Responsible Artificial Intelligence for Health

Ricardo Baptista Leite, MD

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

Founder & President | UNITE Parliamentarians Network for Global Health

Chair | Global Health Policy Lab @ Charité & Harvard, Berlin

Chair | NOVA Center for Global Health, NOVA University, Portugal

Former 4-term Member of Parliament | City Councilor of Sintra | Former Deputy Mayor of Cascais

ricardo.baptistaleite@healthai.agency | @RBaptistaLeite

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Why use Artificial Intelligence?

Industrialization of Healthcare

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Health Factory, Norway, 2010

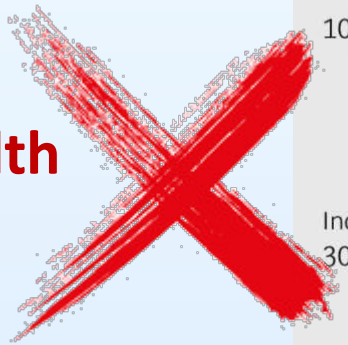
Rising Healthcare Costs and Rising Burden of Disease

↓

Risks of Unsustainability

↓

Universal Health Coverage



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Worse health - mainly for most vulnerable populations

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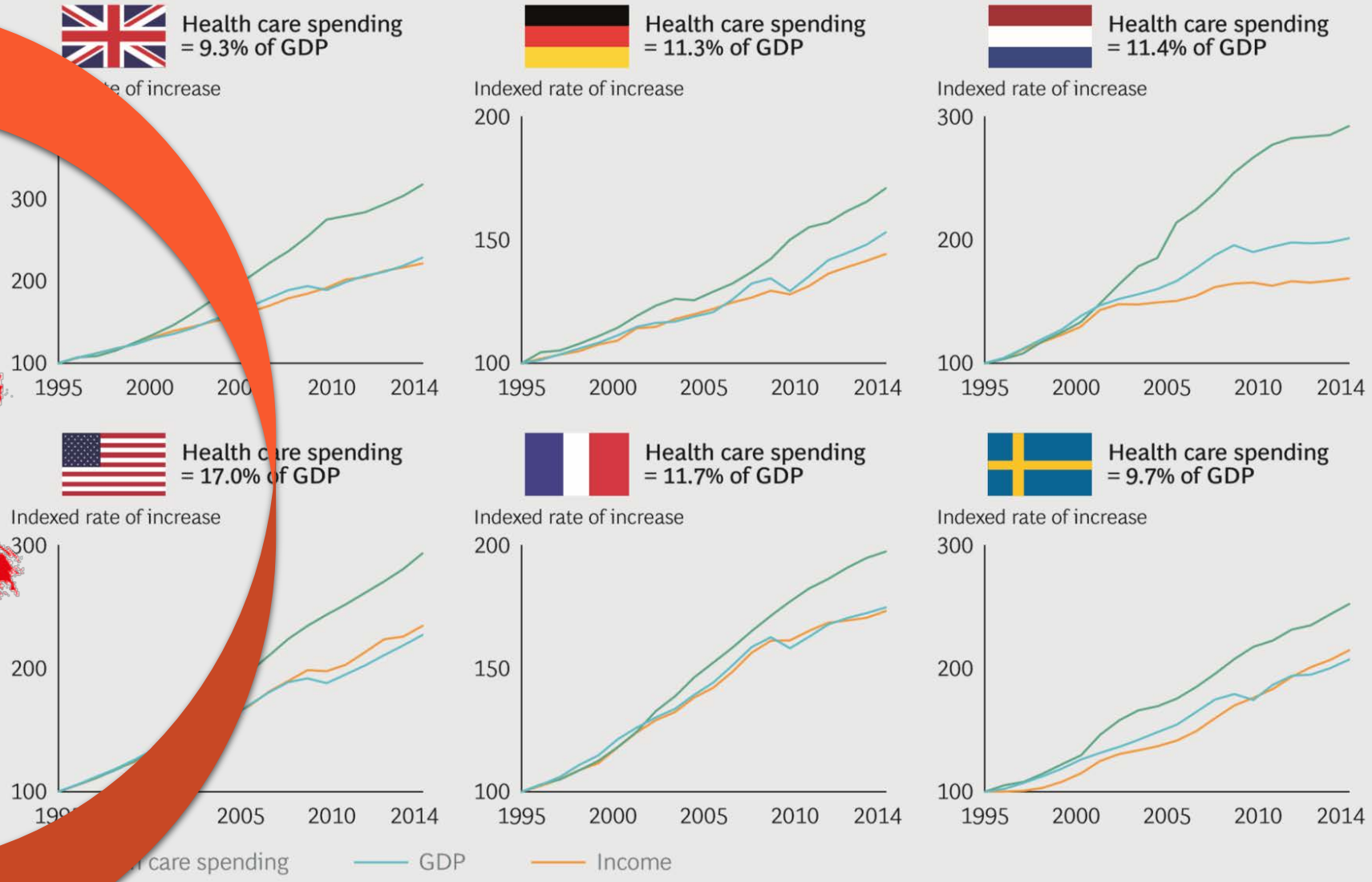
Rise of inequalities and poverty

Health Care Costs Are Rising at Unsustainable Rates



s: Economist Intelligence Unit, May 2015; Organisation for Economic Co-operation and Development; BCG analysis.
otes: The indexes are based on local currencies; 1995 = 100; income = personal disposable income; health care spending as a percentage of GDP is as of 2014.

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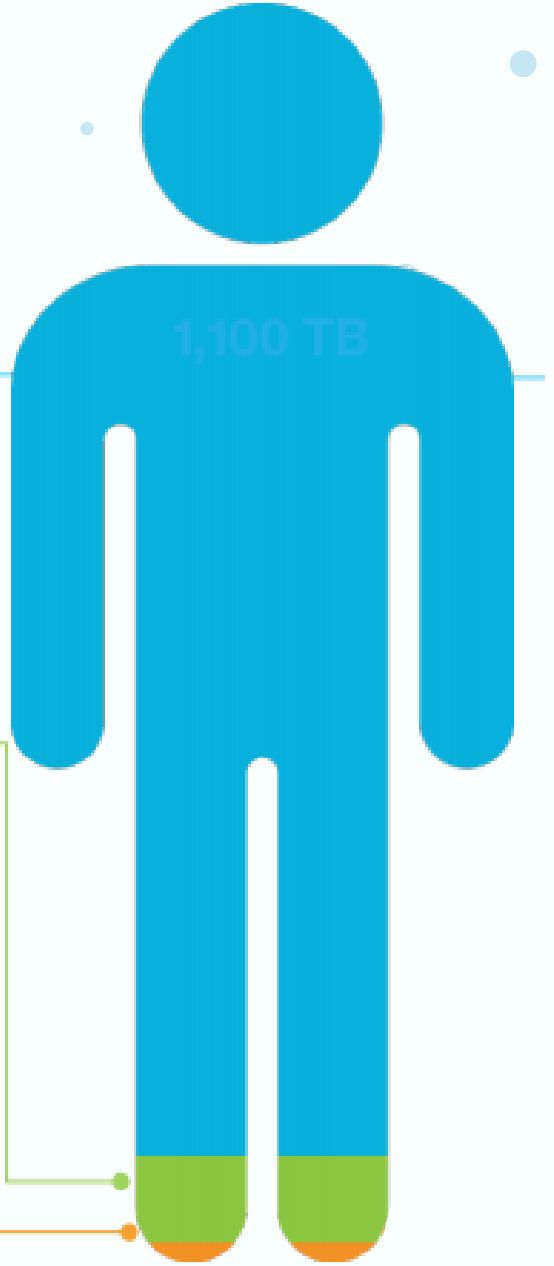
Impact on a person's health status



Exogenous Factors

60%

Environment & Social
Context, Behavior

Genomic Factors

30%

Clinical Factors

10%

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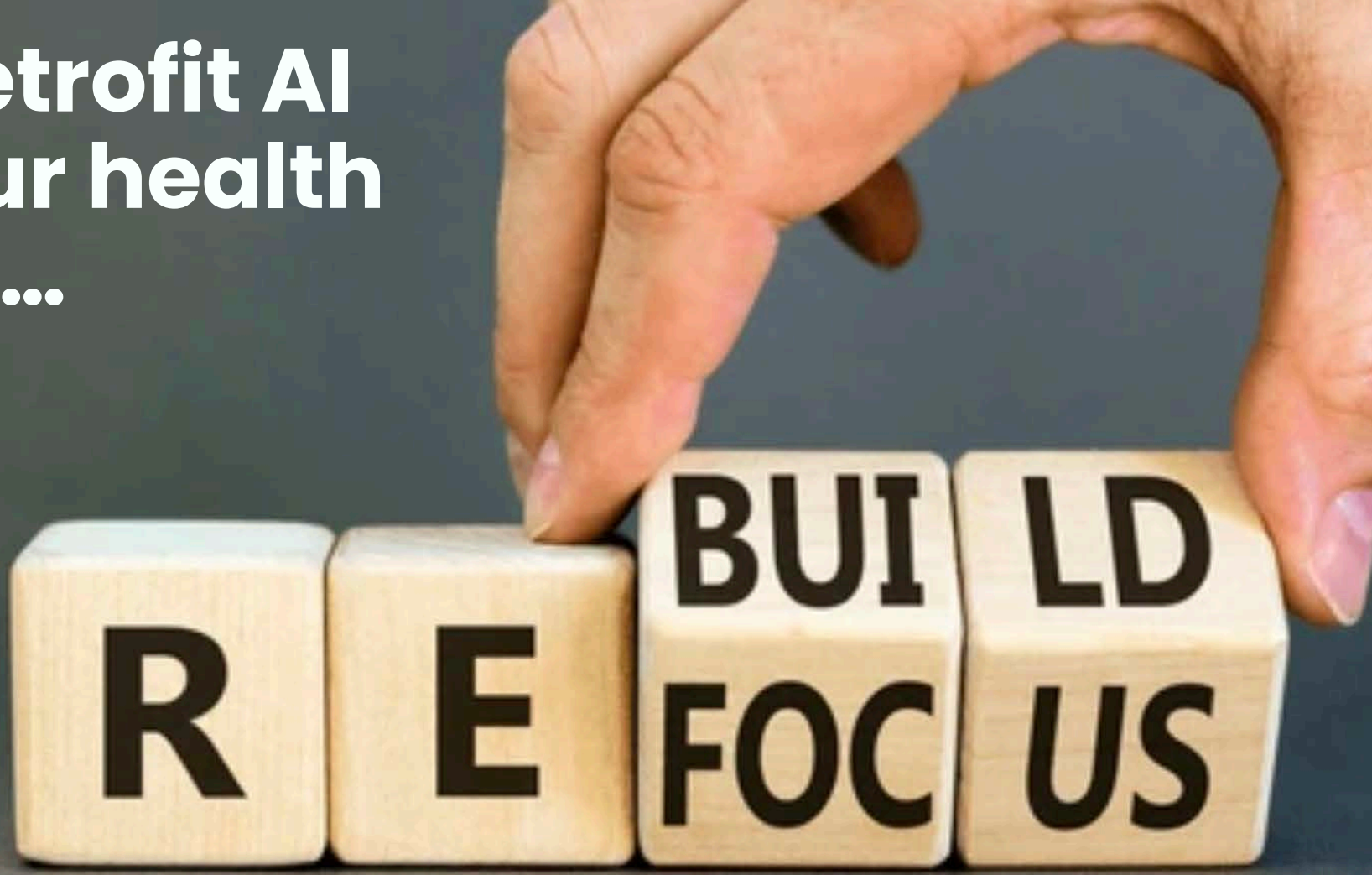
Don’t retrofit AI into your health system…



SHARE OF AI ADOPTION

across various industries

Technology
64%

Financial Services
10%

Health Care & Pharmaceutical
6%

Automotive
4%

Telecommunications
4%

Construction & Real Estate
3%

Energy
3%

Other
6%

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Source: Semantics Visions, April 2024

Why We Should Embrace AI Rather Than Fear It?

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

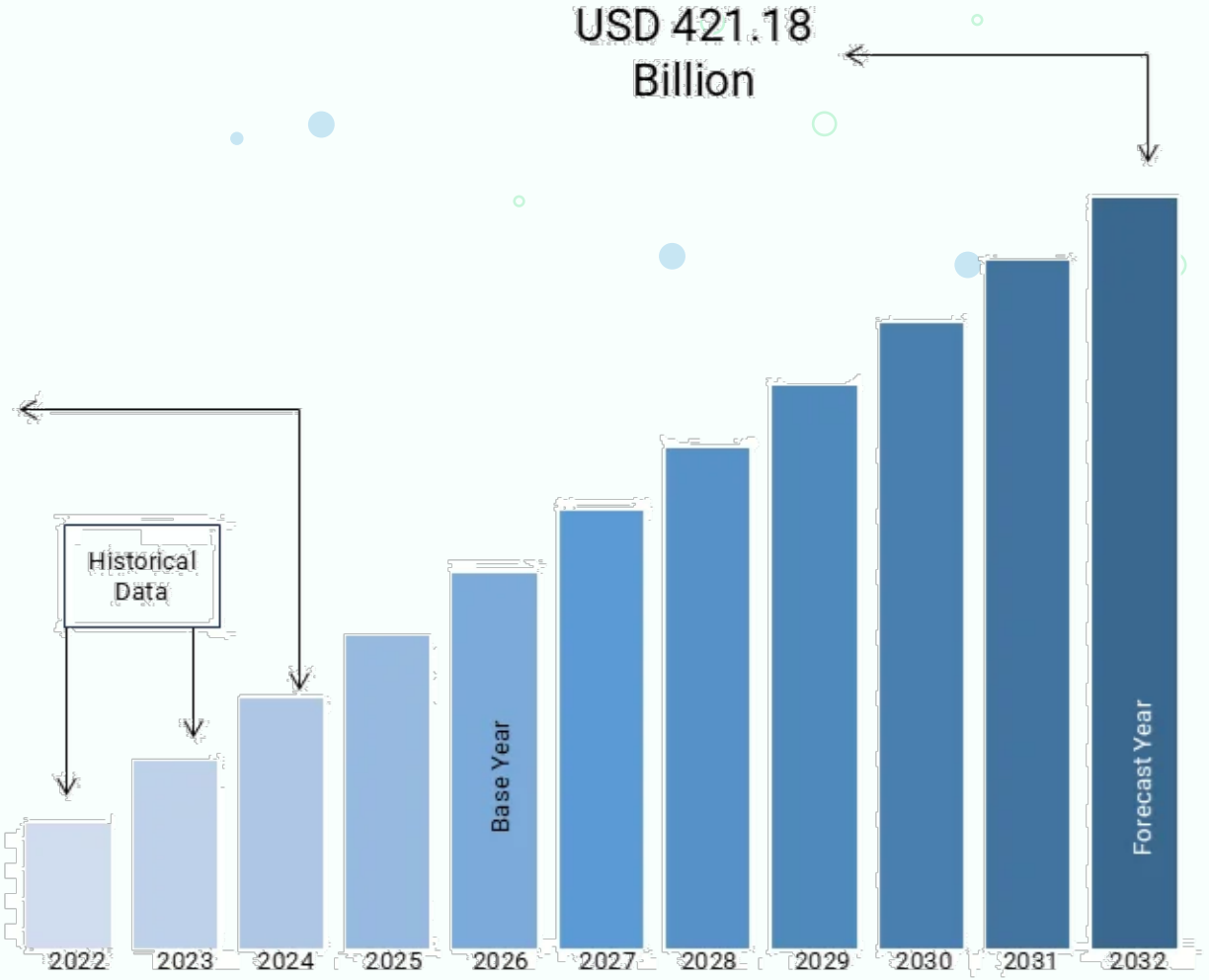
Global AI in Healthcare Market

Market Size Overview

49.8%

Global market CAGR, 2024 - 2032

USD 16.61 Billion



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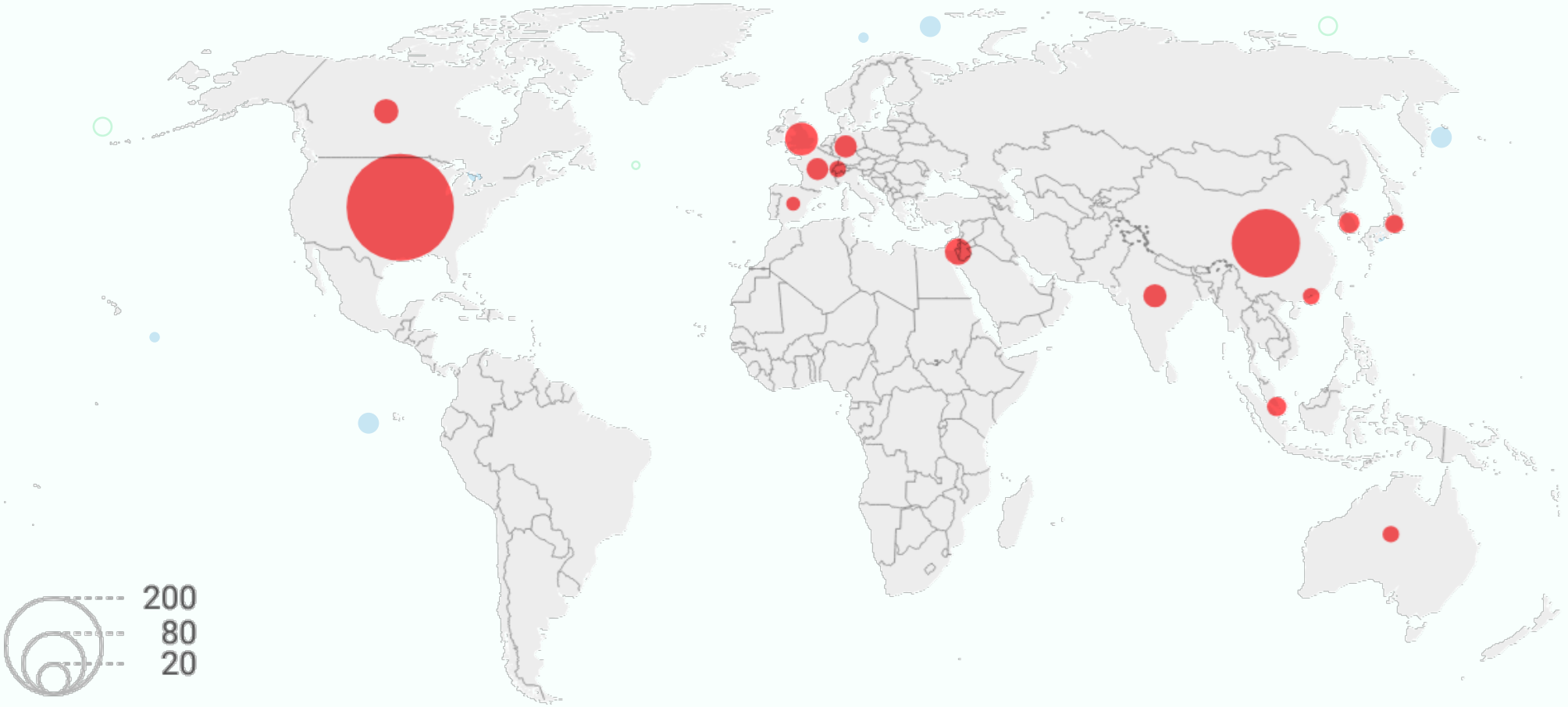
Source: Market Data Forecast Analysis

Private investment in AI by country

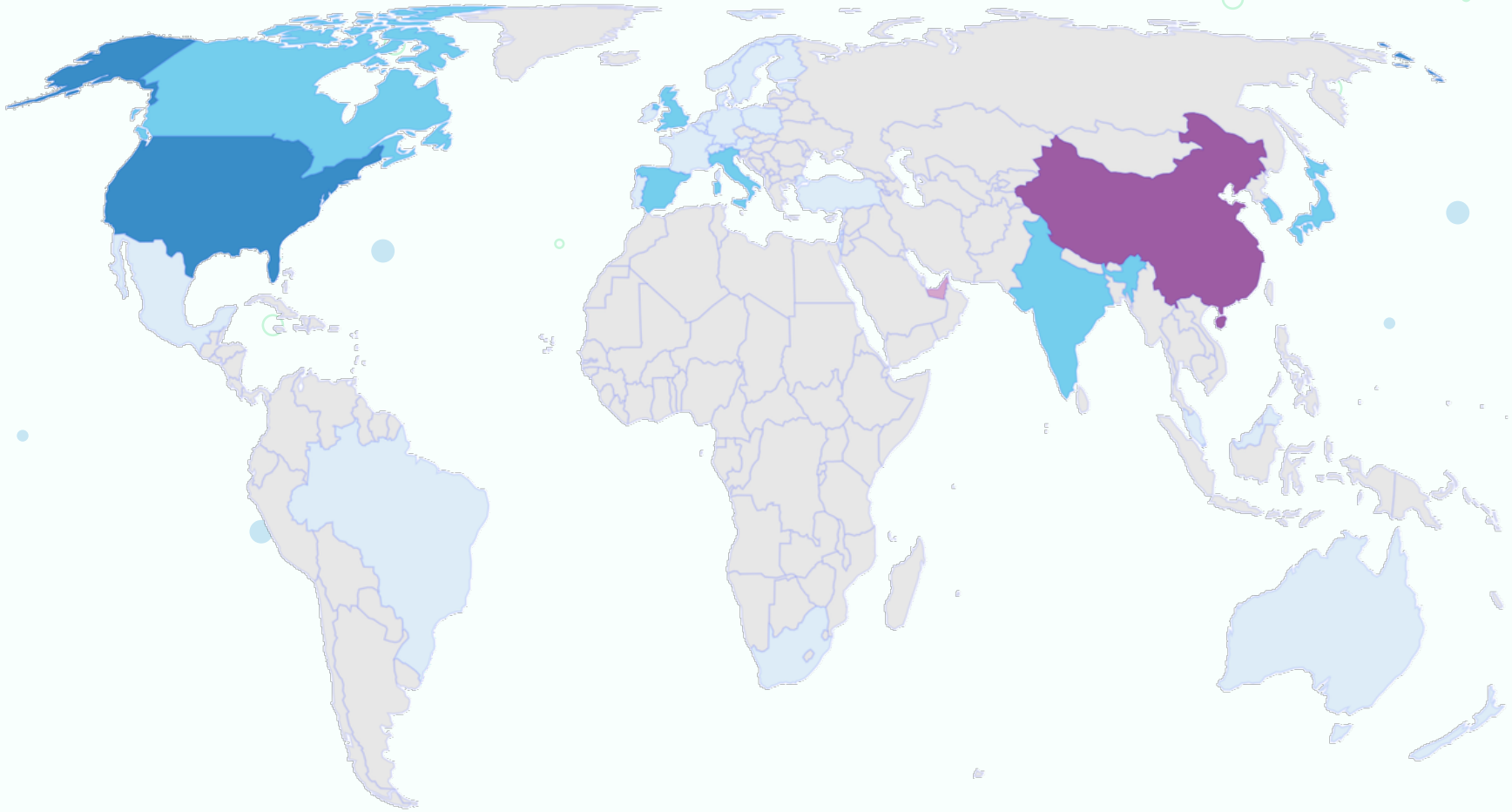
Total for the years 2013 to 2022, in billions of US dollars



Source: Stanford Institute for Human-Centered Artificial Intelligence • Created with Datawrapper

Total AI Public Offering Investment , 2023

Source: Quid, 2023 | Chart: AI Index, 2024



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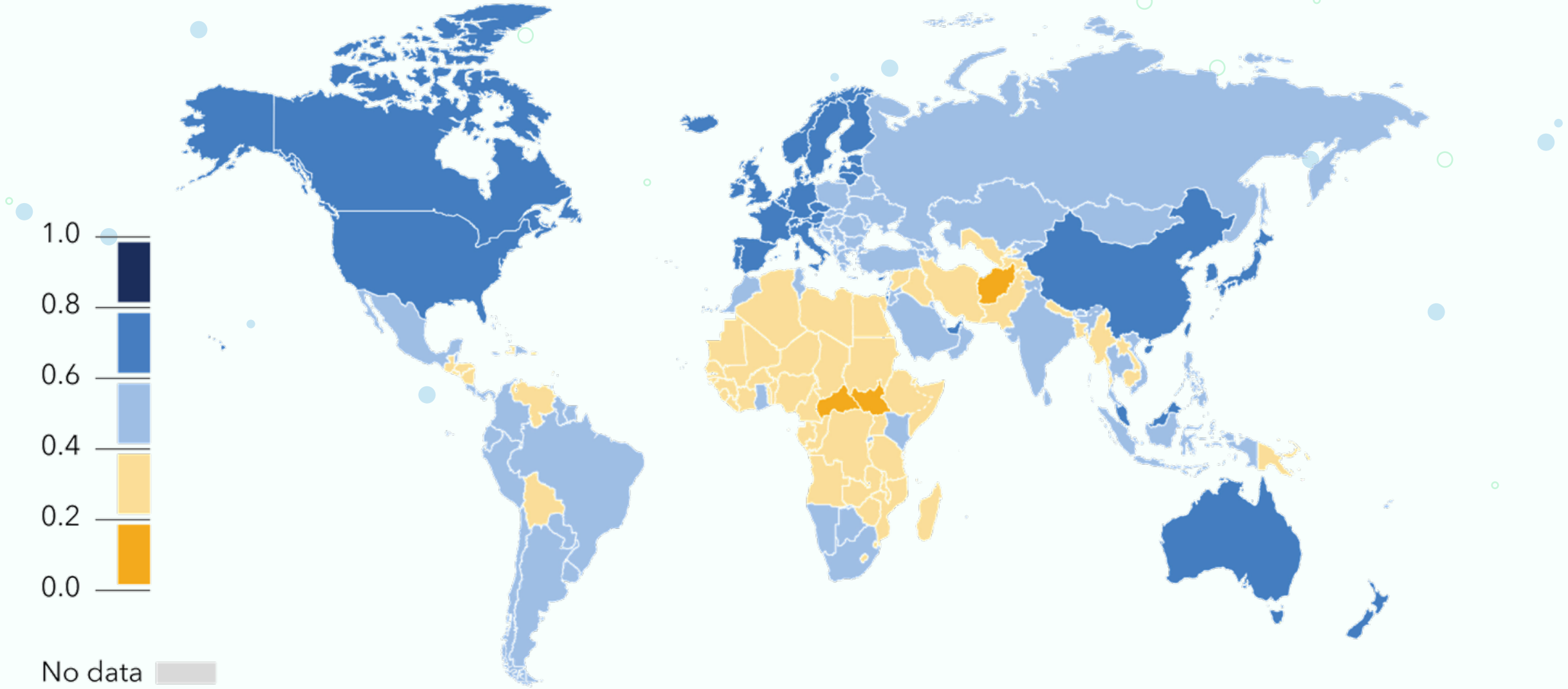
2023

AI Preparedness Index, 2023



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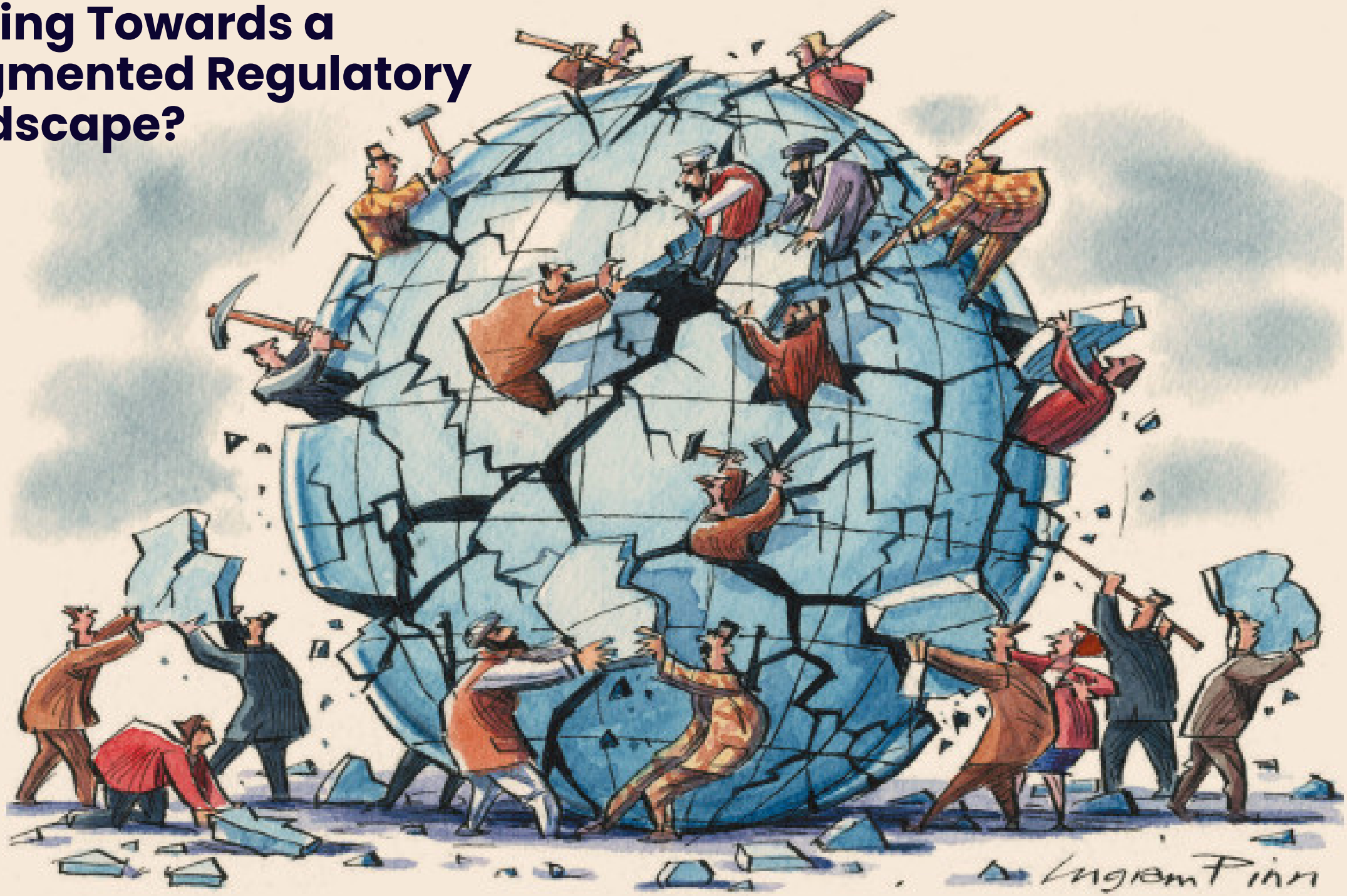
IMF

Moving Towards a Fragmented Regulatory Landscape?



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Mapping AI Governance in Health

From Global Regulatory Alignments to LMICs' Policy Developments

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IDRC · CRDI
Canada

UK International Development
Partnership | Progress | Prosperity

Regulatory Challenges for AI in Healthcare

Global fragmentation	• Navigate **differential requirements** in different countries/regions • Varying approval processes and timelines
Fast evolving AI	• **Fast evolving** AI developments • New regulations and standards in **response to emerging tech**
Data concerns	• **Data security and privacy** • **AI methods have *opaque* inner workings**
Post-market surveillance	• **Monitor safety and effectiveness** of devices • Adaptive learning with more data (need for periodic monitoring)
Health Technology Assessment	• **Undefined pricing and reimbursement models**

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Source: Technology trends and the future of medical devices. Sep 2023.
Hosny A, Parmar C, Quackenbush J, Schwartz LH, Aerts HJWL. Artificial intelligence in radiology. Nat Rev Cancer. 2018;18(8):500-510. doi:10.1038/s41568-018-0016-5
HTA challenge as defined by HealthAI

The Challenge

Lack of effective governance of AI in 'health' increases risks for citizens and systems which stimulates distrust and slow adoption of responsible AI solutions that can lead to better health outcomes for all

'valgis'
TRADE MARK
Each tablet contains
DISTAVAL
24 TABLETS
24 TABLETS
DISTAVAL
25 mg
25 TABLETS
'ASMAVAL'
TRADE MARK
Each tablet contains:
25 TABLETS
'ASMAVAL'
TRADE MARK
Each tablet contains:
25 TABLETS
'ASMAVAL'
TRADE MARK
Each tablet contains:
'DISTAVAL' (THALIDOMIDE) 12·5 mg.
EPHEDRINE HYDROCHLORIDE B.P. 20 mg.
25 TABLETS
'TENSIVAL'
TRADE MARK
25 TABLETS
'TENSIVAL'
TRADE MARK
Each tablet contains:
'DIREMA' (HYDROCHLOROTHIAZIDE) 12·5 mg.
'DISTAVAL' (THALIDOMIDE) 12·5 mg.
12 TABLETS
'VALGRAINE'
TRADE MARK

Learning from Medicines and Medical Devices

Trial Procedure

- Application (EU) Clinical Trial Regulation (536/2014)
- Information: context, relevance, sponsors, protocol, products…
- EU regulation 1901/2006: PIP, PDCO

Market Authorization

- The benefits outweigh the risks is the key principle guiding a medicine's assessment
- Quality, safety, and efficacy are assessed
- Different possible procedures: National, Mutual, Centralized…

HTA Assessment

- Holders of marketing authorization will seek reimbursement
- Different methodologies can be used to assess the economic impact
- Relative efficacy/effectiveness

Pricing and Funding Decision

- National and regional authorities decide on pricing and reimbursement
- EMA has no role in decisions on pricing and reimbursement

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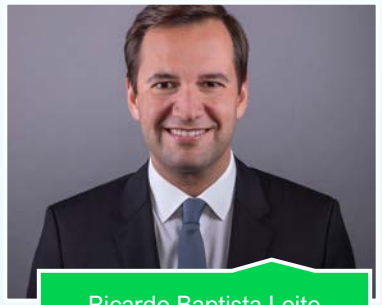
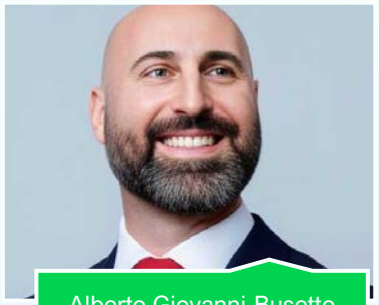
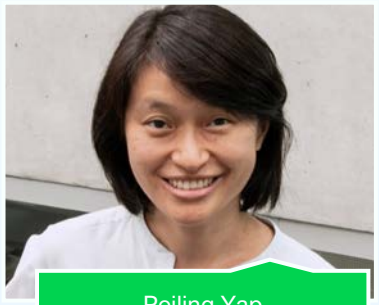


Ricardo Baptista Leite
CEO

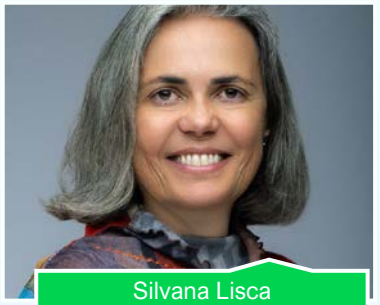


Alberto Giovanni-Busetto
Chief AI Officer

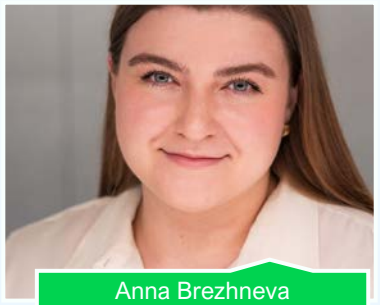


Peiling Yap
Chief Scientist

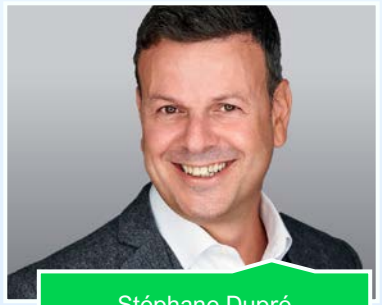
Paul Campbell
Chief Regulatory Officer



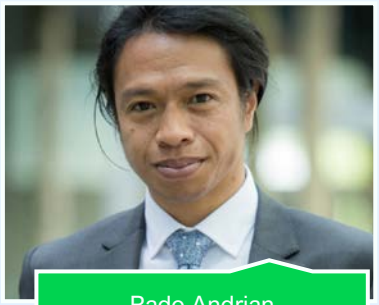
Silvana Lisca
Chief Operations & People Officer



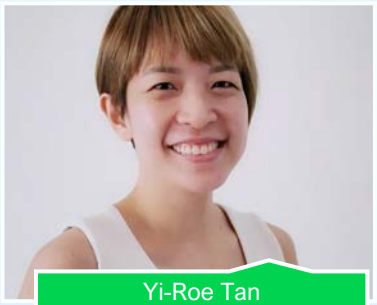
Anna Brezhneva
Resource Mobilization Mananger



Stéphane Dupré
Head of Communication



Rado Andrian
Head of Global AI Programs



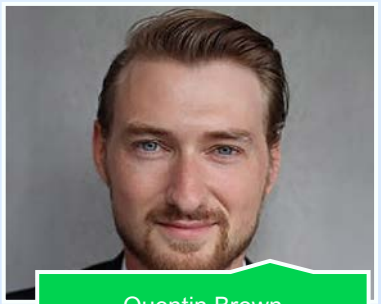
Yi-Roe Tan
Country Implementation Manager

Robin Eede
Financial Manager

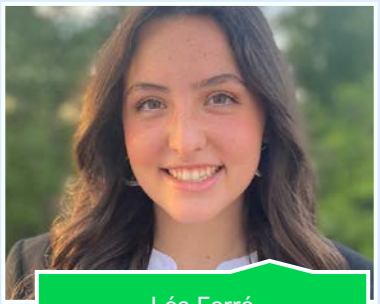
Irene Rey Landeira
Project Coordinator

Luciana Pires
Community & Impact Manager

Amanda Leal
AI Governance & Policy Specialist

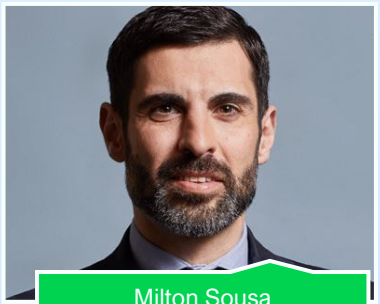


Quentin Brown
Administrative Assistant



Léa Ferré
Resource Mobilization Intern

Gnilane Sagna
Senior Financial Consultant (external)



Milton Sousa
Resource Development Consultant (external)

HealthAI Governance Role

HealthAI serves as a bridge between normative bodies and national and regional regulatory bodies to strengthen capacity and certify their regulatory mechanisms.

Normative Bodies
Set global standards

Interprets Standards

HealthAI

Builds Capacity

Qualifies Bodies

Regulatory Bodies
Validate AI solutions

Facilitates and Stewards

- Global Regulatory Network
- Global Early Warning System
- Global Public Repository of validated AI solutions
- Community of Practice

HealthAI <u>will not</u> define standards. This falls under the responsibility of international and/or national normative and standard setting organizations.

HealthAI <u>will not</u> validate AI tools for health systems. This falls under the responsibility of national and/or regional regulatory bodies.

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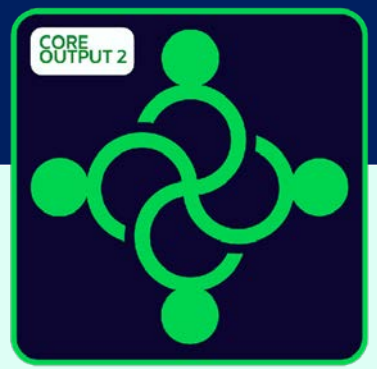
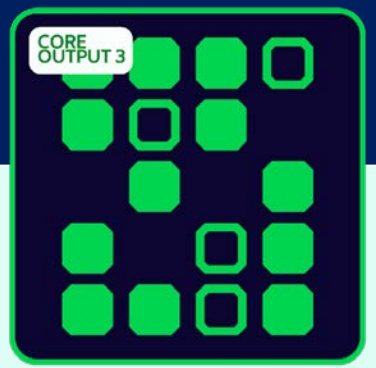
HealthAI | Country Implementation Partner

Responsible AI Solutions for Health

Co-create and certify **National & Regional validation mechanisms** on Responsible AI for Health



Establish a **Global Regulatory Network** for knowledge sharing and adverse events - '**Global Early Warning System**'



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

Deliver **advisory support** on Policies and Regulations

HealthAI Community of Practice

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Join Now Community of Practice

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Thank you

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ricardo.baptistaleite@healthai.agency