EARTO Position Paper on Accelerating AI Adoption in Healthcare through European SMEs

14 July 2026

1. Introduction

European healthcare systems are under structural pressure due to rising costs, demographic change, workforce shortages, and increasing demand for care.[1] Artificial intelligence (AI), combined with the growing availability of health and contextual data, has significant potential to improve clinical decision-making, operational efficiency, and healthcare system performance. By analysing large and complex datasets, AI can support diagnosis, risk prediction, treatment decisions, resource allocation, and operational planning across healthcare systems. Yet its adoption remains limited: despite widespread development and experimentation, AI solutions rarely progress from technical validation to routine clinical use[2,3,4]. Recent European Commission (EC) analysis shows that only around half of healthcare actors report real-world AI use, reflecting a persistent adoption gap linked to fragmented data environments and limited interoperability[5].

European policy is increasingly recognising this challenge across sectors. The AI Continent Action Plan[6], the Apply AI Strategy[7], and the Data Act[8] signal the strategic intent to shift from capability building towards deployment and uptake. Investments in AI Factories, high-performance computing, and Digital Europe initiatives further reflect this shift toward deployment[9]. Europe's challenge is no longer primarily the development of AI technologies, but the ability to integrate and scale them across fragmented healthcare systems[10]. AI adoption depends not only on model capability, but on conditions that enable integration into clinical workflows, interoperable data environments, validation settings, regulatory processes, and healthcare infrastructures[11]. The core challenge lies not in AI development itself, but in the absence of coordinated conditions required for scalable implementation across healthcare systems. RTOs, as translational research actors, connect scientific and technological excellence with industrial capacity and healthcare system needs, helping ensure that AI innovation contributes fully to Europe's ambitions for safe, effective, and scalable healthcare deployment.

2. AI Adoption in Healthcare and Europe's Industrial Competitiveness

AI adoption in healthcare is increasingly linked not only to health system performance but also to Europe's industrial competitiveness. In Europe's health sector, innovation in biotech, medtech, digital health, AI/data, and diagnostics is driven by a diverse ecosystem of actors. In particular, SMEs play an important role in early-stage development and niche innovation, while scale-up and large-scale implementation often depend on larger industry players, alongside RTOs, whose applied research capacities help connect early-stage innovation with industrial-scale deployment and market uptake[12]. Large pharmaceutical and medtech companies, together with healthcare providers and hospitals, play a critical role in late-stage development, clinical validation, regulatory navigation, and the integration of solutions into routine care. Companies integrating AI into healthcare products and services ("AI-adopting") particularly depend on access to interoperable health data, validation environments, and real-world implementation settings. Yet such conditions are often not available at scale across the fragmented European healthcare system[1,2,5]. A key challenge, therefore, lies in the insufficient availability of structured pre-deployment environments that enable validation, system integration, and multi-stakeholder coordination before operational use.

At the same time, AI deployment in healthcare is advancing more rapidly in regions such as the United States and China, where access to health data, integrated provider systems, and large-scale validation and implementation environments accelerate adoption and market uptake[7]. Without stronger framework conditions for deployment, Europe risks limiting the ability of SMEs to validate, scale, and commercialise AI-enabled healthcare solutions. Europe's emphasis on trustworthy AI can constitute a competitive

[1] Health at a Glance: Europe 2024 (OECD)
[2] Study on Health Data, Digital Health and Artificial Intelligence in Healthcare (EC)
[3] The State of AI (McKinsey)
[4] Generative AI in healthcare: Adoption trends and what's next (McKinsey)
[5] Study on the Deployment of AI in Healthcare (EC)
[6] The AI Continent Action Plan (EC)
[7] Apply AI Strategy (EC)
[8] Data Act (EC)
[9] EC supports AI innovation in health and online safety (EC)
[10] InvestAI initiative (EC)
[11] AI Diffusion Report (Microsoft)
[12] Annual Report on European SMEs 2025-2026 (EC)

advantage rather than solely a constraint, provided that privacy-preserving AI methods are sufficiently supported and integrated into healthcare systems. Europe's strengths in research, industrial capabilities, and regulation must therefore translate more effectively into operational capacity and scalable implementation across healthcare systems. In this context, RTOs can help bridge these gaps through their expertise and experience in validation, system integration, and implementation support.

3. Diagnosing Why AI Deployment Remains Difficult in Healthcare

Europe faces persistent challenges in translating its AI-related strengths into routine use across healthcare systems. These challenges are increasingly evident in the context of generative AI and foundation models, where implementation depends not only on model capability, but also on access to compute infrastructure, interoperable data environments, governance frameworks, and integration capacities[13]. The following sections outline the key challenges that continue to limit the validation, implementation, and scaling of AI solutions across European healthcare systems.

3.1 Why AI Innovation Does Not Become Operational Use

Europe produces a high volume of AI-related research and innovation output, yet large-scale AI adoption remains concentrated in regions with access to integrated data environments, computing infrastructure, and markets that enable large-scale AI adoption. In healthcare, the challenge is not primarily technical validation but the integration of AI solutions into clinical workflows, healthcare infrastructures, and regulatory environments. This is increasingly visible in the context of generative AI and foundation models, where implementation depends not only on model capability, but also on interoperable data environments, governance, compute infrastructure, and the ability to integrate AI into operational healthcare settings[13]. Evidence shows that many organisations are able to develop and technically validate AI solutions, but struggle to move from experimentation and pilots into operational use where integration into existing systems is required. In healthcare, this challenge is amplified because solutions must operate across multiple providers, data environments, and regulatory settings. As a result, technically validated solutions often remain local, time-limited, and difficult to scale across healthcare systems. This points to broader structural challenges related to governance, interoperability, implementation capacity, and readiness for deployment at scale[14,15].

3.2 Why SMEs Struggle to Adopt and Scale AI Solutions

SMEs represent a significant share of Europe's digital health, medtech, and diagnostics sector, yet often face structural barriers when deploying and scaling AI-enabled healthcare solutions. Integration of AI functionality requires access to high-quality and interoperable data, iterative validation across clinical environments, continuous performance monitoring after deployment, and conformity with multiple regulatory requirements under the Medical Device Regulation[16], the AI Act[17], and data protection frameworks. These combined requirements often exceed the internal capacities of SMEs, limiting their ability to implement solutions and bring them into routine clinical use at scale. AI adoption in healthcare, therefore, often depends on access to external validation, system integration, and implementation support that SMEs cannot provide independently[18]. At the same time, SMEs must operate across fragmented healthcare systems where differences in data infrastructures, clinical workflows, procurement processes, and reimbursement models require repeated adaptation and validation of the same solution. This leads to duplicated validation efforts, increased costs, and delays in implementation and scaling across healthcare systems. As a result, many SMEs lack access to the conditions required to validate, integrate, and scale AI solutions across healthcare systems.

3.3 Why AI Deployment Requires Translational and System-Integration Functions

Implementing AI solutions in healthcare requires more than technical validation. It also depends on coordinated clinical implementation, regulatory compliance, interoperability, procurement, and integration into healthcare infrastructures and workflows. These functions are typically distributed across healthcare providers, validation infrastructures, regulatory authorities, and translational organisations, requiring coordination across organisational and institutional boundaries. As a result, successful implementation depends not only on technological capability but also on the ability to connect validation, clinical integration, and operational use across fragmented healthcare systems. RTOs play a key role in providing these translational and system-integration functions. They operate validation infrastructures, support interoperability and system integration, and facilitate collaboration between SMEs, healthcare providers, industry, and public authorities. Through their operational links across multiple stages of AI deployment, they help connect technical validation, clinical collaboration, and deployment support under real-world conditions while enabling technology uptake, system integration, and scaling across healthcare systems[19]. Strengthening these translational and system-integration functions is therefore essential to bridge technical

[13] Generative AI and foundation models in the EU: Uptake, opportunities, challenges, and a way forward (CEPS/EC)
[14] Artificial intelligence is reshaping health systems: state of readiness across the European Union (WHO Europe)
[15] Building the foundations for agentic AI at scale (McKinsey)
[16] https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng
[17] https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng
[18] Generative AI in healthcare: Adoption trends and what's next (McKinsey)
[19] Role of RTOs in developing and scaling technologies (Technopolis)

validation, regulatory alignment, clinical implementation, and deployment across fragmented healthcare systems.

Structural Barriers to AI Deployment in Healthcare

Across these challenges, a common pattern emerges. Europe's primary limitation in healthcare AI is not the generation of AI innovation itself, but the ability to translate innovation into operational use at scale and within competitive timeframes. SMEs continue to face structural barriers when scaling AI-enabled solutions across healthcare systems. At the same time, the translational and system-integration functions needed to connect technical validation, clinical implementation, regulatory alignment, interoperability, and deployment support remain fragmented and insufficiently coordinated. As a result, technically validated solutions often struggle to progress into routine clinical use and scalable deployment across European healthcare systems. Addressing these barriers requires coordinated action across funding, validation, infrastructure, regulatory, and deployment pathways. The following recommendations outline key areas where European research, innovation, and health policy can strengthen the conditions required for AI deployment in healthcare.

4. Recommendations for Strengthening AI Deployment in Healthcare

The recommendations below focus on strengthening the conditions required for AI deployment in healthcare, with particular attention to validation, scaling, interoperability, infrastructure access, regulatory continuity, and operational implementation across healthcare systems.

4.1. Shift Funding Towards Deployment and Scaling

European funding programmes[1,7] have significantly strengthened AI research and early-stage innovation, but support for clinical validation, implementation, system integration, and scaling across healthcare systems remains limited. For better continuity between development, validation, and operational implementation, the new FP10, the European Competitiveness Fund (ECF), and the implementation of the Apply AI Strategy should place stronger emphasis on multi-site validation sustainability through reusable platforms, integration into clinical workflows and data infrastructures, as well as cross-border deployment scenarios. This should include support for operational environments where SMEs can validate and scale AI-enabled solutions across healthcare settings, including through infrastructures and system-integration functions provided by RTOs and other translational actors.

Key recommendation: Shift EU funding more strongly from single-aim, project-based AI development towards deployment, reusable platforms and infrastructures, integration, and multi-site clinical validation in order to support operational uptake and scaling across healthcare systems.

4.2. Connect the Stages: Validation, Regulation, and Implementation

Validation, regulatory, and implementation processes are often organised through separate programmes, governance mechanisms, and responsibilities, requiring SMEs to navigate disconnected technical, clinical, and regulatory settings. As a result, evidence generated during validation is not efficiently carried forward into regulatory processes and operational implementation, resulting in repeated effort and delays. European programmes and infrastructures should therefore support continuous pathways that connect technical validation, clinical implementation, and regulatory interaction under real-world conditions. This requires stronger coordination between the different stages of this pathway. RTOs and other system-integration actors help to ensure this continuity by connecting the different stages of the innovation pathway, from technical validation through regulatory interaction to clinical implementation.

Key recommendation: Strengthen the connection of technical validation, clinical implementation, and regulatory processes into continuous and reusable pathways that support operational implementation and scaling across healthcare systems.

4.3. Enable Regulatory Sandboxes for Real-World Validation and Deployment

Regulatory sandboxes should support not only regulatory experimentation but also real-world validation and implementation under operational healthcare conditions. In healthcare AI, this requires early and continuous interaction between developers, healthcare providers, and regulators to address regulatory, clinical, organisational, and interoperability requirements before large-scale implementation. European and national sandbox initiatives should therefore be more closely connected to validation infrastructures, regulatory authorities, and clinical implementation to ensure continuity across the entire pathway. Sandbox activities should also generate reusable evidence that supports subsequent regulatory approval, market

entry, and wider adoption. RTOs and other bridging actors can contribute by supporting real-world validation, system integration, exchange with regulatory authorities, and implementation under operational conditions.

Key recommendation: Enable regulatory sandboxes as controlled validation environments linked to broader regulatory and implementation pathways for healthcare AI, and ensure their sustained operation.

4.4. Create Continuous Pathways from Innovation to Deployment

AI-adopting SMEs often face interruptions when progressing from development to implementation because funding, validation, and implementation are organised through separate programmes and mechanisms. As a result, solutions frequently require repeated validation and adaptation to different operational and regulatory requirements across healthcare systems. European programmes should therefore support continuous progression across development, validation, and operational implementation, including through stronger continuity between funding, validation, implementation, procurement, and innovative reimbursement pathways. RTOs and other intermediary actors can contribute by connecting technical validation, clinical collaboration, system integration, and deployment activities under real-world conditions.

Key recommendation: Create and financially support continuous pathways from innovation to deployment that enable AI-enabled healthcare solutions to progress across development, validation, operational implementation, and market uptake without repeated disruption and revalidation, with priority for solutions of strategic importance to European competitiveness.

The recommendation above focuses on strengthening continuity across funding, validation, regulatory, and deployment pathways. The following recommendations focus on system integration, infrastructure access, and usable health data environments that support the implementation and scaling of AI solutions across healthcare systems.

4.5. Strengthen System Integration for Real-World Use

Even where validation and regulatory pathways are aligned, AI solutions often fail during operational implementation, when they must be integrated into existing products, clinical workflows, and healthcare infrastructures. For SMEs, the main challenge is typically not the availability of AI technologies themselves, but their integration into operational healthcare environments, including interoperability with existing IT systems, adaptation to clinical workflows, continuous performance monitoring, and alignment with organisational requirements over time. Successful operational implementation therefore requires access to healthcare environments, system-level expertise, and sustained deployment support that SMEs often cannot provide independently. EU programmes, including Digital Europe and EU4Health, should therefore provide stronger measures for workflow integration, operational implementation, and post-deployment monitoring under real-world conditions. RTOs and other research actors can contribute to successful operational implementation by supporting system integration, interoperability, and collaboration with healthcare providers under operational conditions, while capturing and feeding back real-world evidence to improve validation, implementation, and scaling.

Key recommendation: Strengthen capacities for real-world integration, post-deployment monitoring, and scaling of AI solutions across healthcare systems, such as workflow integration, interoperability support, and continuous performance validation under operational conditions.

4.6. Strengthen Access to AI Infrastructure and Deployment Support for SMEs

Europe has made significant investments in AI infrastructure, including high-performance computing (HPC), AI Factories, and Testing and Experimentation Facilities (TEFs), to strengthen AI development and deployment capabilities. However, many SMEs still face difficulties accessing and combining the infrastructure and services required for implementation across healthcare systems. At the same time, the requirements for implementation extend beyond computing access, including testing, validation, interoperability, and system integration support. European programmes and infrastructure initiatives should therefore provide more coordinated access models that combine infrastructure, validation, and deployment support throughout the innovation pathway. Reducing administrative and financial complexity and providing clearer access procedures will be key to enabling SME use of these infrastructures. RTOs and other connecting actors can contribute by supporting access to infrastructure together with validation,

interoperability, and system-integration support under real-world conditions and with attention to health data compliance.

Key recommendation: Provide simplified and coordinated access to AI infrastructures, including HPC, AI Factories, and TEFs, together with testing, validation, interoperability, and deployment support for SMEs, e.g., through single-entry access points, bundled services, and other coordinated measures.

4.7. Make Health Data Operationally Usable for AI Deployment

The European Health Data Space (EHDS) and the Data Act establish an important framework for improving access to health data, but access alone does not enable AI deployment in healthcare. In practice, SMEs continue to face difficulties using health data consistently and securely across development, validation, and implementation due to fragmentation across providers and Member States, limited interoperability, varying data quality, and legal and technical barriers related to governance and privacy. EHDS implementation, together with alignment of Data Act implementation, should therefore focus not only on access rights, but also on interoperable and usable data environments that support secure data access, validation, reuse, and cross-border use under GDPR-compliant conditions across different healthcare settings. This includes harmonised access procedures, interoperable data formats, secure environments for development and validation, and feasible access conditions for SMEs within realistic development timelines and resource constraints.

Key recommendation: Implement EHDS and align Data Act implementation to support secure, interoperable, privacy-preserving, cross-border reuse of health data across AI development, validation, and deployment through harmonised access procedures, interoperable data formats, and secure development and validation environments.

5. Conclusion

Europe does not lack AI-related strengths in research, talent, and downstream application potential. The central challenge is the ability to translate these strengths into large-scale adoption across healthcare systems. Looking at AI adoption from the perspective of SMEs makes these challenges particularly visible, as SMEs must navigate fragmented validation, regulatory, infrastructure, and deployment pathways while adapting solutions across multiple healthcare settings. At the same time, deployment increasingly depends on translational and system-integration functions that connect technical validation, clinical implementation, regulatory alignment, interoperability, and market uptake across healthcare systems.

The paper identifies three structural bottlenecks that continue to limit AI deployment in healthcare: the difficulty of translating innovation into operational use, the limited capacity of SMEs to scale AI-enabled solutions across fragmented healthcare systems, and the fragmentation of translational and system-integration functions required for successful implementation.

The recommendations proposed in this paper address these challenges through two complementary areas of action. The first focuses on strengthening continuity across funding, validation, regulatory, and deployment pathways. The second focuses on strengthening system integration, improving infrastructure access, and enabling usable health data environments that support implementation and scaling across healthcare systems. RTOs contribute across both areas by enabling validation, interoperability, deployment support, and access to real-world healthcare environments.

Strengthening Europe's capacity to deploy AI in healthcare will therefore depend not only on advancing AI technologies but on building the coordinated operational conditions required to integrate and scale them safely, effectively, and consistently across healthcare systems. By working together, SMEs, RTOs, healthcare providers, industry, and public authorities can accelerate AI adoption and translate European innovation into better healthcare and stronger industrial competitiveness.

EARTO remains ready to provide additional input on the above-mentioned considerations and topics and to further discuss the implications of this input for the healthcare industry, RTOs and the complete health RD&I ecosystem with all involved stakeholders.

EARTO - European Association of Research and Technology Organisations
Founded in 1999, EARTO promotes RTOs and represents their interest in Europe. EARTO network counts over 350 RTOs in more than 32 countries. EARTO members represent 228,000 highly-skilled researchers and engineers managing a wide range of innovation infrastructures.

RTOs - Research and Technology Organisations
From the lab to your everyday life. RTOs innovate to improve your health and well-being, your safety and security, your mobility and connectivity. RTOs' technologies cover all scientific fields. Their work ranges from basic research to new products and services' development. RTOs are non-profit organisations whose core mission is to produce, combine and bridge various types of knowledge, skills and infrastructures to deliver a range of research and development activities in collaboration with public and industrial partners of all sizes. These activities aim to result in technological and social innovations and system solutions that contribute to and mutually reinforce their economic, societal and policy impacts.

EARTO Working Group Healthcare*: the WG is composed of 100 experts coming from 38 RTOs in 19 European countries. This WG is looking at the implementation of the EU RD&I Framework Programmes (Horizon Europe) addressing the healthcare sector, and especially medical technology, pharmaceuticals, biotech. Its members are conducting technological research for biomedical and medical applications, both for large companies and SMEs. They strongly support the emergence and the growth of spin offs in healthcare technologies. This WG is also looking at how RTOs can be involved in and benefit from projects under the European Digital Programme as well as the EU4Health programme, and also about the specific role of RTOs in Institutionalised Partnerships such as the Innovative Health Initiative.*

EARTO Contact*: www.earto.eu*