infusion pump in a close - loop diabetes management MD*

*Individualized patients’ treatment response prediction for clinical decision support*

*Tumor detection and characterization for Cancer diagnosis & treatment monitoring*

*AI- Agent for symptoms checking (?)*

*LLM- based patients’ discharge summary note (?)*

*Patients’ prioritization in an ICU Management system (?)*

*Population Health Management*

*Healthcare Administration – non - clinical*

*Drug Discovery*

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# Mapping AI Governance in Health

From Global Regulatory Alignments to LMICs' Policy Developments


Download the Report

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IDRC · CRDI
Canada

UK International Development
Partnership | Progress | Prosperity

# United States of America

- **FDA has harmonized its regulatory framework for SaMD with IMDRF guidelines while taking US legislation and context into account.**
- Since 2019, FDA has put forth:
  - Regulatory considerations for AI/ML-SaMD
  - **Good ML Practice for Medical Device Development (jointly published with Health Canada and UK MHRA)**
  - Predetermined change control plans where during pre-market clearance, manufacturers could provide details on predicted planned modifications
    - **Dec 2024:** FDA released the final marketing submission recommendations for a **PCCP for AI-enabled device software functions**
  - Ensuring transparency for AI/ML-SaMD
- **Currently, no other wider AI legislation in place that would apply to the health sector**
  - President's Executive Order on Safe, Secure and Trustworthy AI (emphasizes the creation of new standards for AI safety and security) – Revoked by President Trump

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# European Union

| Area of Consideration | Interplay between EU AI Act and EU MDRs |
|---|---|
| Risk classification | Both adopt a risk-based approach but apply different classification criteria:<br>• MDRs use specific medical-related criteria based on intended use and potential risk of harm to users while AI Act employs broader criteria that considers the impact of the AI systems on fundamental rights and safety.<br>• AI/ML-SaMD that fall under risk classes IIa, IIb or III under the MDRs are automatically classified as high risk AI systems under the AI Act. |
| Regulatory target | MDRs regulate medical devices as a whole, including AI/ML-SaMD, while the AI Act specifically targets the AI component within those devices. |
| Regulatory requirements | There are overlaps between both legislation in areas like risk management, technical documentation and post-market surveillance.<br>• However, clinical evaluation is mandated under the MDRs, while the AI act has additional requirements with regards to data governance, human oversight, transparency, accuracy, robustness and cybersecurity. |
| Conformity assessment | The AI Act aims to integrate its conformity assessment procedures with the MDRs, allowing for a single assessment by NB authorized for both legislations.<br>• In terms of technical documentation, a single set of documentation for both legislation is permitted. |

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# United Kingdom

- **MHRA has established the «Software and AI as a Medical Device Change Programme» in 2021**.
- UK Regulatory Horizons Council published «The Regulation of AI as a Medical Device» in November 2022, complementing MHRA's efforts.
- **In May 2024, MHRA launched a pilot regulatory sandbox (AI-Airlock for AIaMD).**
- With regards to broader AI legislation, UK government issued a white paper «A pro-innovation approach to AI regulation» in 2023
    - Highlighted UK's sector-specific regulatory approach to AI, instead of a cross-sectoral one.
- **In July 2024, new UK government outlined plans for AI regulation**
    - King's speech: Government «will seek to establish the appropriate legislation to place requirements on those working to develop the most powerful AI models.»

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# People ’s Republic of China

- Since 2019, CMDE under NMPA has released several important regulatory guidelines:
  - Elements for the **review of deep learning-assisted decision-making software for medical devices**
  - **Guiding principles for defining classification of AI medical software products**
  - **Guidelines for the review of AI medical device registrations**
    - Latest guidelines outlined standards for quality management systems covering the total product lifecycle
    - Considerations on cyber- and data security and human factors design to improve usability.
- **In terms of horizontal AI legislation, the Cyberspace Administration of China**, along with 6 other Chinese regulators issued the ***“Interim Measures for the Mangement of Generative AI Services”***.
  - In effect **since 15 August 2023 and apply to medical applications**
  - Introduced a “classified and graded” regulatory approach but **specific classifications yet to be released**
  - **Strong emphasis on balancing innovation and security**

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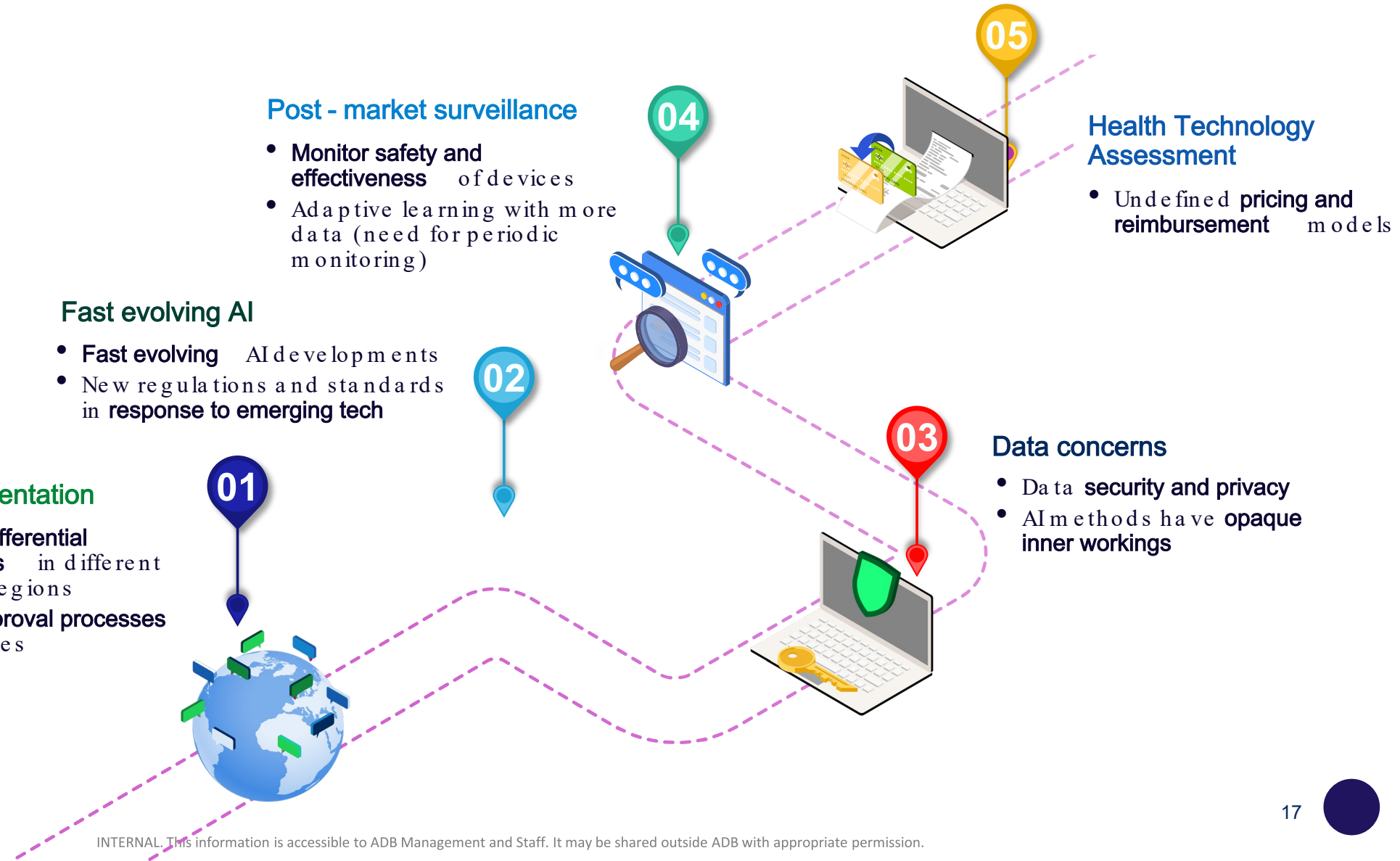
# Regulatory Challenges for AI in Healthcare

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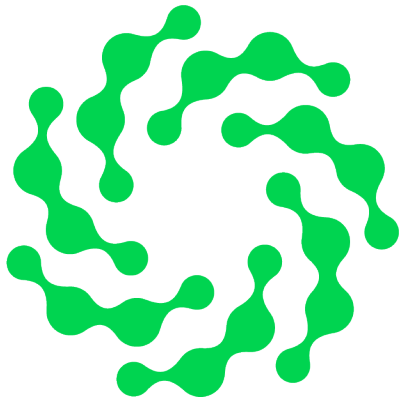
# Trust



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The Global Agency for Responsible AI in Health

# HealthAI Summary

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

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**Regulatory Bodies**
Validate AI solutions


HealthAI DOES NOT define standards

**Facilitates and Stewards**

- Community of Practice
- Global Regulatory Network
- Global Public Repository of validated AI solutions for health

HealthAI DOES NOT validate AI tools for health systems

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# Global Governance Forum

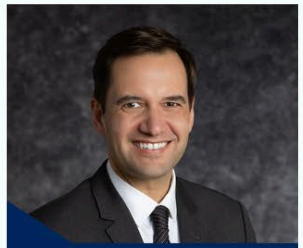
02 December, 2025

Nairobi, Kenya

## HealthAI Community of Practice

Join Now

# HealthAI Team



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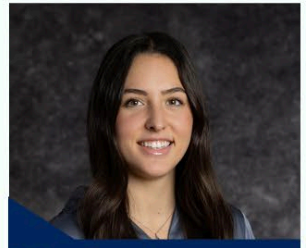

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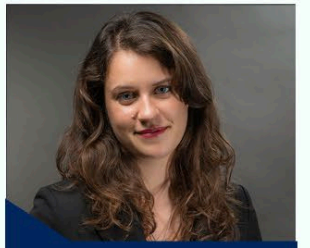

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# Thank you

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