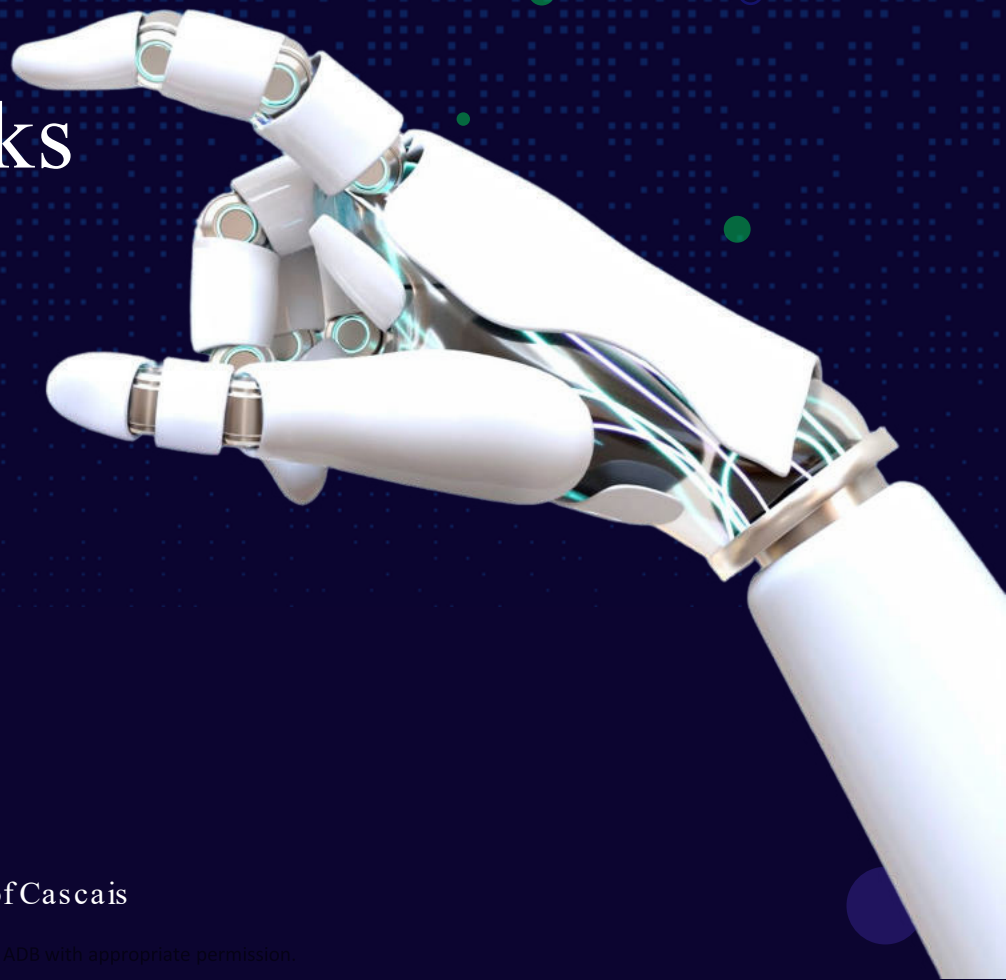
ADB

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

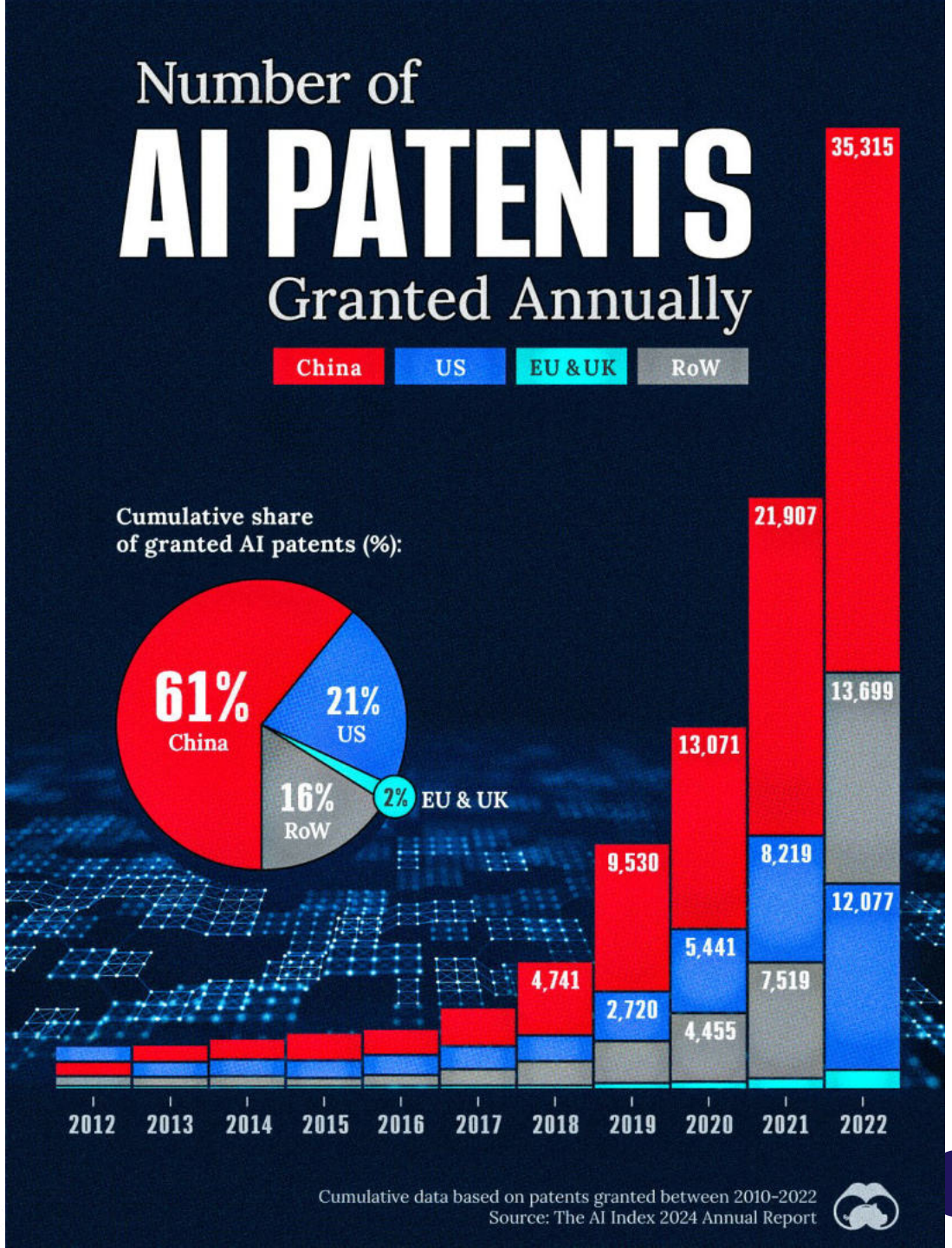
City Council of Sintra | Former 4-term Member of Parliament (Portugal) | Former Deputy Mayor of Cascais

ricardo.baptistaleite@healthai.agency | @RBaptistaLeite

Insights and Forecasts of Patents for AI and ML

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

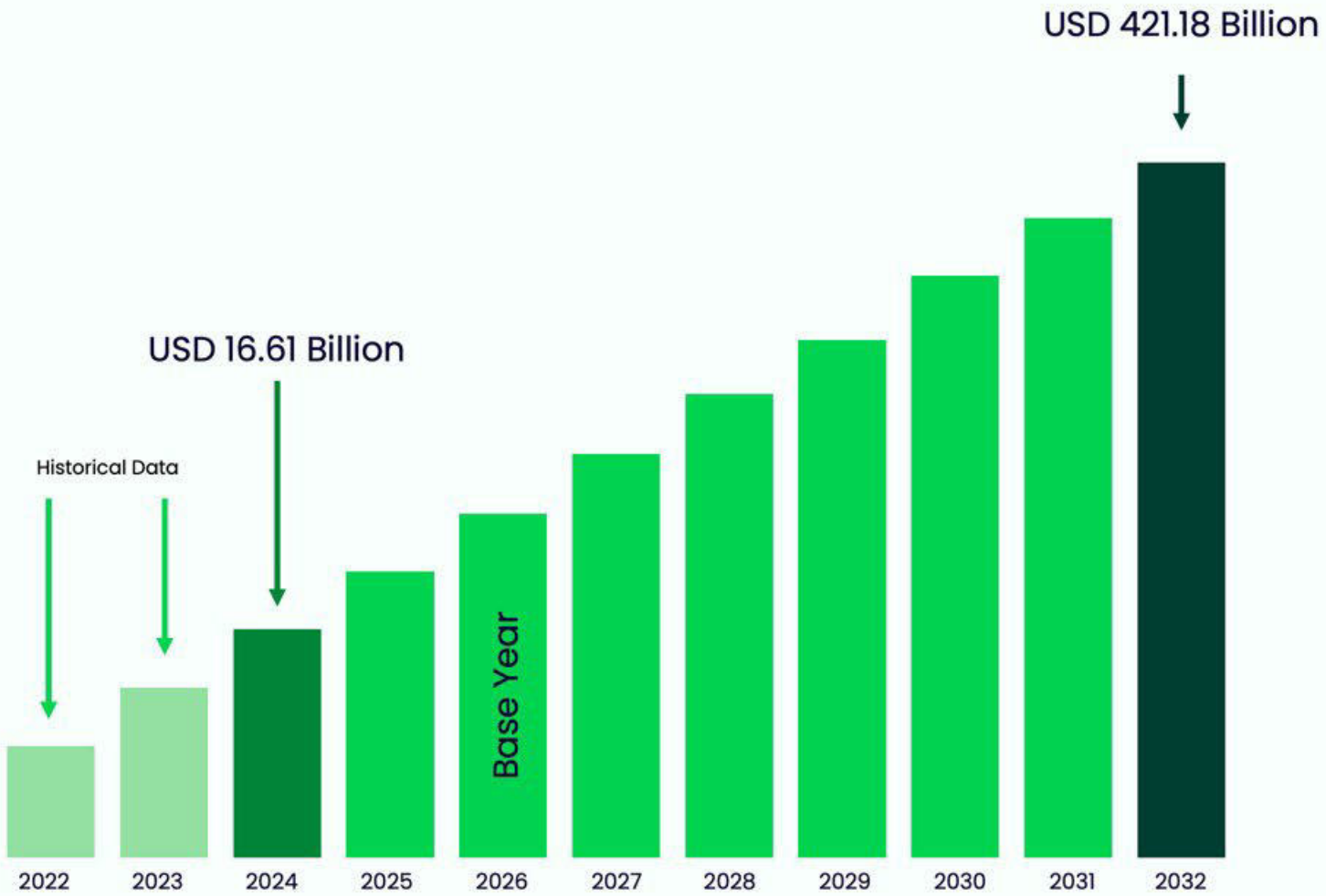
Source: The AI Index 2024 Annual Report



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

@RBaptistaLeite

Rising Healthcare Costs and Rising Burden of Disease

↓

Risks of Unsustainability

↓

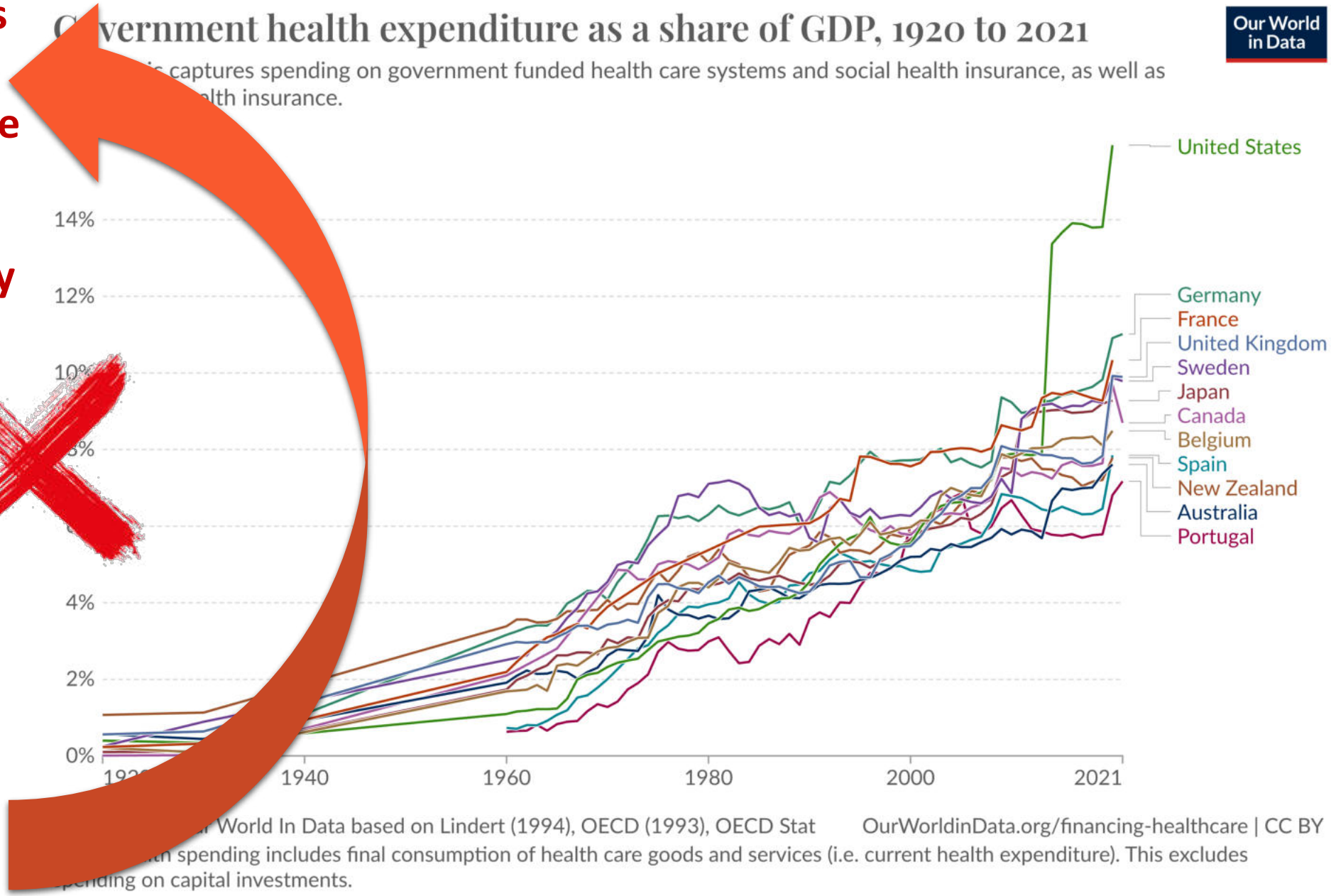
Universal Health Coverage

↓

Worse health - mainly for most vulnerable populations

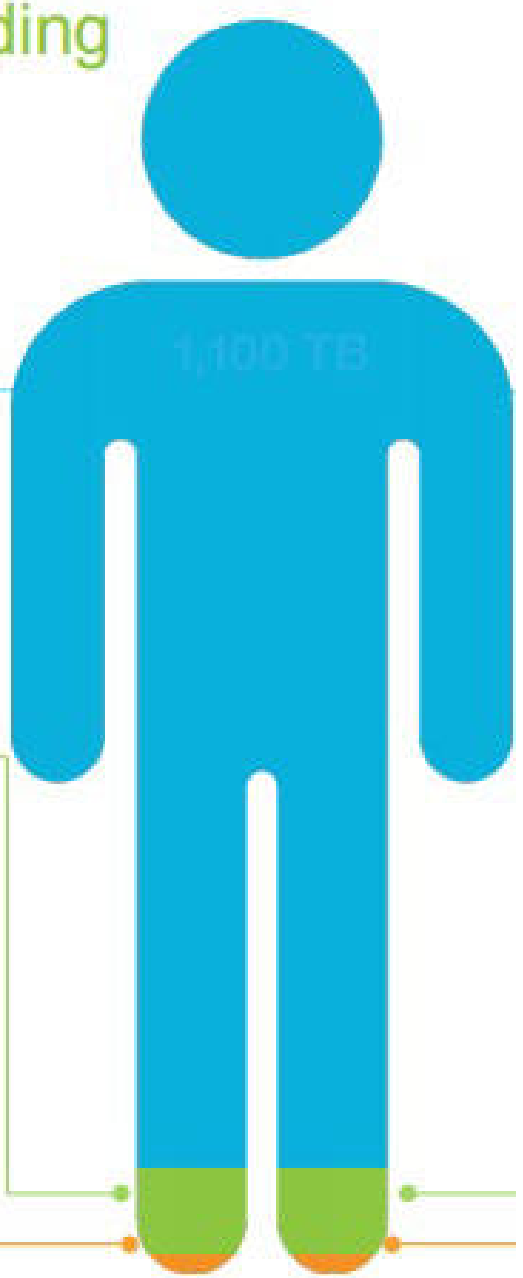
↓

Rise of inequalities and poverty



Personal Data is Exploding

Impact on a person's health status



Exogenous Factors

60%

Environment & Social
Context, Behavior

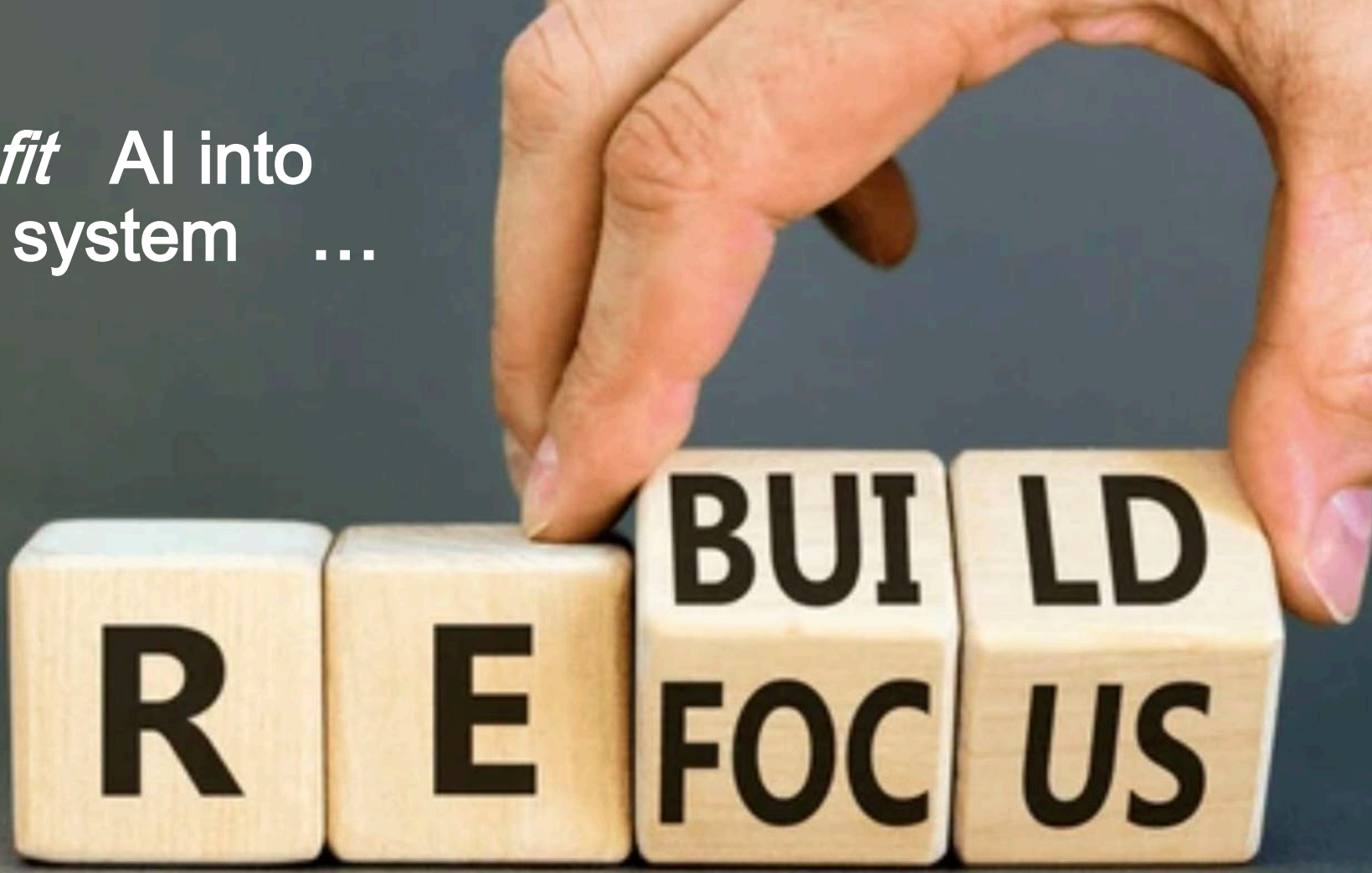
Genomic Factors

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

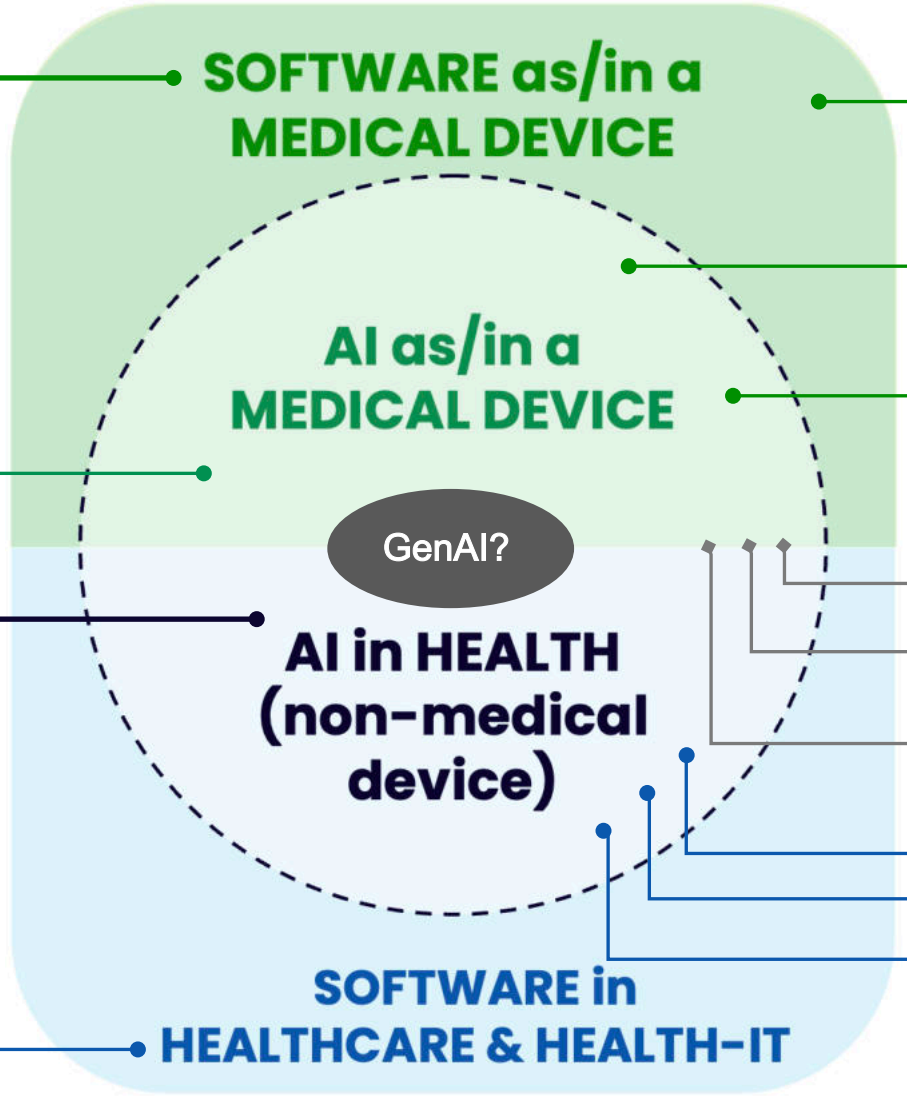
- Standards and Guidance for Medical Devices risk, quality, and product lifecycle management, as well as clinical evaluation

- 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
AI
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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: 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. 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. 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. • 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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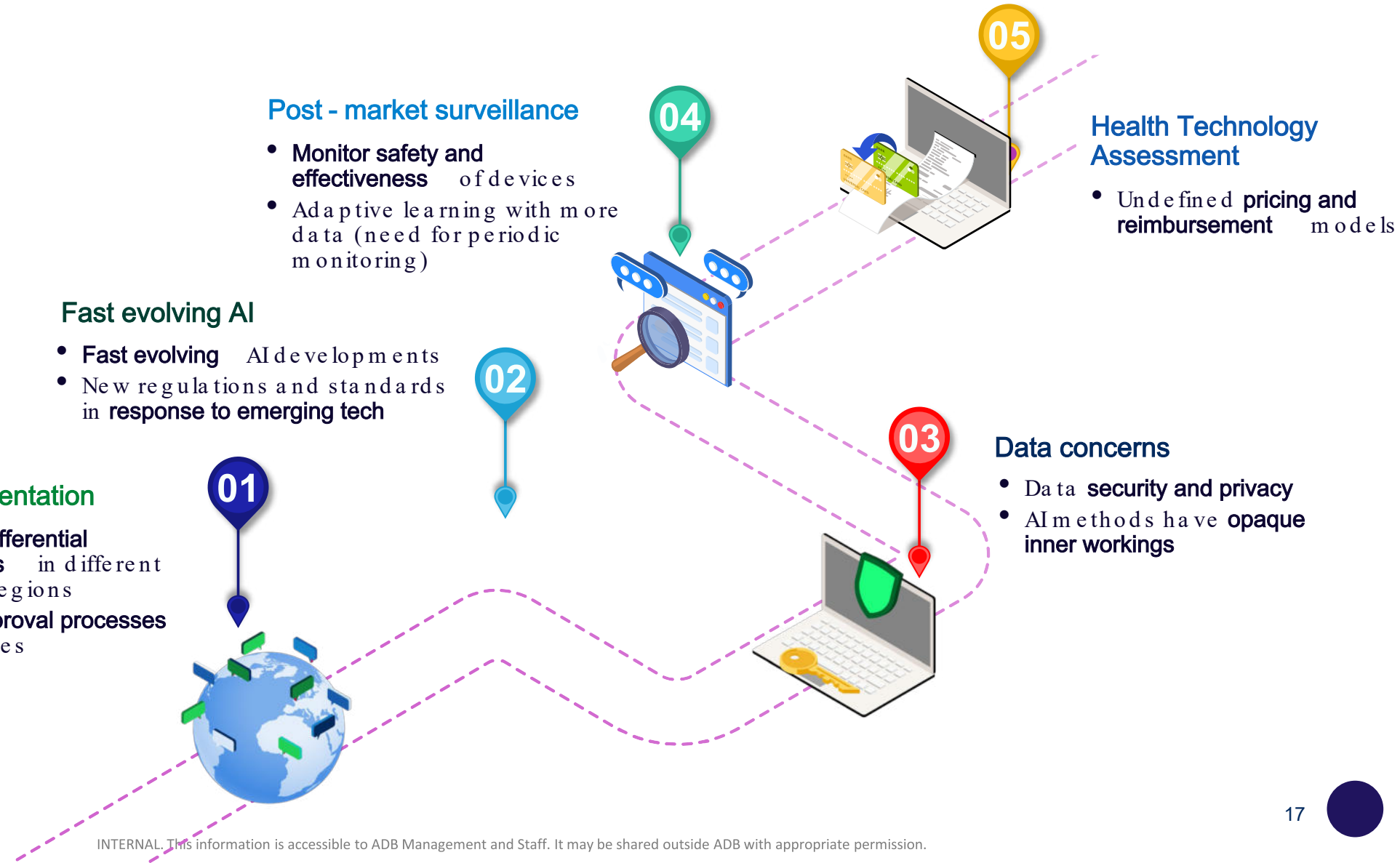
Regulatory Challenges for AI in Healthcare



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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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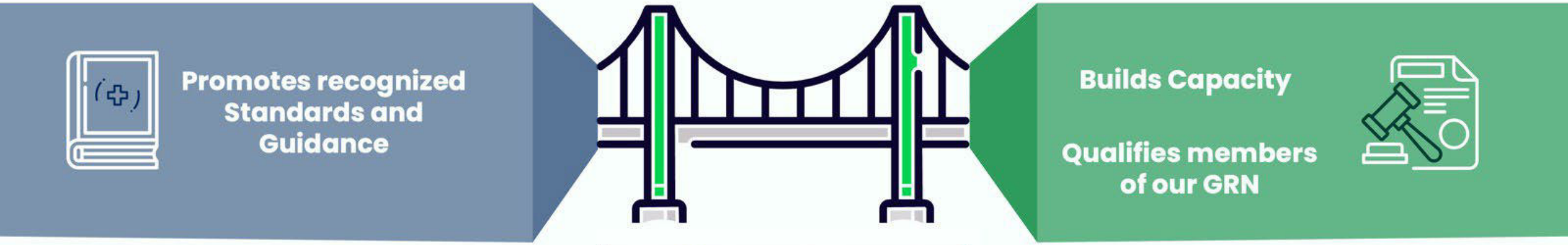
Regulatory Bodies
Validate AI solutions



Promotes recognized Standards and Guidance

Builds Capacity

Qualifies members of our GRN

Facilitates and Stewards

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

HealthAI DOES NOT define standards

HealthAI DOES NOT validate AI tools for health systems

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Global Governance Forum

HealthAI Community of Practice

Join Now

HealthAI Team

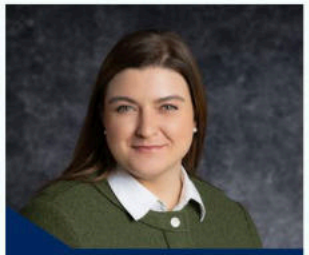
Dr. Ricardo Baptista Leite
CEO

Dr. Peiling Yap
CHIEF SCIENTIST

Dr.Sc. Alberto-Giovanni Busetto
CHIEF AI OFFICER

Silvana Lisca
CHIEF OPERATING & PEOPLE OFFICER

Dr. Paul Campbell
CHIEF REGULATORY OFFICER

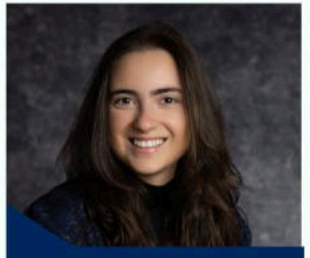


Anna Brezhneva
HEAD OF FUNDRAISING & PARTNERSHIPS

Amanda Leal
AI GOVERNANCE & POLICY SPECIALIST

Irene Rey Landeira
PROJECT COORDINATOR

Stéphane Dupré
HEAD OF COMMUNICATION



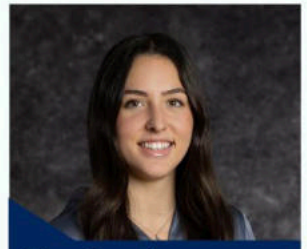
Luciana Pires
IMPACT MANAGER

Rado Andrian
HEAD OF GLOBAL AI PROGRAMS

Quentin Brown
ADMINISTRATIVE ASSISTANT

Yi-Roe Tan
COUNTRY IMPLEMENTATION MANAGER

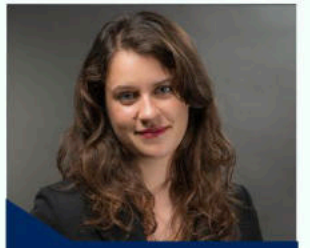
Robin Eede
FINANCE MANAGER



Léa Ferré
FUNDRAISING & PARTNERSHIPS ASSISTANT

Jhon Magkilat
KNOWLEDGE & TRAINING ADVISOR

Antoine Bourrier
PRODUCT OWNER GLOBAL PORTAL



Nadia Masarelli
HR GENERALIST

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Thank you

https://www.**healthai.agency**/

ricardo.baptistaleite@healthai.agency