

AI in the NHS 2026

15 October 2026



We are an independent charitable organisation working to build a healthier UK. Everyone has a stake and a part to play in improving our health. By working together, we can build a healthier society.



Welcome

Dr Hugh Alderwick

Director of Policy and Research

The Health Foundation



Keynote address

Dr Ricardo Baptista Leite

CEO

HealthAI





Emerging challenges presented by AI

... and how different governments and health systems are responding

AI in the NHS 2026 – The Health Foundation
London, October 2026

Dr. Ricardo Baptista Leite, CEO

HealthAI – The Global Agency for Responsible AI in Health

Founder & President | UNITE Parliamentarians Network for Global Health

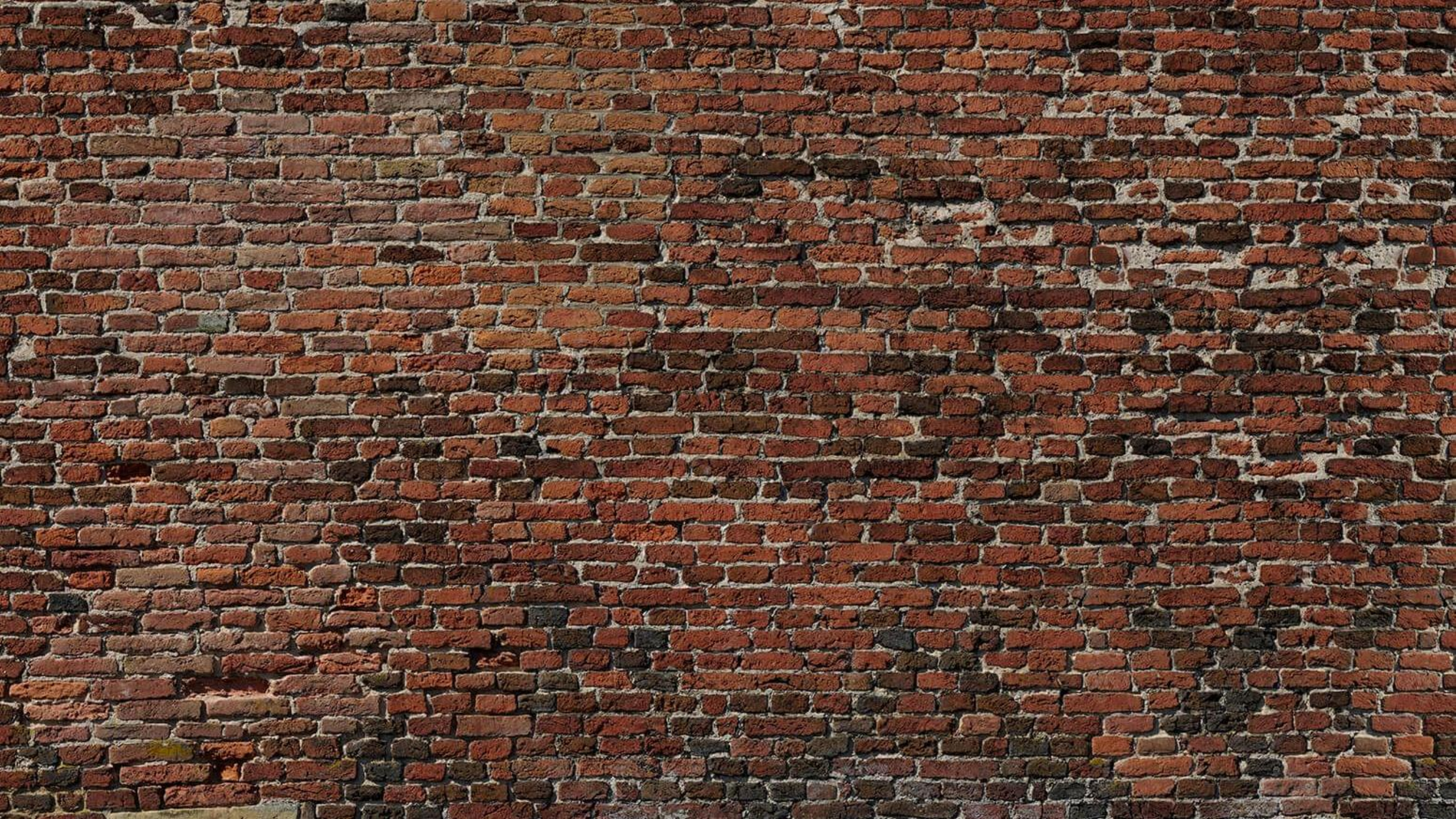
Chair | Harvard-Charité Global Health Policy Lab

Chair | NOVA Center for Global Health

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

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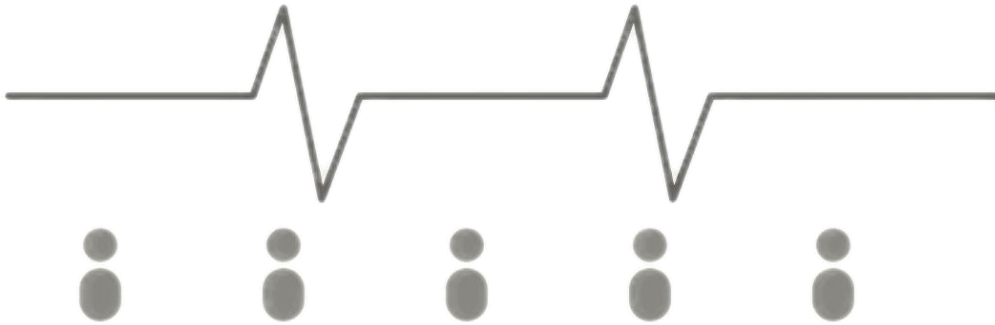
Governance as the infrastructure for trustworthy scale

The **opportunity** is not simply to regulate AI.

It is to build the capability that lets health systems use AI to **accelerate R&D, prevent illness, improve care, increase well-being, and reduce inequities.**

“In terms of equity, **AI will either be the greatest equalizer ever invented, or the worst source of injustice.**”

Bill Gates, August 2026



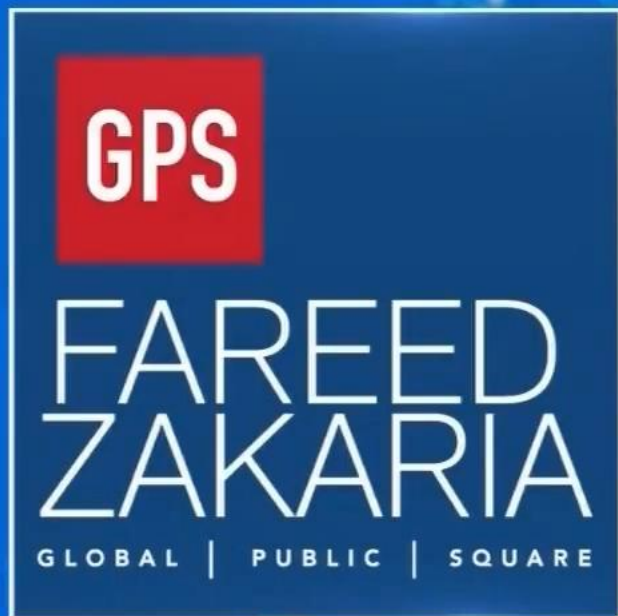
Pre-AI NHS

DON'T *RETROFIT* AI INTO YOUR HEALTH SYSTEM



“

AI retrofitted into legacy workflows may make health systems very efficient at being inefficient.



August 2026



FAREED ZAKARIA
GPS

AI Governance in Health Global Landscape Report 2025



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

Country analysis: Key takeaways



Cross-cutting challenges for responsible AI governance in health across the 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

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-building**.

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**.

European Union

*EU's vision for AI Economic
Competitiveness and Health*



Harnessing AI for Health and Economic Competitiveness: Translating the EU AI Act into Action



The Ambition:

Analyzing the EU's Vision for AI Economic Competitiveness and Health

The Reality:

AI Regulation Implementation Challenges

Analyzing Regulatory Realities against Ambitions:

Synthesis of findings into actionable recommendations.

EU AI Act and Regulatory simplification ambitions

- **EU AI Act** can strengthen the healthcare sector competitiveness, attesting the safety and quality of EU products – **single market enabler**
- **Joint guidance published by MDCG and the AI Board in June 2025**
 - **MDR classification** determines whether AI Act's high-risk obligations apply.
 - **Clarity needed on how conformity assessments will be streamlined in practice.**
- **CSO's concerned** that **simplification** may come at the expense of consumer **protection**, product **safety** and fundamental **rights**



Key takeaways from the national implementation of the AI Act*

*Based on review of implementation across 4 major EU Economies:
France, Germany, Italy and Spain

Coordination between horizontal AI authorities and sector-specific medical device regulators is the challenge for enforcement -- no country has validated dual supervision model.

Countries have different strengths: France in institutional maturity and data governance, Germany in reimbursement pathways, Italy in comprehensive national legislation, and Spain in regulatory experimentation.

All countries have advanced **health data governance architectures** that are central to the AI Act's infrastructure – **EHDS depends on their interoperability and quality**



Market access is the binding constraint on innovation: only Germany and, to a lesser extent, France have structured **reimbursement pathways** to help scale AI tools

Regulatory experimentation is emerging as a governance tool across all four countries, with AI sandboxes, guidance documents, and institutional support programmes accompanying formal enforcement.

United Kingdom

National Commission into the Regulation of AI in Healthcare



Four shifts that make AI Governance - Health System Governance

01 Product performance → Health-system value

Does deployment improve outcomes, equity, workforce experience and sustainability?

02 One-off approval → Lifecycle assurance

Can we monitor drift, updates, versions and differential performance in real-world use?

03 Regulatory fragmentation → Cooperative capacity

Can countries rely on trusted assessments and exchange safety signals?

04 Automating care → Redesigning health

Can AI move us upstream: prevention, earlier intervention and healthier lives?

A framework can be Safe, Trusted and Fast only if it builds these capabilities into daily decisions.

Principles do not govern systems. Capabilities do.

Capability is the practical layer between regulation on paper and safe adoption in real clinical pathways.

National governance

mandates · liability ·
procurement ·
reimbursement · public
accountability

Regulatory assurance

risk classification ·
validation · sandboxes ·
post-market surveillance

Health-system adoption

readiness · workflow
redesign · workforce
support · HTA and value

Learning infrastructure

incident reporting · version
traceability · safety signals
· peer learning

The question for every country is no longer: “Do we have AI principles?”

It is: “Can our system detect, decide, learn and act?”





Safety is no longer a unique moment in time. It is a continuous loop.

- AI Product Development

- Pre-market evidence
- Controlled deployment
- Local performance monitoring
- Version traceability
- Incident escalation
- Learning and updating

Lifecycle Governance

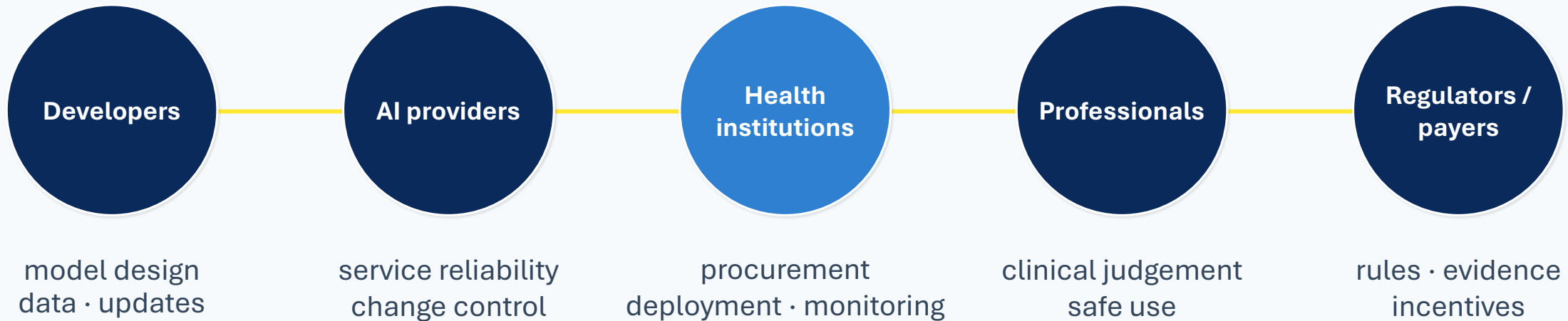
**If we want AI to move fast,
safety cannot stop at approval.**



**Trust is not achieved by placing
a nominal human at the end of
an automated chain.**

No clinician should become the liability sink for systemic failures.

Accountability should follow real control — not merely the last person in the room.



AI harms and evidence will not respect national borders

A responsible global architecture *does not* require one global regulator. It requires **interoperable learning**.

Common expectations | Shared terminology, minimum evidence and governance baselines

Reliance pathways | Trusted assessments that can be re-used and contextualised

Safety signal exchange | Incident reporting and early warning across jurisdictions

Peer learning | Regulators learning from each other's deployments and failures

Governance capacity is a *global public good*.

THE UK OPPORTUNITY

Make “Safe, Trusted and Fast” operational. And make it learnable.

The UK can lead internationally by turning the Commission’s recommendations into a capability model other systems can adapt.

01 A health-transformation test

Fund and **scale** AI that improves pathways, prevention, outcomes and equity — not disconnected pilots.

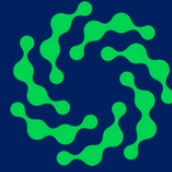
02 A lifecycle assurance operating model

Define **who** monitors what, **how** incidents escalate, and **when** updates trigger reassessment - and **collaborate internationally**.

03 A public learning system

Create transparent **feedback loops** across regulators, providers, professionals, patients and innovators.

A governance model that earns trust - enabling an ecosystem that protects patients, accelerates responsible innovation, and improves health for all



Thank You

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





Break

Panel discussion: What is the long term future for AI in health care?

Dr Joseph Alderman, Postdoctoral Researcher in AI and Digital Health, University of Birmingham

Brian Anderson, Chief Executive, Coalition for Health AI (CHAI)

Madhumita Murgia, AI Editor, Financial Times

Anna Thomas, Founding Director, Institute for the Future of Work

Chair: Tim Horton, Deputy Director, Health and Care Policy, The Health Foundation

Panel discussion: Choosing AI tools – how to speed up evaluative processes without compromising on quality

Mary Dixon-Woods, Director of The Healthcare Improvement Studies (THIS) Institute

Ed Middleton, Interim Director of Strategy, MHRA

Saira Ghafur, Digital Health Lead at the Institute of Global Health Innovation, Imperial and Co-Founder & CMO, Prova Health

Chair: Dr Jennifer Dixon DBE, Chief Executive, The Health Foundation

Panel discussion: Health care at the cutting edge of AI – lessons from the world's leading systems

Bob Klaber, Director of Strategy, Research & Innovation, Imperial College Healthcare NHS Trust

Wonchul Cha, Chief Information Officer, Samsung Medical Centre, Korea

Micky Tripathi, Chief AI Implementation Officer, Mayo Clinic

Davina Lim, Director, Future Systems & Innovation, Ministry of Health, Singapore

Chair: Alex Lawrence, Improvement Fellow, The Health Foundation

Closing comments

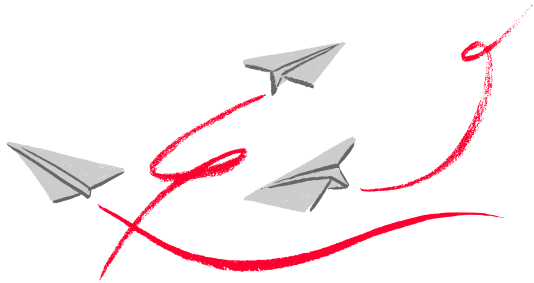
Dr Jennifer Dixon DBE

Chief Executive

The Health Foundation



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