Translating the EU AI Act into action

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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

Methodology

Documentary policy review and analysis

Primary and secondary sources published until April 2026

Legislative instruments, EC communications and strategy documents, reports from CSO, industry associations and research institutes, academic literature

Convenings

Panel at **European Health Forum Gastein 2025**

Friends of Europe Chatham House Roundtable 2025

Stakeholder consultations

Off-the-record consultations

20 individuals including national and EU-level public officials, academia, civil society, and the private sector

The Ambition

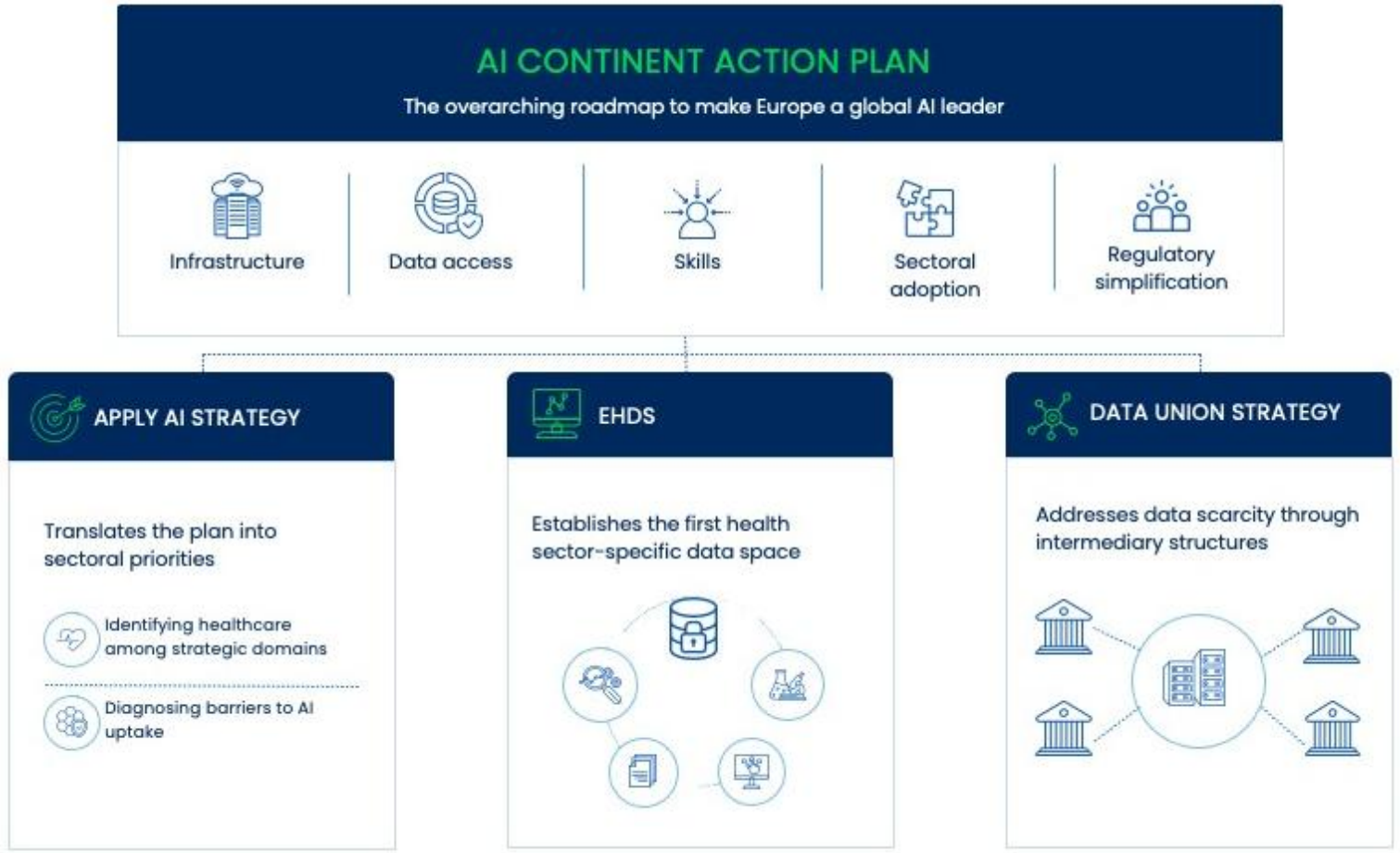
Analyzing the EU's Vision for AI Economic Competitiveness and Health

The AI Continent Action Plan

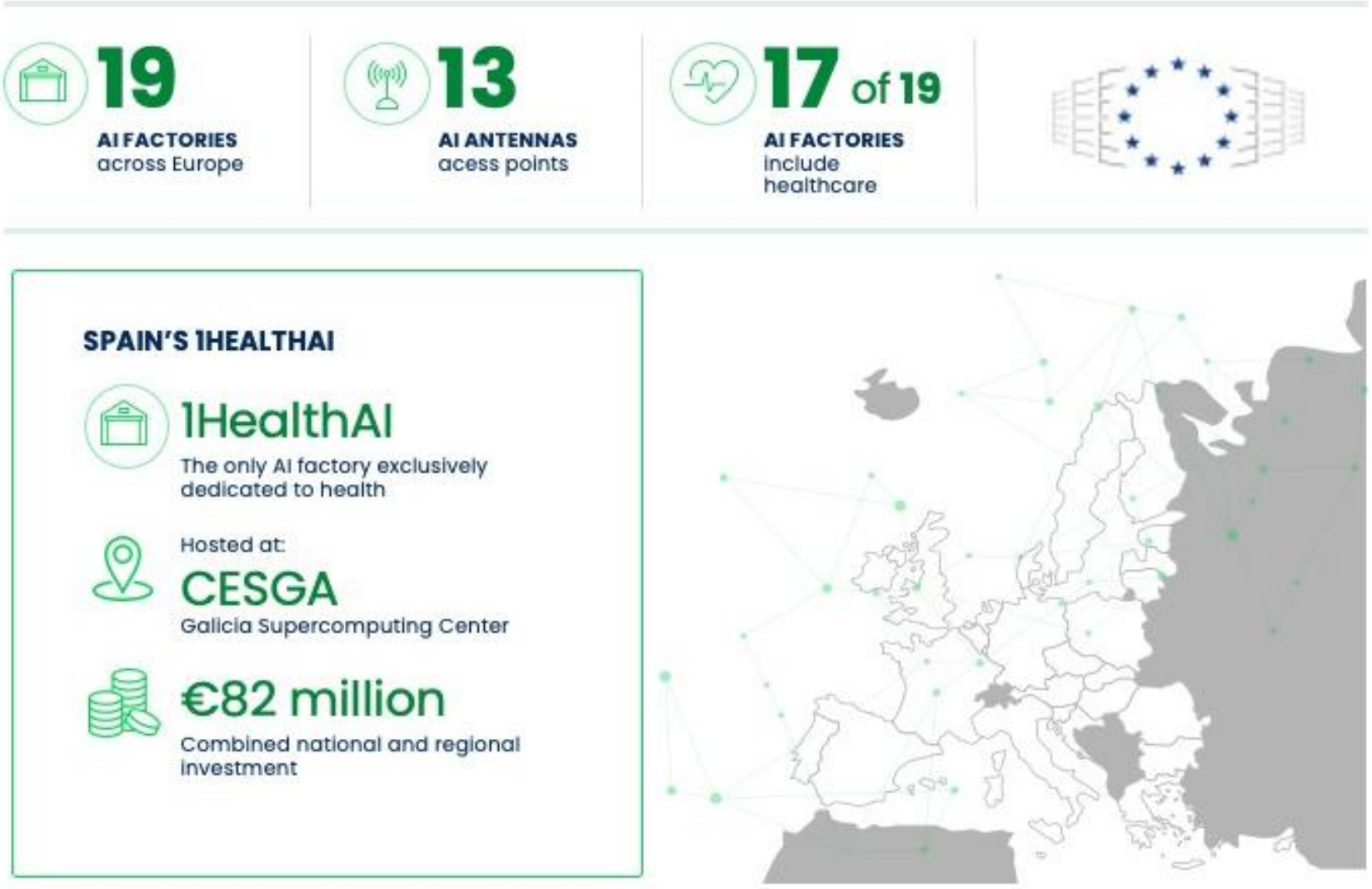
- **EU AI Act** can strengthen healthcare sector competitiveness, attesting the safety and quality of EU products – **single market enabler**

- Does not work in a vacuum – **The AI Continent Action Plan shapes the conditions where the EU AI Act will be implemented**

- Full cross-border health data infrastructure will only be fully deployable in March 2031



EU's AI Factories and Gigafactories



- **AI Factories** are built around AI-optimized supercomputers providing startups, SMEs and researchers access to HPC resources
- **AI Antennas** are smaller-scale access points linked to the main Factories

Regulatory simplification ambitions

- Joint guidance published by MDCG and the AI Board in June 2025:
  - MDR classification determines whether AI Act's high-risk obligations apply.
  - Integrate AI Act's high-risk obligations in the MDR – single frameworks for AI-enabled medical devices.
  - Clarity needed on how conformity assessments will be streamlined in practice.
- AI Act's horizontal scope was designed to function alongisde existing sectoral regulations, simplication efforts might create complexity elsewhere in the enforcement process
- CSO concerned that simplification may come at the expense of consumer protection, product safety and fundamental rights

The Reality

AI Regulation Implementation Challenges

Implementation across 4 major EU economies

Gaps & Risks:

- Multi-authority model signals significant coordination complexity
- No formal AI supervisory designation required under AI Act
- Limited notified body capacity

- KI-MIG still a draft; BNetzA the designated AI supervisory authority operates without full statutory enforcement powers
- Federal states retain market surveillance roles, increasing fragmentation risks

- Dispersed medical device oversight; absence of a centralised national medical devices authority
- Absence of a structured digital health reimbursement pathway

- Dual-agency coordination untested for AESIA-AEMPS
- Absence of a harmonised digital health reimbursement mechanism
- National AI law defining sanctioning regime not yet enacted

NATIONAL IMPLEMENTATION LANDSCAPE

1 FRANCE

France is embedding AI governance within its established health regulation and data protection.

2 GERMANY

Germany is pursuing a dedicated implementation law (KI-MIG), with a central coordination role.

3 ITALY

Italy has enacted the first comprehensive national AI law in the EU (Law No. 132/2025), with AI Act-related.

4 SPAIN

Spain has moved fastest on institutional setup, establishing the first EU AI supervisory agency (AESIA).

Key takeaways for the national implementation of the EU AI Act

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

2. 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.

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

4. 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

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

Final Considerations

Analyzing Regulatory Realities Against Ambitions

Key recommendations for strengthening AI governance in the EU

1. Countries should test their dual supervision architectures for AIaMD through joint mock exercises against hypothetical cases to identify conflicts of competence and operational gaps.

2. The EC and Member States should address regulatory barriers to SMEs' market access and scaling across the EU, prioritising coordination and guidance for harmonised reimbursement pathways.

3. The EC should clarify the interplay between the EHDS, the AI Act, and the MDR—three frameworks split across two Directorates-General—through coordination instruments such as blueprints and roadmaps to guide stakeholders.
    - The integration of AI Act's obligations in the MDR proposed in December 2025 could adequately solve the interplay issue between the AI Act and MDR.

Key recommendations for strengthening AI governance in the EU

4 Member States should formalise channels for knowledge exchange on implementation, building on each country's comparative strengths rather than replicating efforts in isolation, with DG-SANTE and the AI Office facilitating coordination at the intersection of AI and health.

5 Coordination should extend to structured multistakeholder engagement at both national and EU levels, ensuring that oversight structures, conformity assessment procedures, and enforcement priorities incorporate the persepctives of those affected by them.

Access the Report

Thank you!

https://www.healthai.agency/

HEALTH AI

The Global Agency for Responsible AI in Health