ESCP
BUSINESS SCHOOL

IT ALL STARTS HERE

BERLIN | LONDON | MADRID | PARIS | TURIN | WARSAW

© Wisdom Graphics / AdobeStock

LIGHTS - Geopolitics

The European AI health trap: Why innovation fails to scale

ESCP Impact Paper No.2026-23-ENG

Anne PRUVOST

Frédéric Jallat, PhD
ESCP Business School

ESCP RESEARCH INSTITUTE OF MANAGEMENT (ERIM)

ESCP Impact Paper No.2026-23-ENG

The European AI health trap: Why innovation fails to scale

Anne Pruvost*
Frédéric Jallat**

ESCP Business School

Abstract

Artificial intelligence is transforming healthcare across the entire value chain, from clinical decision support and diagnostics to drug discovery and patient monitoring. Despite strong scientific capabilities, abundant health data, and a dynamic research ecosystem, Europe struggles to scale its health AI innovations. This paper argues that the continent's weakness is not technological but systemic. It identifies three interdependent bottlenecks — regulatory friction, data latency, and market adoption constraints — that together create a 'valley of deployment'. Drawing on recent empirical evidence and policy developments, the paper shows how these constraints systematically disadvantage startups and accelerate the transfer of value outside Europe. It concludes with implications for policymakers seeking to reconcile innovation, competitiveness, and responsibility.

Keywords: AI healthcare, digital health, regulation, European competitiveness, innovation scaling

*Health Data & Policy Analyst, Msc Biopharmaceutical Management
**Professor, ESCP Business School

The European AI health trap: Why innovation fails to scale

Introduction – Innovation without deployment

Artificial intelligence is no longer a peripheral technology in healthcare. By early 2026, more than 230 million individuals worldwide were consulting large language models for medical advice, self-diagnosis, and wellness management, at a scale that already rivals many forms of traditional clinical interaction (DialogHealth, 2025). AI applications now extend across the entire care continuum, from diagnostics and imaging to triage, drug discovery, and remote monitoring. For policymakers, these developments appear to offer a possible response to several structural pressures at once, including workforce shortages, ageing populations, and rising healthcare costs (OECD, 2026).

Yet the acceleration of technological capability has exposed a growing asymmetry between innovation and the institutional frameworks meant to govern it. This asymmetry is particularly visible in Europe. The continent benefits from strong public research systems, world-class clinical expertise, and some of the richest longitudinal health datasets in the world. Nevertheless, Europe has been unable to translate these assets into sustained leadership in health AI. The US market is already more than fifteen times the size of France's, while China is expanding at roughly twice the European rate (DialogHealth, 2025). European firms, by contrast, often face a far more fragile trajectory: they remain small, relocate, are acquired, or disappear before reaching meaningful scale.

This paper argues that Europe's relative weakness in health AI is therefore not the result of insufficient talent, inadequate science, or poor data quality. It reflects a systemic failure of deployment. Europe does not lack innovation; it lacks the institutional and market architecture required to convert innovation into adoption. The central problem is therefore not invention, but execution.

This distinction matters because Europe has traditionally approached technological competitiveness through the lens of innovation policy. Yet the challenge emerging in health AI is fundamentally different. Scientific excellence alone is no longer sufficient to secure leadership. The ability to move rapidly from invention to adoption has become equally critical. Europe's challenge is not to design another innovation strategy. It is to build a deployment strategy capable of transforming technological potential into clinical, economic, and societal impact.

The valley of regulation: protection without execution

European regulation reflects a legitimate ambition: to ensure that health AI systems are safe, transparent, and subject to meaningful human oversight. The AI Act, which treats most health AI applications as high-risk, embodies this ambition. However, in practice, the Act does not operate in isolation. It is layered onto pre-existing medical device regulation through the Medical Device Regulation Act and In Vitro Diagnostic Regulation Act, creating a cumulative burden that is unusually demanding for startups and scale-ups (Busch et al., 2024; Team Consulting, 2025).

For many firms, compliance is not merely a matter of legal discipline; it becomes a determinant of commercial viability. The MDR route alone may cost between €200,000 and €500,000 and can take between two and four years, a timeline that bears little relation to typical startup financing cycles (Team Consulting, 2025). Even products that do

not strictly fall under Software as a Medical Device classification frequently remain subject to AI Act obligations approaching comparable levels of documentation and oversight, but with less interpretive clarity (Slijpen et al., 2024). The result is not simply caution. It is delay, uncertainty, and a rising cost of survival.

What makes this problem structurally damaging is not regulation per se, but the way regulation is sequenced. Other jurisdictions have begun to treat regulation as an iterative process that can accompany innovation. Germany's DiGA framework allows temporary reimbursement while evidence is still being generated. The UK's MHRA sandbox permits supervised experimentation before full commercial deployment. The US FDA has moved toward adaptive pathways through instruments such as Predetermined Change Control Plans, allowing certain algorithmic updates without restarting the entire approval cycle (Slijpen et al., 2024). In Europe, by contrast, regulation remains largely gate-based. Innovation is expected to be validated before it can be used, rather than improved through controlled use.

Beyond the AI Act, European institutions have begun to experiment with new forms of deployment support. The Innovative Health Initiative (IHI) launched the BRIDGE project in 2026 to explore integrated regulatory pathways for emerging health technologies. Through its MOSAIC framework, the initiative seeks to bring together regulators, healthcare providers, payers, patients, and innovators at earlier stages of development, reducing some of the fragmentation that currently characterizes the European innovation landscape.

The significance of these initiatives lies less in their immediate operational impact than in what they reveal: a growing recognition that Europe's challenge is not simply to generate innovation, but to create the conditions under which innovation can scale.

Figure 1. The European "valley of regulation":
cumulative compliance burden across the AI Act, MDR/IVDR, and national requirements.

This regulatory architecture creates what may be described as a valley of regulation. Innovation enters the system with scientific legitimacy but encounters an approval environment whose duration, cost, and complexity disproportionately punish smaller firms. In theory, the system protects patients. In practice, it also filters innovators by size rather than quality.

Selection by size rather than innovation

The practical outcome of this regulatory architecture is a market that favors administrative endurance over innovative merit. Large organizations, whether multinational technology firms, incumbent medtech companies, or major hospital groups, have the legal resources and financial runway to absorb prolonged compliance costs. Smaller firms do not. Their exclusion is rarely the result of technical inferiority; it is more often the predictable consequence of a compliance environment calibrated for actors that can afford to wait.

This dynamic is increasingly visible in the composition of Europe's innovation ecosystem. The share of projects involving SMEs has declined in recent years, while larger and more capital-intensive actors have become increasingly dominant (Nelson Advisors, 2025). Funding patterns reinforce this trend. US investors now account for more than 60% of participation in major late-stage European digital health deals, a sign not only of foreign financial presence but also of Europe's weak domestic scale-up capacity (Galen Growth, 2025).

The result is a subtle but consequential form of attrition. Many European startups do not collapse spectacularly; they exit through acquisition. These transactions are often interpreted as success stories, yet they also imply a transfer of strategic capabilities, intellectual property, and decision-making power outside Europe.

The liquidation of Pixium Vision illustrates Europe's 'innovation paradox: the French startup invented a revolutionary AI vision technology but could not survive the costly European regulatory and financing hurdles. Its rescue and acquisition by US-based Science Corporation[1] underscores a growing trend where European intellectual property is systematically absorbed by well-funded American giants

In this sense, Europe is not simply losing firms. It is progressively externalizing the downstream value of innovation that it helped generate.

The inaccessible gold mine: data without deployment

Health data should, in principle, be Europe's strongest strategic advantage. Public healthcare systems generate large-scale, longitudinal, and clinically rich datasets that few other regions can match. Much of the most promising health AI innovation on the continent originates not in private startups but in university hospitals and public research institutions that combine data access with clinical expertise (OECD, 2026). Few regions enjoy such density of public medical infrastructure.

Yet this advantage remains largely theoretical because access to data is constrained by legal complexity, fragmented governance, and institutional latency. In France, for instance, access to the SNDS may require between 12 and 36 months of legal review, institutional contracting, and data standardization before analysis can even begin (Oudbier et al., 2025). In AI development, such delays are not incidental. They are strategic handicaps. By the time a European startup has cleared these procedures, a US or Asian competitor may already have trained, deployed, and iterated its next model generation.

[1] https://www.marketscreener.com/quote/stock/PIXIUM-VISION-16603793/news/Science-Corp-acquired-Intellectual-property-and-related-assets-for-the-Prima-retinal-implant-from-Pi-48065306/

The European Health Data Space is an ambitious response to this problem. In theory, it could convert Europe's latent data advantage into a unique innovation platform by establishing common rules and cross-border access mechanisms. But the timeline is misaligned with the realities of venture-backed innovation. Core operational components will not be fully functional until 2029–2031. For many startups founded today, that means the EHDS will arrive after the decisive window for scaling has already closed. Europe thus lies not only in a valley of regulation, but also in a valley of data: a gap where legacy access systems are too slow, while future infrastructure remains too distant to make a difference

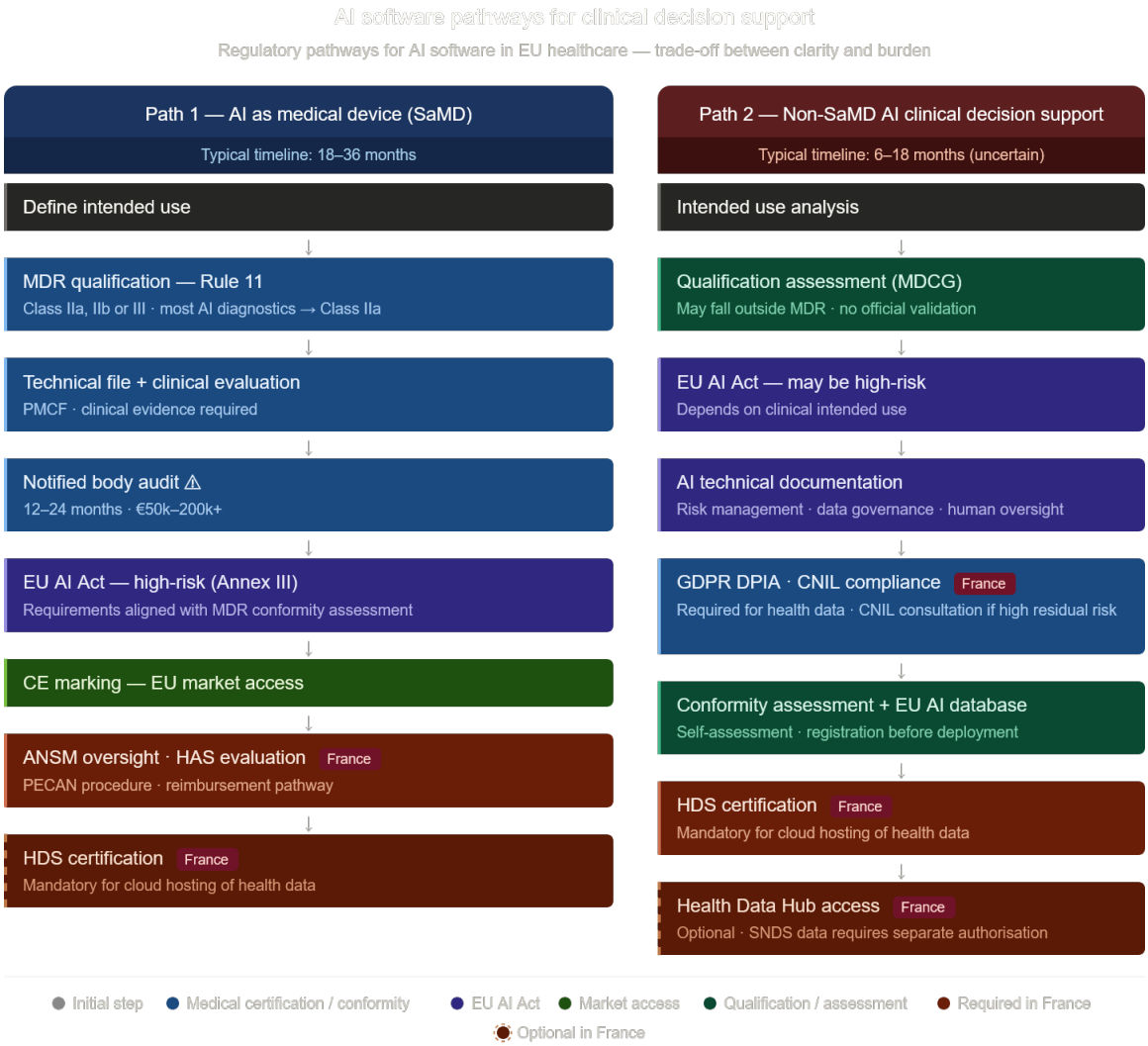

Figure 2. The EHDS implementation gap:
timeline mismatch between startup cycles and operational data availability (adapted from Hussein et al.).

This temporal mismatch has long-term implications. AI systems improve through use, feedback, and iterative deployment. The inability to access health data rapidly enough means that Europe not only delays innovation, but also forfeits the compounding advantages that come from real-world learning.

Adoption barriers: trust, liability, and market structure

Even when firms manage to overcome regulatory and data constraints, a further set of obstacles awaits at the point of adoption. The first is legal. In Europe, liability for AI-assisted clinical decisions remains insufficiently clarified. When patient harm occurs in a decision environment shaped by algorithmic recommendation, the distribution of responsibility

between developer, provider, and healthcare institution remains uncertain (Price et al., 2024). For large incumbents, this ambiguity is a manageable legal risk. For SMEs, it is often an existential one.

The second obstacle is organizational. Trust in AI systems remains uneven among clinicians, not only because of epistemic opacity, but also because the technology is often perceived through the lens of workforce pressure, possible automation, and administrative rationalization. In health systems already under strain, AI may be seen less as a support tool than as a latent instrument of substitution. Even when the technology is clinically sound, these perceptions affect its reception and limit adoption (Medical Law Review, 2026).

The third obstacle is economic. Public healthcare systems operate under procurement models and budget logics that are poorly adapted to the forms of value AI is most likely to generate. Prevention, early detection, workflow efficiency, and reduced administrative burden are real benefits, but they are rarely rewarded directly within reimbursement structures. The result is a familiar but damaging asymmetry: AI can produce measurable value while remaining commercially difficult to sell. Revenue is delayed, customer acquisition costs remain high, and many startups exhaust their runway before adoption becomes sustainable.

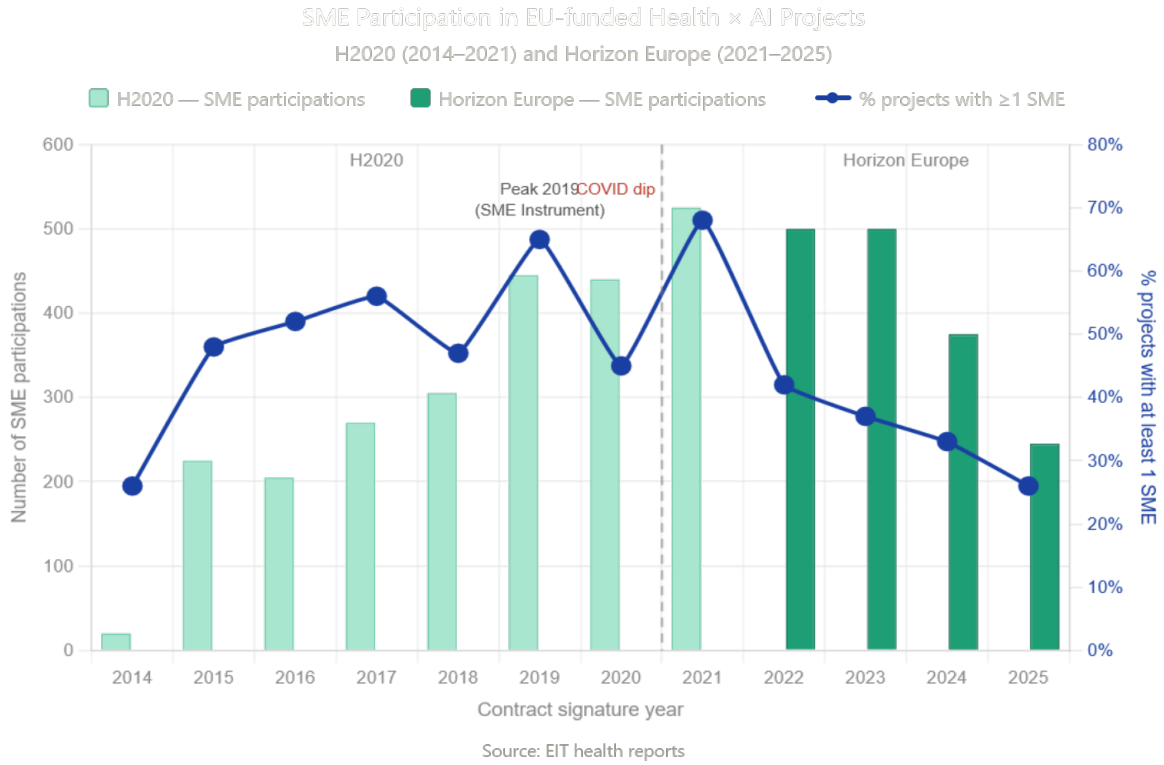

Figure 3. From regulation and data access to adoption barriers: the cumulative "valley of deployment" in European health AI.

From fragmentation to a valley of deployment

Taken separately, regulation, data access, and adoption each appear as familiar policy problems. Taken together, they constitute something more serious: a systemic deployment failure. Regulatory delays slow market entry, data constraints delay model development, and adoption barriers delay commercial traction. These mechanisms are

mutually reinforcing. The longer it takes to certify a product, the less attractive it becomes to investors. The longer data access is delayed, the harder it becomes to prove performance. The longer adoption takes, the less firms are likely to survive independently. Europe therefore does not face a single bottleneck, but a cumulative valley of deployment.

This is the core strategic issue. Europe has built a strong innovation base but has not built an equally strong architecture for scaling. As a result, it behaves less like a leader in health AI than like an upstream supplier of talent, ideas, and datasets to ecosystems better equipped to convert them into market power.

Beyond policy considerations, the findings also carry managerial implications. For innovators, success in European health AI increasingly depends not only on technological performance but also on the ability to navigate regulatory requirements, secure access to clinical data, generate real-world evidence, and achieve market adoption (Kim et al., 2023). For healthcare organizations, the results highlight a growing role in the innovation process, as hospitals and health systems increasingly shape the validation, deployment, and scaling of AI solutions through their data, procurement, and adoption practices (Liao et al., 2022).

Conclusion – From innovation to deployment

Europe stands at a critical juncture. It possesses the scientific capabilities, clinical expertise, data resources, and regulatory ambition required to become a global leader in health AI. Yet these assets do not automatically translate into competitiveness. Without deployment, innovation remains potential rather than power.

The evidence presented in this paper suggests that Europe's challenge is not an innovation deficit but a deployment deficit. Regulatory complexity, fragmented data access, and adoption barriers do not operate as isolated obstacles. Together, they form a systemic architecture that slows the translation of scientific excellence into real-world impact.

Encouragingly, recent initiatives such as regulatory sandboxes, the European Health Data Space, procurement reforms, and integrated innovation frameworks signal an emerging awareness of this problem. What remains uncertain is whether these efforts will be sufficiently coordinated and sufficiently ambitious to alter Europe's competitive trajectory.

The future of European leadership in health AI will depend less on its ability to generate new ideas than on its capacity to transform those ideas into adoption. In this respect, the next phase of European competitiveness will not be defined by innovation policy alone. It will be defined by the emergence of a genuine deployment strategy.

In health AI, the future will belong not to those who invent first, but to those who scale best.

References

Busch, C., Jansen, P., Krämer, A., & Vokinger, K. N. (2024). Navigating the European Union Artificial Intelligence Act for healthcare. NPJ Digital Medicine, 7, Article 246. https://doi.org/10.1038/s41746-024-01213-6.

CB Insights. (2025). Digital health trends 2025. CB Insights.

DialogHealth. (2025). Global health AI market analysis.

European Commission. (2024). Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act). Official Journal of the European Union.

Galen Growth. (2025). European digital health funding report 2025. Galen Growth.

Kim, J.Y., Boag, W., Gulamali, F., Hasan, A., Hogg, H.D.J., Lifson, M., Mulligan, D., Patel, M., Raji, I.D., Sehgal, A. and Shaw, K. (2023). Organizational governance of emerging technologies: AI adoption in healthcare. In proceedings of the 2023 ACM conference on fairness, accountability, and transparency (pp. 1396-1417).

Liao, F., Adelaine, S., Afshar, M. and Patterson, B.W. (2022). Governance of clinical AI applications to facilitate safe and equitable deployment in a large health system: key elements and early successes. Frontiers in digital health, 4, p.931439.

Medical Law Review. (2026). Medical negligence in the age of statistically superior AI. Medical Law Review.

Nelson Advisors. (2025). European HealthTech and AI in healthcare: 2025 mid-year analysis. Nelson Advisors.

OECD. (2026). Scaling artificial intelligence in health. OECD Publishing. https://doi.org/10.1787/a436e12d-en

Oudbier, A., et al. (2025). Shaping the future EHDS: Recommendations for implementation of Health Data Access Bodies in the HealthData@EU infrastructure for secondary use of electronic health data. European Journal of Public Health, 35(Supplement_3), iii32–iii33.

Price, W. N., II, Gerke, S., & Cohen, I. G. (2024). Liability for use of artificial intelligence in medicine. In B. Solaiman & I. G. Cohen (Eds.), Research handbook on health, AI and the law. Edward Elgar Publishing.

Slijpen, G., Kop, M., & Cohen, I. G. (2024). EU and US regulatory challenges facing AI health care innovator firms. Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics; Stanford Law School.

Team Consulting. (2025). Regulation of AI in healthcare: Navigating the EU AI Act and FDA. Team Consulting.