Full Report

HARNESSING AI FOR HEALTH AND ECONOMIC COMPETITIVENESS:

Translating the EU AI Act into Action

2026

HEALTH AI
The Global Agency for Responsible AI in Health

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HARNESSING AI FOR HEALTH AND ECONOMIC COMPETITIVENESS:

Translating the EU AI Act into Action

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Contents

Executive Summary

This report examines how the European Union's policy strategies, regulatory frameworks, and national implementation efforts intersect when it comes to artificial intelligence in the health sector.

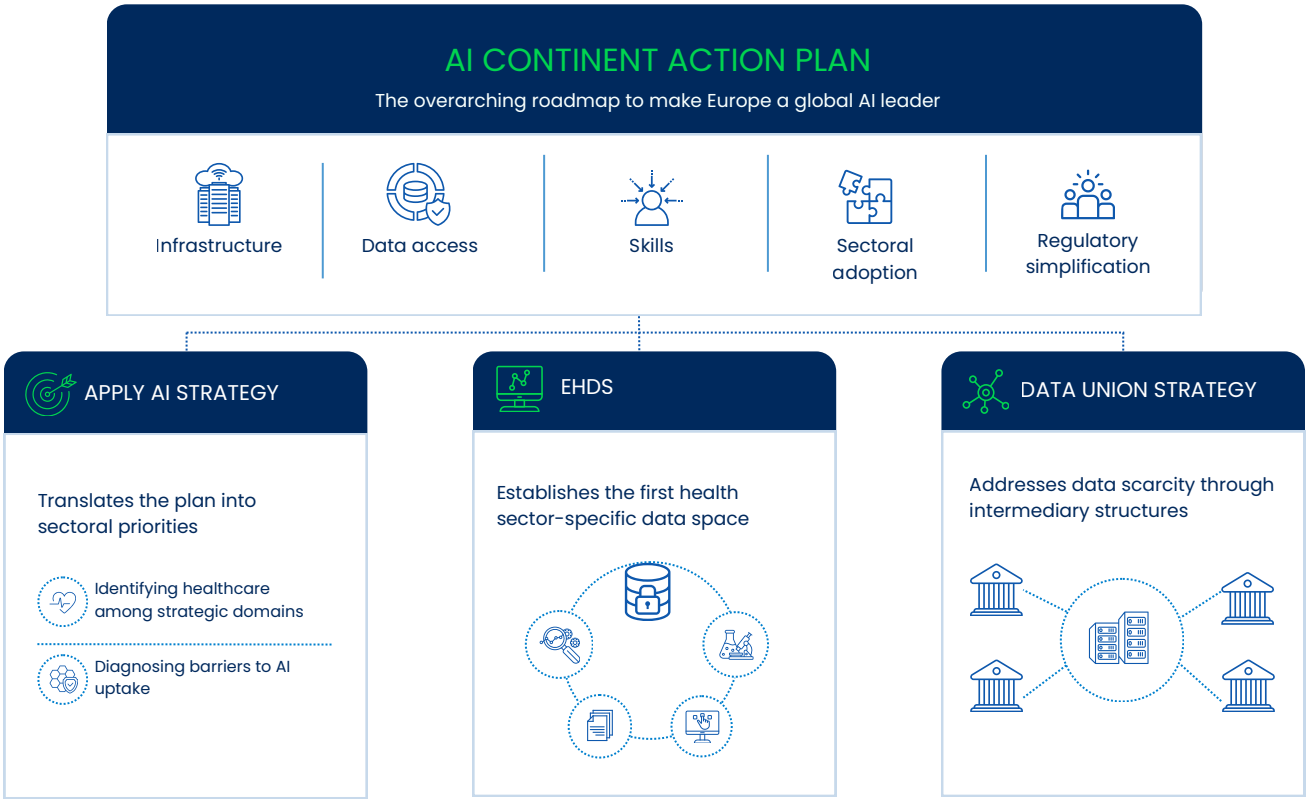
It connects the EU's competitiveness ambitions—articulated through the AI Continent Action Plan, the Apply AI Strategy, the European Health Data Space (EHDS), and the Data Union Strategy—with the operational realities of implementing the EU AI Act (Regulation 2024/1689) across Member States. The analysis draws on policy review, 20 semi-structured consultations with stakeholders from the public sector, civil society, academia, and the private sector, and expert discussions conducted between October 2025 and April 2026.

> *Implementation infrastructure is arriving later than the compliance obligations it is meant to support*

AI in health occupies a uniquely complex regulatory position. It sits at the intersection of patient safety, fundamental rights, sensitive personal data, and product safety regulation, including medical devices. This combination places most healthcare AI applications in the AI Act's high-risk category—triggering the regulation's most stringent compliance obligations, applicable from August 2026, with an extended transition until August 2027 for AI-enabled medical devices requiring third-party conformity assessment.

The EU has matched this regulatory framework with a policy architecture designed to position Europe as a competitive global AI leader. The AI Continent Action Plan provides the overarching roadmap, structured around infrastructure, data access, skills, sectoral adoption, and regulatory simplification. The Apply AI Strategy translates this into sectoral priorities, identifying healthcare among its strategic domains and diagnosing barriers to AI uptake—limited data availability, infrastructure heterogeneity, insufficient AI literacy among health professionals, and lack of trust. The EHDS establishes the first sector-specific data space, enabling secondary use of health data for AI development. The Data Union Strategy addresses data scarcity through intermediary structures such as Data Labs, while depending on the EHDS infrastructure it seeks to complement.

However, the report identifies a consistent pattern: the implementation infrastructure required to deliver on these ambitions is arriving later than the compliance obligations it is supposed to support. Harmonised standards remain incomplete, notified body capacity is insufficient, and the EHDS secondary use framework and harmonisation of health data access bodies will take a few years to be operationalised. In addition, many of the Apply AI Strategy's support measures for healthcare—including guidelines on the AI Act's interplay with other Union law and the European Network of Expertise on AI Deployment in Healthcare—are scheduled to materialise after, or concurrent with, the high-risk provisions taking effect. This mismatch in timelines means that developers and deployers face regulatory obligations without the tools and infrastructure the EU itself has identified as necessary to meet them.



The joint guidance issued by the Medical Device Coordination Group and the AI Board (MDCG 2025-6 / AIB 2025-1) has provided the first authoritative clarification of the AI Act–MDR interplay, but stakeholders continue to stress the need for clarity on how conformity assessments will be streamlined in practice. The regulatory landscape is further complicated by the ongoing simplification debate. The Omnibus proposals, driven by the competitiveness agenda following the Draghi Report, could alter the AI Act's high-risk framework for medical devices—potentially integrating AI Act-specific obligations into MDR conformity assessment where the latter already applies. Stakeholder positions on this prospect are divided: Some view it as a necessary reduction in complexity; others caution that it may transfer regulatory gaps rather than close them.

The notified body bottleneck illustrates the implementation challenge in concrete terms. As of October 2025, 51 notified bodies have been designated under the MDR, but AI Act designation requires demonstrating additional competencies—including AI technology knowledge and data science expertise—that extend beyond traditional medical device assessment capabilities. Proposed amendments to the MDR's Rule 11 classification could reclassify some medical device software to a lower category and reduce the volume of applications requiring third-party assessment. However, some stakeholders have raised questions about whether lower-risk classification adequately reflects the safety implications of AI-driven clinical tools.

Moving from the EU-level landscape and zooming into national-level challenges, the report analyses the implementation landscape across the EU's four largest economies—France, Germany, Italy, and Spain. All four countries are advancing their implementation, but through distinct institutional models shaped by their existing administrative structures and policy priorities. France is embedding AI governance within its established health regulation and data protection framework, though a formal AI supervisory authority has not yet been designated. Germany is pursuing a dedicated implementation law (KI-MIG), with a central coordination role for the Federal Network Agency (BNetzA), though parliamentary approval remains pending. Italy has enacted the first comprehensive national AI law in the EU (Law No. 132/2025), with AI Act-related sanctioning powers expected by October 2026. Spain has moved fastest on institutional setup, establishing the first EU AI supervisory agency (AESIA) and launching the first AI regulatory sandbox in Europe.

NATIONAL IMPLEMENTATION LANDSCAPE

1 FRANCE

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

2 GERMANY

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

3 ITALY

Italy has enacted the first comprehensive national AI law in the EU (Law No. 132/2025).

4 SPAIN

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

Five cross-cutting findings from France, Germany, Italy, and Spain:

- Coordination between horizontal AI authorities and sector-specific medical device regulators is the defining challenge for enforcement, and no country has yet validated its proposed dual supervision model in practice.
- Countries are specialising in different implementation strengths. France in institutional maturity and data governance, Germany in reimbursement pathways, Italy in comprehensive national legislation, and Spain in AI regulatory sandboxes.
- All four countries have advanced health data governance architectures that are central to the AI Act's infrastructure, but whose interoperability and quality will determine whether the EHDS delivers on its promise.
- Market access—not market authorisation—is the binding constraint on innovation. Only Germany and, to a lesser extent, France have structured reimbursement pathways for health technologies that can help scale AI tools as well, while Spain and Italy lack comparable mechanisms, leaving approved AI tools without the budgetary and legal basis for clinical adoption.
- Regulatory experimentation is emerging as a governance tool across all four countries, with AI sandboxes, guidance documents, and institutional support programmes accompanying—rather than replacing—formal enforcement.

Five recommendations for strengthening AI governance in health in the EU:

- Countries should test their dual supervision architectures for AI in medical devices before high-risk requirements take effect. This can be done, for instance, through joint mock exercises against hypothetical cases to identify conflicts of competence and operational gaps before they are exposed by real incidents.
- The European Commission and Member States should address regulatory barriers to SMEs' market access and scaling across the EU, prioritising coordination and guidance for harmonised reimbursement pathways so that regulatory approval translates into clinical use.
- The European Commission should prioritise further clarifying the interplay between the EHDS, the AI Act, and the MDR—three frameworks split across two Directorates-General. This can be done through blueprints and roadmaps that guide stakeholders, particularly healthcare-focused SMEs, ahead of enforcement deadlines. Further regulatory integration should be considered a potential solution to the issues arising from the interplay.
- 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. The AI Board could potentially expand its function from regulatory coordination to operational peer learning.
- Coordination should extend to structured multistakeholder engagement at both national and EU levels, ensuring that implementation decisions—on oversight structures, conformity assessment procedures, and enforcement priorities—incorporate the perspectives of those affected.

NATIONAL IMPLEMENTATION LANDSCAPE

While this report centres on the health sector, where the convergence of high-risk classification, sensitive data, and sectoral regulation creates a particularly complex implementation landscape, the structural challenges it identifies—mismatches in timelines, institutional fragmentation, and gaps between regulatory ambition and enforcement capacity—are likely to reproduce across other high-risk domains as the AI Act's full application approaches. The EU's ambition is substantial, the legal frameworks are in place, and the strategic vision is articulated. But the implementation infrastructure and capacity lag behind the compliance timeline. The EU's global AI governance leadership depends on closing that gap.

1

SECTION

Introduction

Introduction

AI in health sits at a unique regulatory intersection: with patient safety and sectoral regulations, fundamental rights, sensitive personal data, and product safety regulations, including medical devices. This combination places AI in health in the high-risk tier of the AI Act's risk classification and triggers the most stringent compliance obligations. **The AI Act thus assumes an important role in the EU's competitiveness and innovation policies. It is a regulatory framework that may strengthen healthcare sector competitiveness by attesting the safety and quality of EU products and enabling a single market for them.** In addition, it doubles as a legal blanket that reinforces fundamental rights in the AI age.

Beyond the regulatory efforts, the European Commission has launched a set of initiatives designed to position the EU as a global AI leader and to ensure that regulatory requirements are matched by enabling conditions. These include policy strategies that position healthcare as a strategic priority: the AI Continent Action Plan [1], the Apply AI Strategy [2], and beyond. Other initiatives include InvestAI, which will mobilise €200 billion in AI investment across the EU to build infrastructure such as gigafactories through public-private partnerships [3]. In addition, a network of 19 AI Factories provides researchers and companies with access to high-performance computing resources to create cutting-edge AI models and applications and the GenAI4EU programme, which has allocated approximately €700 million for generative AI development in strategic sectors, including healthcare [4]. Moreover, the European Health Data Space (EHDS), establishing a unified framework for the secondary use of health data in research and AI development, was also adopted in this context of recognising health as a strategic priority [5].

Ultimately, the EU's AI-focused strategic initiatives laid out in the AI Continent Action Plan and the Apply AI Strategy shape the conditions under which the AI Act and similar legislations will be implemented in the health sector. The extent of dedicated investments, computing infrastructure, and the availability of training data determine the AI ecosystem in the EU and highlight the benefits of integrating it.

On the other hand, when enabling conditions are lagging—as is currently the case with AI Act oversight structures across countries, harmonised standards development, and notified body capacity, for instance—the compliance landscape becomes more uncertain and more costly to navigate, despite investments in infrastructure and AI competitiveness. As such, **institutional coordination and enforcement capacity must be addressed with as much enthusiasm as announcements of data centres and investment strategies.** This report focuses on analysing the presence and extent of institutional coordination and enforcement capacity in EU-level policies and in the AI Act national implementation landscape across Europe's four largest economies: France, Germany, Italy, and Spain.

The dual character of healthcare as both a strategic innovation frontier and a high-risk regulatory domain warrants careful consideration of how economic competitiveness policies, leadership ambitions, and regulatory layers interact. As important as the EU AI Act is for securing rights, it is crucial to acknowledge that, having entered into force with an incomplete implementation architecture, it creates uncertainty for European healthcare stakeholders. It affects patients, healthcare providers, innovators, and Member States' regulators. This uncertainty is further compounded by ambiguous interactions between the EU AI Act, data, and medical device regulations.

The following sections analyse the fragmented system of ambitious AI leadership goals and complex governance architecture to lay out a clear map of how these layers intersect when it comes to AI in health, and what can be improved as the EU and national governments move forward with implementation.

Methodology

This report draws on policy review and analysis of a range of primary and secondary sources published by April 2026. These include, but are not limited to, legislative instruments and recitals, European Commission communications and strategy documents, regulatory guidance published by public institutions, press releases and position papers from key institutions, news coverage, OECD studies, legal analyses, and reports by civil society organisations, industry associations, and research institutes. Academic literature was reviewed where it offered empirical evidence on AI adoption patterns or regulatory analysis.

To validate the analysis and add further nuance to the documentary review's findings with practitioners' insights, the authors conducted 20 semi-structured, off-the-record consultations with a diverse group of stakeholders, including national and EU-level public officials, academia, civil society, and the private sector. In addition, a panel discussion on "Harnessing AI for Health and Economic Competitiveness: Translating the EU AI Act into Action" was conducted at the 2025 European Health Forum Gastein, and a Friends of Europe Chatham House roundtable convened 25 stakeholders for further insight in November 2025, including public-sector officials at both the national and EU levels, industry and regulatory affairs professionals, and civil society representatives.

2

SECTION

The Ambition: Analysing the EU's Vision for AI Economic Competitiveness and Health

The Ambition: Analysing the EU's Vision for AI Economic Competitiveness and Health

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The EU's approach to AI builds on a long-standing digital economy strategy shaped by global leadership ambitions and the persistent tension with the United States (U.S.) and China in an accelerating geopolitical race [6]. Establishing a European signature in this race has involved a rules-based approach, in which regulation is positioned as a driver of innovation alongside efforts to identify and address structural financial and infrastructural bottlenecks [7]. In addition, the European signature includes strengthening its single market approach and promoting safer, more accurate AI systems aligned with fundamental rights, as per Regulation (EU) 2024/1689 (the AI Act) [8][9]. The underlying logic is that regulation builds harmonisation and public trust across countries, unlocking adoption at a greater scale.

In 2018, the European Commission launched the first European AI Strategy, "Artificial Intelligence for Europe," which compared AI's impact on the economy and society to that of steam engines and electricity [10]. The strategy sought to place the EU ahead of technological developments in AI, from investment and research to development, deployment, and uptake across the economy. Since then, a succession of strategies, investment programmes, and regulatory instruments have been launched to advance that ambition, consolidated under the AI Continent Action Plan of April 2025, which serves as the EU's current foundational roadmap for global AI leadership [11].

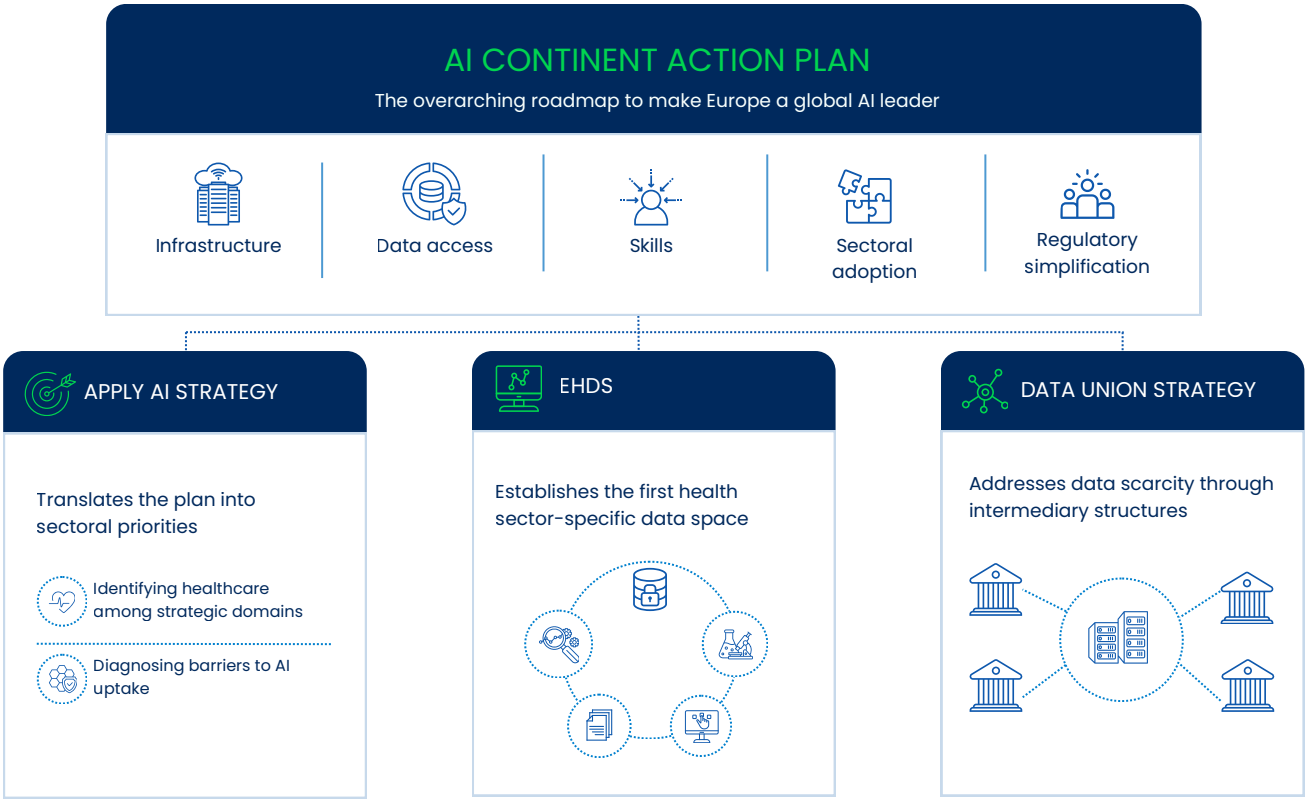
Healthcare is a critical domain where this ambition is put to test. A recent Commission-funded study found that U.S. digital health investment volumes were more than triple those of the EU between 2019 and 2024, with U.S. vendors capturing 63% of the global market compared to 28% for European vendors [12]. Although AI is increasingly perceived as a strategic priority among EU digital health companies, only 23% of them are investing in AI/ML and 20% in generative AI. This gap represents a policy opportunity for further incentives and enablers to drive stronger AI investment and adoption in European health systems. The EU's ability to close the gap depends on translating ambition into concrete levers for AI innovation in health systems across Member States.

The subsections that follow review the key competitiveness and innovation policies launched as part of, or referenced by, the AI Continent Action Plan, with a focus on their intersection with the health sector: the extent to which they identify healthcare as a strategic priority, the specific stages of the AI lifecycle they target (research, development, deployment, monitoring), and the current state of their implementation.

AI Continent Action Plan

The AI Continent Action Plan, published on April 9, 2025, is the EU's foundational roadmap for AI competitiveness. It is structured around five pillars: i) building large-scale AI and data computing infrastructure, including AI Factories and Gigafactories; ii) increasing access to high-quality data; iii) advancing algorithm development and sectoral AI adoption; iv) strengthening AI skills and talent; and v) facilitating regulatory compliance and simplification [13]. The plan's premise is that global leadership depends on widespread AI uptake in strategic sectors, which in turn requires infrastructure, data, a qualified workforce, and a regulatory environment that enables rather than obstructs deployment.

The Plan adopts a high-level, horizontal approach designed to touch upon all sectors of the European economy. Mentions of healthcare are anecdotal, as are those of other sectors such as energy and education. The Plan's impact on the health sector is visible through the Apply AI Strategy's sectoral measures, and the Data Union Strategy's provisions for health data availability. The AI Continent Action Plan establishes the infrastructure and policy architecture, but the translation into operational conditions for healthcare depends on downstream instruments whose implementation timelines and outcomes remain uncertain.



> *The AI Continent Action Plan is the EU's foundational roadmap for AI competitiveness*

An overview of EU's Infrastructure ambitions: The AI Factories and Gigafactories

The European High-Performance Computing Joint Undertaking—EuroHPC JU—has established a network of 19 AI Factories across Europe, built around AI-optimised supercomputers that provide startups, SMEs, and researchers with access to high-performance computing resources. An additional 13 smaller-scale access points linked to the main Factories, the AI Antennas, complement the network [14].

Healthcare is one of the most frequently cited priority sectors across the AI Factories network. According to the European Commission, 17 of the 19 AI Factories include healthcare among their focus areas [15]. Spain's 1HealthAI, hosted at the Galicia Supercomputing Center (CESGA) with €82 million in combined EU, national, and regional investment, is the only AI Factory exclusively dedicated to health.

19
AI FACTORIES
across Europe

13
AI ANTENNAS
acess points

17 of **19**
AI FACTORIES
include
healthcare

SPAIN'S 1HEALTHAI

1HealthAI

The only AI factory exclusively dedicated to health

Hosted at:

CESGA

Galicia Supercomputing Center

€82 million

Combined national and regional investment

Apply AI Strategy

As a pillar of the AI Continent Action Plan's overarching vision for European competitiveness, the Apply AI Strategy is developed with a sectoral approach in mind, prioritising healthcare and pharma as strategic sectors, along with ten others. Published on 8 October 2025, the strategy addresses a concrete problem: boosting AI adoption and innovation across the region, particularly among SMEs. As part of ramping up AI adoption—currently limited to 13.5% of businesses and 12.6% of SMEs, according to the official document—the strategy supports a "buy European" policy, particularly for AI use in the public sector, with a focus on open source AI tools.

In healthcare, the Commission diagnosed the following barriers to AI uptake: i) limited availability of high-quality data, ii) heterogeneity of infrastructures, iii) limited AI literacy among health professionals, and iv) insufficient trust [2]. The strategy's measures to address health-related challenges, drawn from its implementation roadmap, are summarised in the table below.

Table 1: AI in health measures in the European Commission's Apply AI Strategy

	TARGET DATE	TYPE OF ACTION	MEASURE	KEYWORDS
2025	**Q4, 2025 onwards**	Flagship action	Promote AI model contractual clauses. These clauses will serve as a best practice framework for the public procurement of AI-based solutions, guiding public authorities in ensuring effective, ethical, transparent, and accountable AI deployment.	Guidelines Public procurement AI in the public sector AI deployment
	Q4, 2025	Other actions	Support scaling up of trustworthy AI in cardiovascular health and responsible use of AI for prevention.	AI medical devices AI deployment
2026	**2026**	Flagship action	Propose appropriate actions to streamline and enable quicker market entry of medical devices without compromising safety.	AI medical devices AI deployment
	Q1, 2026	Flagship action	Develop guidelines on the classification of AI systems as high-risk.	Guidelines Risk mitigation
	Q2, 2026	Flagship action	Set up an AI Observatory to provide robust indicators to assess the impact of AI in the currently listed and future sectors, monitor developments and trends.	AI evaluation AI monitoring
	Q2, 2026	Other actions	Facilitate access to European computing capacities (e.g. AI Factories) to developers and providers for innovation in healthcare, including in biotech drug development for advancing therapies and rare disease treatments.	Infrastructure AI research and development AI in science
	Q2, 2026	Other actions	Foster the next generation of AI solutions for biomedical research, including drug discovery and development.	AI research and development AI in science

TARGET DATE	TYPE OF ACTION	MEASURE	KEYWORDS
2026			
Q2 2026	Other actions	Support the deployment of AI agents for healthcare professionals in different medical care domains, including administrative tasks.	AI agents AI deployment
Q3, 2026 onwards	Flagship action	Develop guidelines on the AI Act's interplay with other Union law.	Guidelines Institutional coordination
Q3, 2026 onwards	Flagship action	Accelerate the adoption of European scalable and replicable generative AI solutions in public administrations to improve the quality of services provided to citizens. This will include the creation of a comprehensive technical and policy toolkit to support the development of generative and agentic AI solutions.	AI in the public sector Public procurement AI deployment
Q4, 2026	Flagship action	Launch an AI drug discovery challenge for potential new drugs that could be used to address unmet medical needs and treat diseases that have proven difficult to cure.	AI research and development AI in science
Q4, 2026	Other actions	Develop EU guidance on the responsible use of AI in pharmacovigilance and for regulatory activities.	Guidelines AI in the public sector
Q4, 2026	Other actions	Accelerate the uptake of virtual human twins (VHTs) and related innovative AI solutions for healthcare and drug development by facilitating ecosystems.	AI in science
2027			
Q2, 2027	Flagship action	Establish a European network of AI-powered advanced screening centres to accelerate the introduction of innovative tools for prevention and diagnosis making in healthcare facilities and bringing healthcare services to underserved areas.	AI medical devices Infrastructure AI deployment
Q4, 2027	Flagship action	Establish European Networks of Expertise on AI Deployment in Healthcare to consolidate guidelines and best practices. It will deliver deployment playbooks, guidelines including on local validation (performance in clinical practice) and post-deployment monitoring, design principles and set the foundations for exchanging best practices on AI deployment in healthcare.	AI deployment Guidelines AI monitoring Institutional coordination
Q4, 2027	Other actions	Foster collaboration in key areas such as primary care and chronic disease management for the development and scale up of equitable AI in Healthcare.	Institutional coordination AI research and development

Keywords in the table were assigned by the authors, and relate to the nature of the initiative, its scope, its domain, and the target AI lifecycle stage.

First, a pattern worth noting on the timeline: **Measures that could facilitate the implementation of the EU AI Act by providing greater clarity and engaging key stakeholders may only be completed after, or concurrent with, the AI Act's high-risk provisions taking effect.** For instance, the guidelines on the AI Act's interplay with other Union law (Q3 2026), the European network of AI-powered screening centres (Q2 2027), and the European Network of Expertise on AI Deployment in Healthcare (Q4 2027). This means that instead of providing implementation support ahead of the obligations coming into force, those actions may only be executed afterwards, which may limit their impact.

Second, the nature of most of the actions is instructional: **The dominant category across the health actions is guidelines, playbooks, and best-practice frameworks.** This is consistent with the Commission's institutional role during the implementation phase, which comprises issuing delegated and implementing acts, guidance documents, and funding programmes. The question is whether these tools will arrive with sufficient lead time and practical specificity to help shape national implementation of the EU regulatory stack before compliance deadlines.

In addition, it's worth noting that the nature of some of the actions remain unclear, especially those using verbs such as "foster" and "support." The lack of more concrete details around those policies may create obstacles to proactive coordination and engagement of interested actors. Importantly, the Apply AI Strategy actions comprising guidelines should focus on promoting actionable steps that foster alignment among actors across Member States, while those actions setting up new structures and resources can leverage conditional funding mechanisms to incentivise steps and best practices.

Third, the **stakeholder engagement mechanisms** created by the Apply AI Strategy—the Apply AI Alliance [16] and the AI Observatory [17]—are designed to convene and inform about sectoral insights, real-world use cases, and AI's impact on the ground. The Commission has also established a flagship multistakeholder action for healthcare: the European Network of Expertise on AI Deployment in Healthcare, to be established through COMPASS-AI, a DG SANTE-led programme focused on scaling AI in clinical practice, with initial emphasis on cancer care and healthcare access in remote regions [18]. COMPASS-AI will advance coordination for AI in health by convening multidisciplinary working groups to create deployment playbooks, clinical validation guidance, and post-deployment monitoring standards [19].

However, there remains a need to gather relevant actors from across Member States to exchange and align on implementation activities, enforcement resource allocation, and discuss structural differences in national health systems that shape how AI is adopted in practice. Whether coordination through dialogue can generate sufficient traction across 27 different healthcare systems remains an open question.

Finally, looking forward, the Apply AI Strategy calls on Member States to reassess their national AI strategies to align with the strategy's sectoral approach. This step will require allocation of budget and resources and revised responsibilities across levels of administration [20]. Sectoral AI strategies remain underdeveloped in the EU [21]. Member States should leverage upcoming AI in Health strategies to further operationalise resource allocation, launch institutional programs, and formalise cooperation initiatives with other countries to advance the AI uptake in health.

European Health Data Space

Although more than 30% of the world's data assets consist of health data, less than 3% are used for decision-making, due to fragmented frameworks, regulatory complexity, and social barriers [22]. The European Health Data Space (EHDS) Regulation 2025/327 entered into force on 26 March 2025 to fill that gap, marking the first sector-specific Common European Data Space. The regulation aims at three objectives: i) empowering individuals to access and control their personal electronic health data across EU borders; ii) enabling the secure and trustworthy reuse of health data for research, policymaking, and related activities; and iii) creating a single, interoperable market for electronic health record (EHR) systems [23].

The EHDS enables the secondary use of electronic health data for the "training, testing, and evaluation of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems, and digital health applications," increasing legal certainty previously lacking under GDPR-only interpretations and addressing a major barrier identified by stakeholders for AI development [24]. In alignment with OECD's diagnosis that fragmented data foundations are a primary barrier to AI adoption in health across its member countries, and the call for findable, accessible, interoperable, and reusable (FAIR) data supported by health data authorities and secure processing environments [25], the EHDS Act has established the need for Health Data Access Bodies (HDABs) [26]. Their role as gatekeepers for secondary data use requests includes issuing data permits through standardised procedures and requiring processing within secure environments with strict purpose limitation and prohibitions on re-identification [27].

AICare@EU

The **AICare@EU** is an umbrella framework by the European Commission focused on addressing barriers to AI deployment and scaling in clinical practice. Initiatives include research, guidance, and collaboration with international organisations.

One of the projects in this framework is **SHAIPED**, which supports Health Data Access Bodies in enabling AI development through optimised data pathways. It leverages **HealthData@EU** infrastructure established under the **EHDS**, while ensuring alignment with both AI Act requirements and, where applicable, MDR/IVDR obligations for AI systems qualifying as medical devices [28].

The EHDS regulation will be implemented in phases. By March 2027, the Commission must adopt key implementing acts including EHR system technical specifications, and Member States must designate National Digital Health Authorities. By March 2029, rules on secondary use will apply for most health data categories, including EHR, alongside some primary use provisions, such as patient summaries. The second wave of primary use categories (medical images, lab results, hospital discharge reports) will become operational by March 2031, when secondary use rules will extend to remaining categories including genomic data.

With data governance at the crux of AI in health, developers and deployers still need to navigate a fragmented landscape when dealing with health data. **The phased approach to EHDS implementation leaves developers and deployers with fragmented national frameworks in the interim.** As with the AI Act's implementation, readiness levels vary from country to country. Although plans are underway for further secondary legislation, the European Commission should focus on releasing agile instruments that can solve the coordination uncertainties, bearing in mind parallel timelines that may affect the optimal implementation of the EHDS.

Data Union Strategy

The Data Union Strategy, published on 19 November 2025 alongside the Digital Omnibus proposal, addresses data scarcity, which has been recognised as a central constraint for AI competitiveness in the EU [29]. While the EU generates vast amounts of data, there are practical barriers to use: fragmented national systems, regulatory complexity, and burdensome requirements for SMEs and researchers to access data. A recent study by the European Commission has highlighted that, among the enabling factors for AI adoption, access to high-quality data and data spaces was perceived as the most challenging to obtain [30]. The strategy responds to this problem through three pillars: i) scaling up access to high-quality data for AI development, ii) streamlining the EU's data regulatory framework, and iii) safeguarding European data sovereignty in international flows.

To expand the supply of usable data, the strategy establishes the Data Labs, new intermediary structures designed to curate and federate sector-specific datasets and link Common European Data Spaces with AI ecosystems. In addition, the Open Data Directive promotes crowdsourcing for domain-specific and smaller-language data. These initiatives are expected to be adopted by mid-2026. For healthcare, it's worth noting that the Data Union Strategy complements and depends on the EHDS.

The Data Union Strategy's initiatives—such as the Data Labs and data quality standards—build on the EHDS infrastructure, improving the availability and curation of health datasets for AI training. On the other hand, the strategy inherits the EHDS's own implementation challenges. The secondary use framework will not become operational for most health data categories until March 2029, and full deployment extends to March 2031.

This means that during the critical period when AI Act compliance obligations take effect, the full cross-border health data infrastructure of the EHDS will not yet be available. Developers will have to rely on fragmented national arrangements, bilateral agreements, or proprietary datasets in the interim.

A further tension lies in the strategy's treatment of the GDPR. The Data Union Strategy explicitly positions itself as operating within existing privacy frameworks. Yet, as some stakeholders consulted during our research have noted, the EU's broad definition of personal data constrains many of the data-sharing ambitions the strategy sets out, and Member States have applied GDPR provisions with significant variation, creating precisely the kind of fragmentation the strategy seeks to overcome.

The Data Union Strategy therefore depends on the pace of EHDS implementation across Member States, the willingness to address GDPR-related fragmentation in health data governance, and whether Data Labs and interoperability standards can deliver high-quality health datasets timely.

The EU's Regulatory Simplification Ambitions

Since the publication of the Draghi Report in September 2024, the EU has reoriented its approach to AI regulation towards a greater focus on economic competitiveness of the single market. The Digital Omnibus and the Digital Omnibus on AI proposed in November 2025 were part of the regulatory simplification pillar presented in the EU AI Continent Action Plan. The proposals aim to reduce obligations across the digital rulebook and grant an extension to the EU AI Act's deadlines as part of competitiveness measures [31] [32].

While the European Commission asserts its commitment to fundamental rights protections, civil society actors have called out the substantive shift in premise—from frameworks designed primarily to protect individuals, to adaptations that brought AI adoption and reducing business burden to the centre stage instead [33][34][35]. The tension between the EU's "regulatory power" identity, marked by the "Brussels effect" [36], and its competitiveness agenda continues as the two objectives are being pursued simultaneously. The AI Act seeks to bring legal certainty to developers and deployers, while also establishing a governance threshold that elevates European technology to the highest standards of quality and safety. However, its outcome will depend on pending consequential policy and legislative decisions.

The potential changes to the EU AI Act proposed in the Omnibus are particularly salient in the health domain, where a broad range of applications fall under the high-risk category. Stakeholders across the healthcare ecosystem have varying positions on the issue. Some see the need to integrate the AI Act's high-risk obligations in the MDR [37] to provide one single framework for AI-enabled medical devices, while others question whether this proposal to streamline conformity assessment is desirable. There have been concerns about a lack of action in solving the regulatory complexity leading to delays in the delivery of medical innovations to patients [38]. On the other hand, it has been argued that the EU AI Act's horizontal scope was designed to function alongside existing sectoral regulations, and that efforts to simplify it might create complexity elsewhere in the enforcement process [39].

Civil society organisations have also expressed concerns that regulatory simplification may "come at the expense of consumer protection, product safety, children's rights, and fundamental rights" [40].

Under the MDR, software qualifies as a medical device when it is intended by the manufacturer to be used for one or more specific medical purposes, such as diagnosis, prediction, or treatment of disease, regardless of whether it operates as standalone software or as part of a hardware device. The majority of AI-based medical device software falls into Class IIa or higher, which requires third-party conformity assessment by a notified body [41]. It is this classification threshold that triggers the AI Act's high-risk designation under Article 6(1): an AI system qualifies as high-risk when it is a medical device, or serves as a safety component of one, and is subject to third-party conformity assessment under the MDR/IVDR.

The joint guidance published by the Medical Device Coordination Group and the Artificial Intelligence Board in June 2025 (MDCG 2025-6 / AIB 2025-1) provides the first authoritative clarification of this interplay, stating that the AI Act's high-risk classification does not alter the device's risk class under the MDR [42]. In fact, the MDR classification determines whether the AI Act's high-risk obligations apply. In addition, it explains that the two frameworks are complementary rather than duplicative: manufacturers can integrate AI Act testing, documentation, and reporting requirements into existing MDR/IVDR procedures, and a single set of technical documentation can serve both frameworks.

However, stakeholders consulted throughout the preparation of this report have stressed the urgency of having a clear understanding of how conformity assessments will be streamlined in practice. As stakeholders' attention shifts from legislative discussions to mapping out implementation readiness, it is crucial to understand how national governments have been operationalising the AI Act and how that impacts the healthcare sector. The following section will present an overview of the implementation landscape in France, Germany, Italy, and Spain.

3

SECTION

The Reality: AI Regulation Implementation Challenges

The Reality: AI Regulation Implementation Challenges

> *The operational reality of AI regulation in health will be shaped by uneven national implementation capacity.*

Regardless of how regulatory simplification is conducted, the implementation stage is what will define whether innovation, safety, and fundamental rights can be promoted and upheld. Therefore, this report focuses on analysing potential gaps in AI Act implementation and laying out next steps that will support Europe in its twofold mission of AI competitiveness and robust governance.

Legislation such as the AI Act is designed for the logic of a single market, yet the significant variation in national implementation can undermine this objective. The regulatory simplification debate concerns what the rules say and how they may change, whereas the implementation challenge concerns how those rules are operationalised on the ground. This distinction matters because the two processes are governed by different institutions: EU-level lawmaking is conducted among the European Commission, the Parliament, and the Council, while implementation is the responsibility of Member States in their own jurisdictions. National governments have some leeway in interpreting and enforcing EU regulations in line with their own institutional structures, administrative traditions, and policy priorities. While the EU determines the substance of obligations and the Commission has a crucial role with supporting guidelines and implementing acts, Member States exercise substantial control over enforcement [43]. This division is both a feature and a tension of the EU regulatory model: it seeks harmonisation while also preserving Member States' autonomy and acknowledging the diversity of contexts they operate in.

In addition to how EU rules are implemented, the speed in which Member States act also varies. Recent cross-country evidence by the OECD (2026) illustrates the implementation gap across EU Member States. Although most countries are actively assessing gaps in existing legislation (44%, 12 of 27) or amending laws to align with upcoming EU rules (37%, 10 of 27), only 7% (2 of 27) have issued practical guidance on applying existing liability regimes to AI, and just 22% (6 of 27) provide "ethics-by-design" guidance. Institutional oversight remains fragmented: 56% (15 of 27) have at least one agency responsible for approving AI systems, but post-market monitoring is far less developed [25]. These findings confirm that, even with identical EU-level obligations, the operational reality of AI regulation in health will be shaped by uneven national implementation capacity.

Member States realities vis-à-vis AI in health vary. Despite relatively advanced levels of AI adoption in areas such as diagnostics and patient interaction tools, and a clear alignment around expected benefits (improving care, efficiency, and workforce support), funding, implementation pathways, and legal clarity continue to lag. Taken together, these patterns suggest that the main challenge is operationalising governance mechanisms capable of driving systemic change and supporting safe and scalable AI deployment in health.

Notified bodies' cautionary tale

The long-standing issue of notified bodies' capacity constraint to assess medical devices against the MDR requirements exemplifies upcoming challenges for the EU AI Act as well. This issue has been noted by stakeholders interviewed for this report, and was also evident in the desk research that supported the country analysis presented in the upcoming subsections. The MDR requirements already cause a backlog for the assessment of medical devices by the notified bodies across the EU. As of October 2025, 51 notified bodies have been designated under MDR [44], but AI Act designation requires demonstrating specific competencies under Article 31, including AI technology knowledge and data science expertise. Not all MDR-designated notified bodies are pursuing AI Act designation, and the competencies required under Article 31 of the AI Act extend beyond traditional medical device assessment capabilities [45].

The proposed amendments to the MDR's Rule 11 classification, included in the December 2025 MDR/IVDR simplification proposal, could reclassify a broader range of medical device software as Class I, potentially reducing the number of AI systems that trigger high-risk status under the AI Act and easing capacity pressure [46]. On the other hand, it raises questions about whether lower-risk classification adequately reflects the safety implications of AI-driven clinical tools [47].

Even if a structural reshuffling of how the AI Act interacts with existing product safety laws—like the MDR—takes place, with changes to risk classification or only one set of conformity assessment for AI in medical devices, the bottleneck created by notified bodies is not automatically addressed. Furthermore, in the near or medium term, this issue can be compounded by technological progress. With the development of more advanced AI, the creation of new software—be it an AI system or traditional software embedded in a medical device—may be significantly expedited. However, increasing the offer of innovative medical devices on the market will still depend on notified bodies' capacity to assess a larger volume of applications.

Implementation landscape across the EU's four largest economies

The backdrop to regulatory implementation comprises a larger set of policies and institutional structures that have been identified as enablers for scaling AI in health. The graph below zooms into the four largest economies in the EU and assesses the existence of such elements, drawing from the OECD (2026) study on AI governance in health across its Member States [25].

Table 2: An Overview of the adoption of AI in Health instruments in France, Germany, Italy, and Spain

INSTRUMENT	FRANCE	GERMANY	ITALY	SPAIN
National AI strategy or action plan specific to health	✓	✗	✗	✓
National AI strategy referencing health	✓	✗	✓	✓
National strategy for cloud-based resources for health	✓	✓	✓	✓
National interoperability strategy for health	✓	✓	+-	✓
National digital security strategy for health	✓	✓	✓	+-
National legislation on AI	+-	+-	✓	+-
National legislation on AI in health	✓	✗	+-	+-
Regulatory sandbox for AI in health	+-	✗	+-	✓
Medical device legislation incorporates AI	+-	+-	+-	✓
National oversight body for AI in health	✓	✗	+-	✓

LEGEND ✓ Adopted ✗ Not adopted +- Partly adopted N/A Not Applicable

Adapted from: OECD (2026). Scaling Artificial Intelligence in Health. p. 41.

The following subsections further expand on the emerging implementation landscape in France, Germany, Italy, and Spain. We present an overview of the current state of the EU AI Act implementation with a focus on the health sector, alignment with the EU's broader competitiveness ambitions, and healthcare market access realities. The analysis is illustrative rather than exhaustive, seeking to highlight the institutional gaps and structural factors that may shape how the AI Act's ambitions translate into enforcement reality for AI across different health systems.

Table 3 presents an overview of five key dimensions: (i) AI supervisory authority and mandate, identifying the competent authority (or proposed authority) under the AI Act and clarifying its functions, including whether it acts as market surveillance authority, coordinator or single point of contact; (ii) medical device supervisory authority and mandate, detailing the authorities responsible under the MDR/IVDR and their role in overseeing AI-enabled medical devices; (iii) notified bodies (MDR/IVDR) and AI Act accreditation status, reviewing the availability of notified bodies, the designation of notifying and accreditation authorities, and the current progress of accreditation under the AI Act; iv) health technology reimbursement, assessing the existence (or absence) of structured pathways for the reimbursement of AI-based medical technologies; and (v) potential gaps, highlighting delays, legal uncertainties or coordination challenges affecting implementation.

Taken together, these dimensions reveal a consistent pattern in the EU regulatory landscape: despite differences in institutional design, all four countries exhibit structural delays in operationalising the AI Act, particularly in authority designation. In addition, in most cases, countries rely on distributed, sectoral supervision models rather than fully centralised authorities.

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).

> *Despite differences in institutional design, all four countries exhibit structural delays in operationalising the AI Act.*

Table 3: The AI Act's implementation and health sector landscape in France, Germany, Italy, and Spain

	AI SUPERVISORY AUTHORITY & MANDATE	MEDICAL DEVICE SUPERVISORY AUTHORITY & MANDATE	NOTIFIED BODIES CAPACITY [48]	REIMBURSEMENT FOR HEALTH TECHNOLOGIES	INFRASTRUCTURE	GAPS & RISKS
FRANCE	**EU AI Act implementation status:** Formal designation pending. **Proposed model:** Multi-authority, with expanded AI scope [49], e.g.: **DGCCRF:** operational coordination of the AI Act implementation; single point of contact and national coordination authority. **CNIL:** data protection. **ARCOM:** audiovisual and digital communication. **DGE:** directorate general for enterprises; strategic coordination of the AI Act implementation; represents France in the EU AI Board.	**ANSM:** National competent authority for medical devices under MDR and IVDR. **Mandate:** Market surveillance, vigilance reporting, notified body oversight, and clinical investigation authorisation. Requires French-language documentation for higher-risk devices [50]. **Dual-model:** ANSM and DGCCRF are expected to share the oversight of AI-enabled medical devices [51].	1. GMED SAS 2. AFNOR	**Reimbursement through PECAN [52].** Fast-track provisional reimbursement for digital medical devices (DTx) and remote monitoring systems [53].	**AI Factory France:** Decentralised consortium led by GENCI with partners including CEA, CNRS, Inria, and Station F. Will use the upcoming Alice Recoque exascale system; currently leverages Jean Zay, Adastra, and Joliot-Curie. Healthcare explicitly listed among priority sectors.	1. No formal AI supervisory designation under Art. 70 of the AI Act. The enforcement pathway for high-risk AI in health that does not overlap with the MDR remains undefined. 2. Limited notified body capacity: only two MDR-designated notified bodies, creating a potential bottleneck for AIaMD conformity assessments. 3. A multi-authority model means significant coordination complexity; some cases are shared between at least two authorities, e.g., AI medical devices.
GERMANY	**EU AI Act implementation status:** Designation pending. Draft KI-MIG (2025) in legislative process [54]. **Proposed model:** Multi-authority **BNetzA:** primary MSA, single point of contact, hosts KoKIVO coordination centre [55]. **BaFin:** MSA for high-risk AI in regulated financial activities. **BAuA:** central coordination for Union-level incident notifications under Art. 79 and 81 AI Act [56]. *Sector authorities retain competence in their fields [57].*	**BfArM:** National competent authority for medical devices under MDR and IVDR. **Mandate:** Market surveillance, vigilance system, clinical investigation authorisation, classification consultations. **Key feature:** BfArM also administers the DiGA reimbursement mechanism for digital health applications [58].	1. TÜV SÜD Product Service GmbH 2. DQS Medizinprodukte GmbH 3. SZUTEST Konformitätsbewertungsstelle GmbH 4. SLG PRÜF UND ZERTIFIZIERUNGS GMBH 5. TÜV Rheinland LGA Products GmbH 6. mdc medical device certification GmbH 7. DEKRA Certification GmbH 8. Berlin Cert GmbH 9. DNV MEDCERT GmbH 10. TÜV NORD CERT GmbH	**Reimbursement through DiGA and DiPA:** DiPA has analogous pathway for digital care applications for home care recipients, under same procedure as DiGA [59].	JUPITER AI Factory (JAIF): Built around JUPITER, described as Europe's most powerful supercomputer, JU communications and Jülich materials. Healthcare is explicitly listed among JAIF's focus sectors.	1. KI-MIG still a draft: BNetzA operates de facto without full statutory enforcement powers. 2.Federal structure: federal states retain market surveillance roles, increasing procedural complexity and fragmentation risks. 3. DiGA covers software-based therapeutics, telemonitoring, and clinician-facing tools.No equivalent structured reimbursement pathway for AI-powered medical devices beyond the DiGA scope.

ITALY

AI SUPERVISORY AUTHORITY & MANDATE

EU AI Act implementation status: MSA formally designated by Law No. 132/2025. First EU Member State to adopt a comprehensive national AI law [60]. Implementing decrees expected within 12 months of October 2025 to confer full sanctioning powers [61].

Proposed model:

MSA: ACN (National Cybersecurity Agency) single point of contact with EU institutions. Supervision, inspection, sanctions.

Notifying authority: AgID (Agenzia per l'Italia Digitale). Innovation promotion, conformity assessment procedures, accreditation, and monitoring of conformity assessment bodies.

MEDICAL DEVICE SUPERVISORY AUTHORITY & MANDATE

Ministry of Health / Regional authorities: competent authorities for medical devices under MDR and IVDR, with coordination through the Ministry of Health.

AIFA (Agenzia Italiana del Farmaco): competent authority for medicinal products.

Structure: Italy's medical device supervisory architecture is more dispersed than France, Germany, or Spain. Responsibilities are distributed across the Ministry of Health and 20 regional health agencies (SSR). No single unified national agency equivalent to ANSM, BfArM, or AEMPS.

AI intersection: Law 132/2025 establishes conditions for secondary use of health data for AI development in scientific research, subject to prior notification to the Italian DPA.

NOTIFIED BODIES CAPACITY [48]

1. ISTITUTO SUPERIORE DI SANITA'
2. TUV Rheinland Italia SRL
3. CERTIQUALITY S.r.l.
4. ICIM S.P.A.
5. ENTE CERTIFICAZIONE MACCHINE SRL
6. IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.
7. Eurofins Product Testing Italy S.r.l.
8. BUREAU VERITAS ITALIA S.P.A.
9. ITALCERT SRL
10. KIWA CERMET ITALIA S.P.A.
11. MTIC InterCert S.r.l

REIMBURSEMENT FOR HEALTH TECHNOLOGIES

No national fast-track reimbursement pathway for digital health applications equivalent to Germany's DiGA or France's PECAN [63].

Reimbursement is managed through the national healthcare service (SSN). Recent updates included some new digital technologies (e.g. voice recognition systems), but no structured mechanism for AI-based clinical tools [64].

Bill on digital therapies: A parliamentary bill to formally recognise digital therapies as therapeutic tools and establish a reimbursement framework was under discussion, but hasn't been voted on yet [65].

INFRASTRUCTURE

IT4LIA AI Factory: Utilises the EuroHPC Leonardo supercomputer LISA and GAIA cloud, and expects a new AI-optimised supercomputing system from the beginning of 2026.

GAPS & RISKS

1. Independence concern: AgID and ACN are government bodies, which raises questions about the independence requirement under Art. 70 AI Act [66].

2. Sanctioning powers pending: full enforcement powers are deferred to legislative decrees mandated by Law 132/2025 (Art. 24), to be adopted by October 2026; as of March 2026, no decrees have been issued, leaving AgID and ACN without full sanctioning authority and creating a temporary enforcement gap.

3. Dispersed medical device oversight: absence of a centralised national medical devices authority creates coordination complexity for AIaMD pathways.

4. Absence of a structured digital health reimbursement pathway creates obstacles to the deployment of AI-based clinical tools through the SSN.

SPAIN

AI SUPERVISORY AUTHORITY & MANDATE

EU AI Act implementation status: Formally operational, first EU Member State to designate a dedicated AI supervisory agency. Draft bill of national AI law approved first reading March 2025, still in parliamentary process.

AESIA (Agencia Española de Supervisión de la Inteligencia Artificial): MSA, notifying authority, and single point of contact. Established RD 729/2023 (Aug 2023); operational June 2024; full sanctioning powers in August 2025 [67].

Mandate: Supervision, inspection, enforcement of AI Act; management of national AI sandbox (RD 817/2023); technical guidance; AI literacy initiatives.

MEDICAL DEVICE SUPERVISORY AUTHORITY & MANDATE

AEMPS (Agencia Española de Medicamentos y Productos Sanitarios): national competent authority for medical devices under MDR and IVDR.

Mandate: Full MDR and IVDR implementation, including notified body oversight, market surveillance, borderline classification, and national registries (CCPS and RPS).

Dual-agency model: AESIA supervises horizontal AI Act obligations; AEMPS supervises AIaMD under MDR/IVDR. Designed to avoid duplication, but coordination in complex AIaMD cases has not yet been tested in practice.

NOTIFIED BODIES CAPACITY [48]

1. Centro Nacional de Certificación de Productos

REIMBURSEMENT FOR HEALTH TECHNOLOGIES

No national fast-track reimbursement pathway equivalent to Germany's DiGA or France's PECAN [68].

INFRASTRUCTURE

1HealthAI: Aims to position Europe as a global leader in One-Health products, services, and research. Hosted at the Galicia Supercomputing Center (CESGA). The initiative spans climate–health interactions, genomics, personalised medicine, sustainable agri-food systems, blue biotechnology, pharmaceutical innovation, and environmental health.

BSC AI Factory: A joint initiative of Spain, Portugal, Türkiye and Romania, built on an upgrade of MareNostrum5. Healthcare explicitly listed among priority sectors.

GAPS & RISKS

1. National AI law defining domestic sanctioning regime and inter-authority coordination not yet enacted.

2. Dual-agency coordination untested: AESIA-AEMPS model is formally established but operationally unproven in complex AIaMD enforcement cases.

3. Spain's absence of a harmonised reimbursement mechanism may be a bottleneck for the scaling of innovative AI solutions for healthcare.

France

> *France embeds AI governance within established structures for health data oversight, MDR, and public innovation investment*

POLICY DIMENSION	FRANCE APPROACH
Investment	€4B national AI investment • €7.5B France 2030 digital health funding
AI Act Implementation	Multi-authority governance model under development
Medical Device Regulation	ANSM oversees MDR & IVDR implementation
Market Access	PECAN supports early reimbursement for digital health solutions
OVERALL SUMMARY	Existing institutions with high maturity level in health regulation and data governance leveraged to operationalise the EU AI Act

France is leveraging its existing institutional and regulatory framework to implement the EU AI Act, rather than modifying national laws to adapt to it. The operationalisation of the AI Act will focus on establishing enforcement and oversight powers. This approach embeds AI governance within established structures for health data oversight, medical device regulation, and public innovation investment [69].

In July 2025, France launched its National Strategy for AI and Health Data, a unified national policy framework linking the deployment of AI in healthcare with comprehensive governance of data, infrastructure, cybersecurity, and clinical-economic evaluation [70]. This strategy emphasises the importance of a solid data foundation [71], and seeks to operationalise the AI Act through pre-existing and evolving national instruments while aligning with the EHDS [72].

France has committed around €4 billion in public investments in AI through its national AI strategy (OECD, 2025) [73]. A dedicated function of national coordinator for AI was created for the strategy's implementation to facilitate inter-ministerial coordination. Furthermore, France sought to position itself as an "AI powerhouse" by creating the first European AI Safety Institute and hosting the AI Action Summit in Paris, in 2025. At the event, a €109 billion international funding initiative supported by public and private sector entities was announced [74]. Beyond AI investments, France has committed €7.5 billion to advancing digital health under the France 2030 plan [75].

The AI Act's implementation is still incipient—a formal AI supervisory authority hasn't yet been designated [76]. France is developing a multi-authority governance model with both sectoral regulators and horizontal authorities, such as the

Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) [77]. Although a draft governance framework was published in September 2025 proposing a market surveillance model involving seventeen existing authorities, spearheaded by the data protection authority, National Commission on Informatics and Liberty (CNIL), DGCCRF, and the Regulatory Authority for Audiovisual and Digital Communication (ARCOM), with oversight from the Ministry of the Economy, the necessary legislative provisions were withdrawn from the parliamentary adaptation bill. As a result, more than five months after the August 2025 deadline set by the AI Act, the formal designation of an AI supervisory authority remains pending.

The National Agency for the Safety of Medicines and Health Products (ANSM) acts as the competent authority for medical devices under the MDR and IVDR [78]. It is complemented by CNIL, which provides proactive supervision of health data processing, and practical guides that also supports AI Act requirements on data quality, traceability, and representativeness [79][80]. These institutions work in close coordination with the Health Data Hub, which organises secure access to and reuse of high-quality health data for research and innovation through formal authorisation processes [81]. CNIL has cumulated regulatory innovation experience through its sandboxes on digital health, edtech, and AI in public service. The digital health sandbox was launched in 2021, focused on GDPR compliance [82].

Regarding market access for medical devices, the Advance Digital Care (PECAN) scheme enables early deployment and provisional reimbursement of digital medical devices and remote monitoring solutions [83].

Overall, France's model demonstrates that institutions that already present a high level of maturity in health regulation and data governance can seek alignment with the EU AI Act, leveraging it for enforcement. The effectiveness of this approach will depend on securing enforcement capacity within existing institutions through expanded budget and personnel, if needed, and inter-institutional coordination.

Germany

> *Germany proposes maintaining sectoral regulatory oversight, and establishing a central coordinating role ensuring implementation of the AI Act*

POLICY DIMENSION	GERMANY APPROACH
Investment	€5B public AI funding • JUPITER exascale supercomputer
AI Act Implementation	Operationalising of act through proposed KI-MIG bill
Medical Device Regulation	BfArM is the national competent authority for MDR and IVDR
Market Access	DiGA links AI Act compliance with rapid reimbursement
OVERALL SUMMARY	Effective coordination between horizontal and sectoral authorities will be essential

Germany is operationalising the EU AI Act through an implementation law—the KI-MIG bill [84], adopted by the Federal Cabinet in February 2026 and now awaiting parliamentary approval. The KI-MIG draft proposes maintaining sectoral regulatory oversight for AI products already covered by existing EU product legislation, such as medical devices, and establishing a central coordinating role to ensure implementation of the AI Act framework [85][86].

The coordination of the proposed model is assigned to the Federal Network Agency (BNetzA), which has been operating as the de facto primary market surveillance authority and the single point of contact referred to in Article 70(2) of the AI Act [87]. BNetzA hosts the KoKIVO, the national Coordination and Control Centre for the Implementation of the AI Regulation, which serves as a national-level operational hub for coordinating information exchange and consistent application of the AI Act across federal authorities and the 16 federal states [88].

Furthermore, Germany is also advancing on regulatory innovation, with a trilateral pilot project conducted by BNetzA, the Hessian Ministry for Digitalisation and Innovation, and the Federal Commissioner for Data Protection and Freedom of Information. The project simulated key requirements, processes and challenges of an AI regulatory sandbox under the AI Act using real start-up cases. Notably, one of the main outputs was a detailed roadmap showing how the AI Act and the MDR interact when developing a medical device with an integrated high-risk AI system [89].

On the medical device vertical, the Federal Institute for Drugs and Medical Devices (BfArM) is the national competent authority for the MDR and IVDR. BfArM combines market surveillance, vigilance and clinical investigation authorisation with administration of the DiGA reimbursement pathway. The Paul-Ehrlich-Institut (PEI) retains oversight of certain IVDs involving biological substances.

In alignment with EU-level ambitions for AI competitiveness, Germany had committed approximately €5 billion to public AI funding by 2025 [90]. Investments include compute infrastructure, with the JUPITER exascale supercomputer at the Jülich Research Centre, Europe's fastest supercomputer and core of the JUPITER AI Factory [91], and the national German Health Data Lab (FDZ Gesundheit) at BfArM, which provides pseudonymised health data from approximately 90% of the population for AI training and research [92]. These elements were driven by Germany's 2018 National AI Strategy, AI Action Plan, and High-Tech Agenda [93].

Healthcare market access relies on the Digital Health Applications (DiGA) pathway, established by the 2019 Digital Healthcare Act [94]. It serves as the main instrument linking AI Act compliance with rapid reimbursement in Germany [95]. Once safety, quality, data protection and preliminary evidence requirements are approved by BfArM, the application is eligible for provisional reimbursement for up to 12 months under statutory health insurance (GKV), covering 73 million beneficiaries. From 2026, at least 20% of the reimbursement price is tied to measured real-world outcomes. As of December 2025, 58 DiGAs were listed, generating 1.6 million prescriptions and over €380 million in cumulative GKV reimbursements [96]. However, DiGA and DiPA focus mainly on therapeutics and telemonitoring; most AI-powered diagnostic tools and clinical decision support systems still lack an equivalent scalable reimbursement route.

In sum, Germany aims to accelerate evidence-based deployment of trustworthy AI solutions within Europe's largest healthcare market (€538 billion annual spend) [97], while addressing remaining governance gaps through existing sectoral authorities and a central coordination mechanism brought by the KI-MIG bill. However, given that KI-MIG has not yet been enacted, BNetzA operates with limited statutory enforcement powers, while the federal states retain significant market surveillance roles, adding procedural complexity [98]. Effective coordination between horizontal and sectoral authorities, alignment of conformity assessments and clear pathways for healthcare institutions developing AI solutions will be essential to achieving those objectives.

Italy

> *Italy's Law No. 132/2025, first comprehensive national AI Law in the EU, entered into force on 10 October 2025*

POLICY DIMENSION	ITALY APPROACH
Investment	€1B public AI investment • €2.5B National AI Strategy 2024-2026
AI Act Implementation	First comprehensive national AI Law in the EU
Medical Device Regulation	Competence lies within MoH and the 20 regional health agencies
Market Access	No structured reimbursement pathway for AI-based clinical tools
OVERALL SUMMARY	Dispersed medical device oversight and absence of market access enablers are main challenges for AI uptake in healthcare

Italy is operationalising the implementation of the EU AI Act in the health sector by adopting the first comprehensive national artificial intelligence law in the European Union, Law No. 132/2025, which entered into force on 10 October 2025 [99]. This law supplements the EU regulation with sector-specific rules that embed AI governance within Italy's constitutional framework and public health system. In addition, it emphasises human-centric decision-making and aligns with its broader ambitions for technological sovereignty and digital health innovation.

Under Law 132/2025:

- the Agenzia per l'Italia Digitale (AgID) acts as the notifying authority, responsible for promoting innovation, defining conformity assessment procedures, accrediting, and monitoring conformity assessment bodies.
- The Agenzia per la Cybersicurezza Nazionale (ACN) serves as the market surveillance authority and single point of contact with EU institutions, handling supervision, inspections and sanctions.
- Full sanctioning powers remain pending until the adoption of implementing decrees (expected by October 2026).

Italy's human-centred approach requires that AI systems in healthcare serve only as support tools for prevention, diagnosis, treatment, and therapeutic decision-making, with responsibility and decisional power remaining exclusively with licensed medical professionals. The Italian AI Law specifically states that the patient has a right to be informed about the use of AI technologies, but it is still not entirely clear what kinds of information should be provided to the patient to comply with this provision.

For medical devices, competence lies with the Ministry of Health and the regional health agencies (SSR) [100], resulting in a dispersed structure without a single national agency equivalent to those in France or Germany.

Regarding healthcare market access enablers for AI uptake, Italy does not yet have a national fast-track reimbursement pathway comparable to Germany's DiGA or France's PECAN [101]. Digital health technologies are reimbursed through the National Health Services' (SSN) Essential Levels of Assistance (LEA), defined at the national level by the Ministry of Health in coordination with the Ministry of Economy and Finance and supported by the National Commission for LEA updating. Implementation and purchasing decisions are carried out at the regional level [102]. However, there is no structured, harmonised mechanism specifically for AI-based clinical tools or software as medical devices. Furthermore, reimbursement decisions are decentralised, with each administrative region managing its own purchasing and adoption processes independently [103].

This governance structure is coupled with targeted public investment and AI infrastructure. Law no. 132/2025 foresees up to €1 billion in direct support for AI, cybersecurity and quantum computing, managed by the Italian public development bank Cassa Depositi. Italy's National AI Strategy 2024-2026 foresees approximately €2.5 billion in total public AI investment [104]. These resources are complemented by the National Recovery and Resilience Plan (PNRR), which allocated €15.63 billion to health with strong emphasis on telemedicine, digitisation of the SSN (Servizio Sanitario Nazionale) and proximity care networks [105]. Key infrastructure includes five supercomputers—notably, the Leonardo system at Cineca—and the National Strategic Hub for cloud computing [73].

Italy has further embedded AI within its public health infrastructure by establishing a centralised national AI platform managed by AGENAS (Agenzia Nazionale per i Servizi Sanitari Regionali), integrated with the electronic health record ecosystem [106]. In practice, this platform (MIA - Medicina e Intelligenza Artificiale) is being deployed as a clinical decision-support tool for general practitioners and other healthcare professionals within the public health system, enabling them to query AI systems in natural language and receive evidence-based suggestions for diagnosis, treatment pathways, chronic disease management, and preventive care [107]. Consistent with Italy's human-centred approach, these systems support but do not replace clinical judgement, with full responsibility remaining with licensed medical professionals. At the data governance level, the law qualifies AI-driven health research as an activity of "relevant public interest," facilitating secondary use of anonymised or pseudonymised health data under supervised conditions overseen by the Data Protection Authority [108]. This distinction clarifies that, while the data framework primarily enables research and innovation, the national AI platform itself is designed for real-world clinical use.

Italy's success will depend on how it manages regional fragmentation, aligns institutional actors, and turns normative structures into practice.

Spain

> *Spain's governance model adopts a dual-agency structure for AI-enabled medical device oversight*

POLICY DIMENSION	SPAIN APPROACH
Investment	R&D investment for AI and digital health grew 6.9% in 2024, above EU's average
AI Act Implementation	Created first AI supervisory agency in the EU, AESIA
Medical Device Regulation	AEMPS handles MDR/IVDR conformity assessment through a centralised notified body
Market Access	Reimbursement of AI-based solutions managed at regional level
OVERALL SUMMARY	Regulatory experimentation, evaluation and coordination have been embedded into the structure of Spain's health system

Spain is operationalising the implementation of the EU AI Act in the health sector through a dedicated AI national supervisory agency, while integrating the horizontal requirements of the regulation directly into its existing medical device and digital health architecture. Spain's approach comprises early regulatory experimentation through AI sandboxes, sector-specific governance tools, and strategic funding and innovation support measures within its decentralised National Health System (Sistema Nacional de Salud- SNS) [109].

Spain created the first AI supervisory agency in the EU, the Agencia Española de Supervisión de la Inteligencia Artificial (AESIA). Established by Royal Decree 729/2023 (August 2023), AESIA became fully operational in June 2024 and obtained full sanctioning powers in August 2025 [110]. It acts as market surveillance authority, notifying authority, and single point of contact with EU institutions. Its mandate includes supervision, inspection, and enforcement of the AI Act, as well as management of Spain's national AI regulatory sandbox.

In November 2023, well before the AI Act's full applicability, Spain launched the first regulatory sandbox for AI in Europe, aligned with the EU AI Act, to test high-risk AI systems (risk management, data governance, technical documentation, human oversight, and post-market monitoring) [111]. The sandbox has published practical guidance for healthcare AI applications. For instance, a smart insulin pump that analyses multimodal patient data (glucose levels, physiological parameters, medical history, diet and physical activity) to automatically determine insulin dosing, illustrating how AI Act requirements apply to high-risk clinical systems [112].

By December 2025, AESIA had already published 16 non-binding technical guides, developed through sandbox experimentation with industry and experts [113]. The guidance offers practical recommendations to providers and deployers of high-risk AI systems. AESIA emphasises that these documents are living resources, subject to regular updates to reflect evolving standards and European Commission guidelines.

Spain's governance model adopts a dual-agency structure for AI-enabled medical device oversight. AESIA supervises the horizontal AI Act obligations, while the Spanish Agency of Medicines and Health Products (AEMPS) handles the MDR/IVDR conformity assessment through the National Centre for Certification of Medical Devices (CNCps), a centralised notified body. AEMPS serves as the national competent authority for the full implementation of the EU MDR/IVDR, market surveillance, borderline classification and national registries [114]. The interaction between both agencies is further supported by the broader regulatory framework applicable to in-house hospital manufacturing: Under Royal Decree 192/2023, hospitals must comply with the requirements of Article 5.5 of the EU MDR, including prior notification to AEMPS; and, where relevant, these custom-developed tools must also be assessed within the applicable EU AI Act framework [115].

This coordinated framework is reinforced by the Artificial Intelligence Strategy for the National Health System (eIASNS), formally adopted in November 2025 by the Interterritorial Council of the SNS, which establishes common procedures for risk classification, clinical utility evaluation and organisational impact assessment across all Autonomous Communities [116].

Healthcare market access in Spain lacks a national fast-track reimbursement system. Reimbursement of digital health technologies and AI-based solutions is managed at regional level: Each of the 19 Autonomous Communities independently handles purchasing and adoption decisions [117]. In September 2025, the Ministry of Health launched a public consultation on a preliminary bill for a Law on Digital Health, which, if enacted, could establish a more harmonised national framework for big data, digital technologies and emerging tools. The consultation document also proposes a framework for the incorporation of digital health products into the SNS basic portfolio of services and for the financing of digital care solutions by the SNS, which would facilitate market access to innovative tools [118]. As of March 2026, the bill remains in the pre-legislative stage [119].

Public investment and strategic infrastructure further support Spain's competitiveness in AI, digital health, and biotechnology. The Strategic Project for the Recovery and Economic Transformation (PERTE Salud de Vanguardia) has mobilised more than €2.8 billion (public and private) since 2021 for personalised medicine, advanced therapies and healthcare digitalisation, while the earlier ENIA strategy (2020–2023) committed approximately €600 million. Spain's R&D investment grew 6.9% in 2024, above the EU average. Spain has also built key infrastructure for AI, including the MareNostrum 5 supercomputer (Barcelona Supercomputing Centre, ~314 petaflops) [122], and set out a national High-Performance Computing investment plan for further improvements [123].

In sum, Spain has embedded regulatory experimentation, evaluation and coordination into its health system, and is seeking to align its structure with emerging EU-level obligations. The main challenge is not a lack of structure, but maintaining alignment across territories as the system evolves.

Takeaways from the AI Act implementation landscape in France, Germany, Italy, and Spain

Building on the analysis of the landscape for the AI Act implementation in France, Germany, Italy, and Spain, the points below summarise trends that have stood out about the national approaches:

1 Coordination across authorities is the defining challenge for enforcement

Inter-institutional coordination is the central force of regulatory implementation. Yet, the coordination between horizontal AI authorities and sector-specific medical device regulators remains unproven, and the decentralised nature of health systems in Germany, Spain, and Italy adds a further layer of fragmentation that EU-level policy does not account for. In France, not all supervisory authorities have yet been formally designated. In Germany, the dual BNetzA/BfArM model for AIaMD remains untested. So does the AESIA-AEMPS model in Spain. Institutional fragmentation in health predates the EU AI Act, which adds further complexity to solving it.

2 Spain, Germany, France, and Italy are specialising in different strengths

All four countries link the implementation of EU regulations to their existing national ambitions. France stands out for integrating AI in health regulation, data protection, and health data reuse through its national strategy. Germany is focused on accelerating AI deployment to maintain leadership in technology and health markets. Italy champions a rights-based, human-centric approach to AI in health, highlighting clinical autonomy and patient information. Spain leverages its AI sandbox to position the country as a leader in regulatory innovation and AI governance. Countries should ramp up coordination for knowledge exchange to learn from one another and fast-track their national implementations in areas that may be underdeveloped.

3 Data is at the crux of AI and health regulatory infrastructure

While countries are still lagging in setting up regulatory authorities' mandates and operations to comply with the AI Act, they have already established health data governance architectures that are central to the AI Act regulatory infrastructure. France governs health data access and reuse through the Health Data Hub and the CNIL. Germany does so through FDZ Gesundheit. Italy does so through a national platform integrated with its EHR system. Spain does so through the Secretaría General de Salud Digital, Información e Innovación del SNS (SGSDII), which the draft Digital Health Law identifies as the national digital health authority and national health data access body. The quality and interoperability of these national systems will determine whether the EHDS delivers on its promise. They will also determine whether the EU's AI competitiveness ambitions in health have a viable data foundation.

4 The innovation bottleneck is not only market authorisation, but also market access

Germany is the country that has gone the furthest in funding mechanisms for market access to medical devices, through DiGA and DiPA, though access to diagnostics and clinical decision support systems remains limited. France also has a relatively structured pathway through PECAN. By contrast, Spain and Italy still lack a comparable national, harmonised, and rapid pathway for clinical AI or SaMD.

The lack of harmonised reimbursement practices creates barriers for European SMEs to scale approved AI products in their countries and abroad. After obtaining regulatory approval, they must navigate divergent national and subnational coverage decisions, pricing mechanisms, and funding criteria. For patients, this translates into unequal access to the same level of technological innovation in healthcare across Europe.

5 Regulatory sandbox as a governance tool is not new, but is on the rise

Spain is the strongest example, with its AI regulatory sandbox and technical guidance. France shows similar potential through CNIL's sandbox for AI projects aimed at improving public services. Germany concluded a pilot project for a simulation of an AI regulatory sandbox and launched institutional support tools such as the AI Service Desk. Italy has been more legislative and normative in AI governance, but has a track record in sandboxes, with the Sperimentazione Italia initiative from 2020, which may indicate a level of readiness to implement the AI Act's sandbox provision. The AI Act implementation in health is accompanied by regulatory learning instruments.

4

SECTION

Final Considerations: Analysing Regulatory Realities against Ambitions

Final Considerations: Analysing Regulatory Realities against Ambitions

> *The EU's ability to resolve implementation challenges in health will signal its capacity to credibly implement the AI Act across sectors*

The EU has built an ambitious and interconnected policy architecture for AI in health, spanning the AI Continent Action Plan, the Apply AI Strategy, the EHDS, and the Data Union Strategy, among others. But the implementation infrastructure required to deliver on those ambitions is arriving later than the compliance obligations it is supposed to support. The AI Act's high-risk provisions may take effect before harmonised standards are finalised, before notified body capacity is adequate, before overlaps with the MDR are solved, and—although not directly dependent on each other—before the EHDS secondary use framework and HDABs are fully operational. This mismatch in timelines means that developers and deployers face regulatory obligations without all the tools and infrastructure the EU itself has identified as necessary or desirable to meet them.

The analysis of the implementation landscape across the four largest economies confirms this pattern at the national level. Just as the European Commission is moving forward with ambitious plans and structures, countries are taking action through draft bills or enacted laws and expanded institutional mandates. In France, the government has proposed an oversight structure, though AI supervisory authorities haven't been formally designated yet. Germany's implementation law awaits parliamentary approval. Italy enacted the first national AI law, and AI Act-related sanctioning powers should be granted soon. Spain has moved fastest on institutional setup, with a dedicated national AI agency, but the efficiency of the model is still to be tested. What is needed is further institutional coordination and alignment among institutions at the national and the EU level to optimise efforts.

While this report centres on the health sector, where the convergence of high-risk classification, sensitive data, and sectoral regulation creates a particularly complex implementation landscape, the structural challenges it identifies (timeline mismatches, institutional fragmentation, and gaps between regulatory ambition and enforcement capacity) are likely to recur across other high-risk domains as the AI Act's full application approaches. The EU's ability to resolve these challenges in health will signal its capacity to credibly implement the regulation across sectors.

Overcoming fragmentation across EU countries

The brief analysis of the countries' AI Act implementation reality leads to the following question: Is full homogeneity possible (and desirable) in a political system defined by the coexistence of multiple forms of State? **A central benchmark for implementation should consider the minimal functional uniformity necessary for regulation to be effective in a political system marked by varied forms of State and enforcement realities.** In practice, this means ensuring that core regulatory processes—conformity assessment procedures, market surveillance protocols, and the division of competences between horizontal AI authorities and sectoral regulators—produce equivalent outcomes across Member States, even where the institutional arrangements delivering them differ. Without this baseline, a developer compliant in one jurisdiction may face materially different expectations in another, undermining the single market logic the AI Act is designed to serve.

The AI Act can only fulfil its promise if the EU ensures that structural differences do not become obstructive divergences. This equilibrium will be decisive for Europe's position in global competition.

Europe cannot allow the complexity of its own institutional architecture to become a brake. But neither can it sacrifice the fundamental principle that defines its political identity: the idea of a union that does not dissolve differences but integrates them. **When it comes to AI governance, the real test for the EU is no longer drafting technically sophisticated rules, but achieving harmonisation without homogenisation.**

Increasing institutional coordination within the European Commission

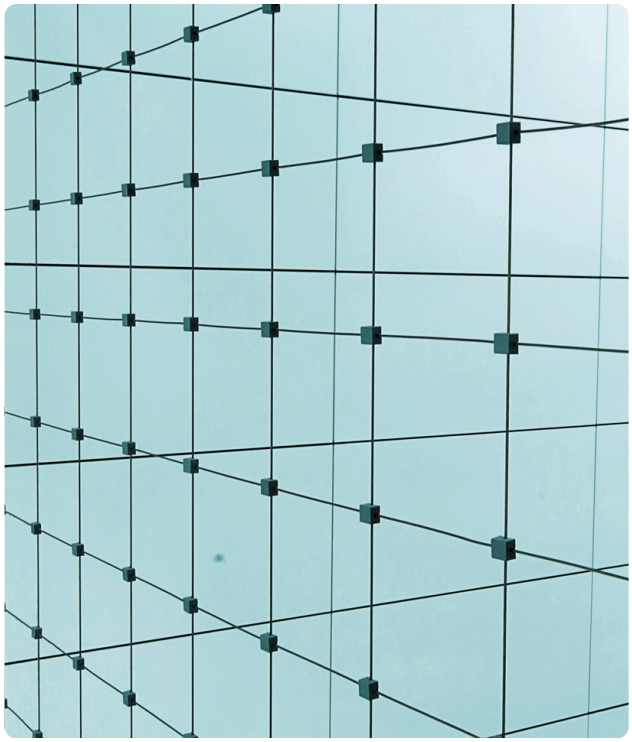
Beyond the fragmentation challenge across the EU, there is also the challenge of coordination within European institutions, such as the European Commission. EHDS and AI Act are led by different Directorates-General within the European Commission; DG SANTE oversees the EHDS, while DG CNECT leads on the AI Act and hosts the European AI Office. Medical device regulation under the MDR/IVDR involves both DG SANTE (for health policy aspects) and the Medical Device Coordination Group (MDCG), which coordinates implementation across Member States. While the Commission has tried to address this division with several coordination mechanisms, such as the MDCG and AI Board outputs, further action is needed to bridge institutional boundaries and provide clarity to stakeholders. Similar initiatives may help them navigate the complex regulatory landscape at the intersection of data, infrastructure, AI development, and deployment.

Furthermore, given the staggered timelines for the EU AI Act and the EHDS, it is unclear whether datasets accessed through EHDS mechanisms will automatically satisfy the AI Act's Article 10 requirements, subjecting manufacturers to fragmented national arrangements in the interim. Operational readiness across EU Member States remains uneven. Moreover, although the MDCG/AIB joint guidance provides a coordination model for the interplay between the MDR and the EU AI Act, equivalent formal guidance on EHDS interactions with either framework has not yet been issued.

A potential risk from these staggered timelines is that technical and governance coordination challenges may be underestimated, with misalignment between regulatory frameworks only becoming apparent once significant implementation investments have been made. Furthermore, this regulatory uncertainty may become a barrier to investment and innovative product development, particularly for SMEs without the resources to navigate fragmented interim arrangements.

Negotiations on the Digital Omnibus point to compliance timeline changes: High-risk requirements for AI systems embedded into regulated products such as medical devices will likely be extended to August 2028, while rules for high-risk systems such as emergency triage tools or healthcare eligibility systems, will likely become applicable in December 2027.

The EHDS infrastructure, meanwhile, will not become operational for most health data categories until March 2029, and for the remaining ones by March 2031.



Recommendations

1 Countries should test the dual supervision architecture for AI systems in medical devices

The distributed model of regulatory oversight for AIaMD, shared between sectoral and horizontal AI authorities, hasn't yet been validated in practice. The countries analysed in this report haven't yet developed concrete procedures for resolving conflicts of competence in complex AIaMD cases. In the interim until high-risk requirements are enforced and countries can test their proposed oversight model, it would be prudent to test them internally, through, for instance, joint readiness exercises against hypothetical cases of AI in medical devices. Such exercises would mitigate the risk of future inaction or inefficiency driven by ambiguity, where no single authority assumes full responsibility and gaps in effective oversight remain largely invisible until brought to light by a concrete incident. In addition, learning from precedents of analogous circumstances—such as the interplay between GDPR enforcement and health data governance—can help set the dual oversight process on a successful track.

2 The European Commission and Member States should address regulatory barriers to SME's market access and scaling across the EU

In Europe, a healthcare AI tool can comply with all regulatory requirements of the AI Act and the MDR and still fail to be used in clinical practice. This is because market access does not depend on regulatory authorisation only, but on the existence of concrete financing and payment mechanisms that enable its effective adoption. In the absence of clear, fast and harmonised reimbursement pathways, even a certified AI system risks remaining outside the real circuits of the health system. Without a reimbursement code, an applicable health technology assessment (HTA) process, or a public procurement scheme that incorporates it, hospitals lack the legal and budgetary basis to adopt it.

This gap may lead to scenarios in which innovation is trapped in a state of limbo between "approved" and "scalable." This market access bottleneck should be a priority for the European Commission as it rolls out its competitiveness strategy.

3 The European Commission should clarify the interplay between the EHDS and other EU policies and regulations

There is a lack of clarity to stakeholders on how the European Commission's internal coordination is working to solve staggered timelines across policies and regulations. The three regulatory frameworks most relevant for AI in health—AI Act, EHDS, and MDR/IVDR—are split between two directorates, leaving external stakeholders with no clear picture of how and to what extent the two directorates interact. The MDCG/AIB effort, although still insufficient to clarify all issues regarding the AI Act and the interplay between the MDR and IVDR, is a coordination format that the European Commission should consider improving and replicating. Further regulatory revisions can also help address the interplay issues. In addition, agile instruments that address coordination uncertainties may take the form of blueprints and roadmaps that inform the public about upcoming actions and guide them through regulatory changes, with a particular emphasis on healthcare-focused SMEs.

4 Countries should coordinate and share knowledge on implementation.

As implementation progresses, there will be fertile ground for structured knowledge exchange among Member States. The country analyses in this report show that France, Germany, Italy, and Spain are each advancing on different fronts: France on institutional maturity and data governance integration, Germany on reimbursement pathways, Italy on comprehensive national legislation, and Spain on regulatory experimentation and early institutional operationalisation. These are not competing models but complementary experiences.

Formalising channels for peer learning on AI Act implementation in health (through working groups, shared case repositories, or coordinated pilot programmes) would enable countries to build on one another's progress rather than replicate efforts in isolation. The AI Office is well positioned to facilitate such exchanges, and existing mechanisms like the AI Board already offer a basis for cross-border cooperation. The AI Board's coordination function can be expanded to cover knowledge-sharing focused on health sector challenges.

5 Coordination should extend to structured multistakeholder engagement

Democratic legitimacy in AI governance requires that implementation is not confined to inter-institutional processes but incorporates the perspectives of developers, deployers, healthcare professionals, patients, and civil society. The European Commission has established models for this—the Apply AI Alliance, the AI Observatory, and the structured dialogue convened by the AI Office. However, at the national level, the variation in stakeholder inclusion is significant: some countries have embedded consultation mechanisms into their implementation strategies, while others have not. As implementation decisions become more granular (involving different oversight bodies, documentation and conformity assessment procedures, operationalising transparency, and establishing enforcement priorities) the participation of those affected by these decisions will help authorities to focus on realising the AI Act's promises on the ground. Coordination frameworks should formalise stakeholder input at both national and EU levels as implementation advances. Importantly, multistakeholder structures should be leveraged for collective action in achieving the EU's competitiveness agenda, rather than for performative engagement.

> *The effective implementation of the AI Act in health depends not only on the existence of rules but on the institutional and technical capacity to apply them.*

The effective implementation of the AI Act in health depends not only on the existence of rules but on the institutional and technical capacity to apply them. When authorities are not yet fully designated or consolidated, the system loses the capacity to keep pace with the obligations it has set for itself. This report has documented a consistent pattern across the EU's policy architecture and its largest Member States: the ambition is substantial, the legal frameworks are in place, and the strategic vision is articulated. However, the implementation infrastructure lags behind the compliance timeline. Closing that gap is not a technical adjustment; it is the condition on which the credibility of the EU's regulatory model depends.

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HEALTH AI
The Global Agency for Responsible AI in Health

Driving Responsible AI for a Healthier Future

About HealthAI

HealthAI - The Global Agency for Responsible AI in Health, is a Geneva-based, independent nonprofit driving equitable access to AI-powered health innovations. Collaborating with governments, international organizations, and global health leaders, HealthAI focuses on AI governance and regulation to ensure AI transforms healthcare for all. Positioned at the intersection of healthcare, artificial intelligence, and policy, HealthAI aims to bridge the gap between emerging technologies and accessibility, particularly in low- and middle-income countries. By fostering trust, governance, and collaboration, HealthAI is shaping a future where health technologies benefit every population worldwide.

How HealthAI Can Support Member States

HealthAI can support EU governments and ministries of health in navigating the implementation gap identified across the regulatory landscape. The organization's established track record in capacity strengthening and regulatory implementation across its Global Regulatory Network provides a foundation for practical engagement with Member States facing similar structural challenges.

HealthAI's support encompasses:

- **Implementation readiness assessments** to identify AI in health governance gaps and priorities
- **Capacity strengthening for regulators and policymakers** through technical assistance and tailored training with a focus on EU AI Act implementation
- **Peer learning facilitation** connecting Member States to share regulatory tools and operational solutions
- **Access to governance resources,** including implementation guidance and validation instruments developed through multi-country collaboration

This approach recognizes that successful implementation requires operational capacity, institutional coordination, and sustained knowledge exchange beyond policy design alone.

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