AI:Dental & Kempelen Institute of Intelligent Technologies

Healthcare Innovation and Artificial Intelligence in European Union

Aligning Goals with Societal Benefits Across Emerging Sectoral Frameworks

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AI:Dental

Abbreviations

AI means artificial intelligence.

AIA or **AI Act** means European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))

AID or AI:Dental means AID s.r.o., with its registered seat in Bratislava, Slovakia.

EHDS means European Health Data Spaces

EHDS Provisional agreement or **EHDS Regulation** means Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space (provisional agreement)

EU means European Union.

KInIT means Kempelen Institute of Intelligent Technologies with its registered seat in Bratislava, Slovakia.

MDR means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

TEHDAS means Towards European Health Data Space project, carried out by 25 European countries and co-ordinated by the Finnish Innovation Fund, Sitra.

SITRA means foundation selected by the Member States to coordinate the follow-up joint action due to the successful TEHDAS project.

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Foreword

Whereas AI:Dental is a Slovak startup aiming to be a responsible AI provider in the healthcare industry and be thought leader in shaping healthcare innovation and MedTech and Europe.

AI:Dental has as its mission to democratise dental health through AI by enhancing precision, affordability and accessibility in education and patient care.

Kempelen Institute of Intelligent Technologies is an independent, research, non-profit institute focusing on artificial intelligence and related disciplines. KInIT's mission is to support scientific excellence and its transformation to responsible innovations by bridging the private and academic sectors, encouraging knowledge sharing, talent development and circulation, and advocating quality, ethics, and fairness including public policy advising.

Whereas artificial intelligence is at the core of our research and business.

Whereas we value the role of SMEs and startups in the innovation and economy.

Whereas we carefully consider development and deployment of AI in sensitive areas including healthcare.

Whereas we appreciate the value of the public debate on societal impact of artificial intelligence in general.

Whereas KInIT has published the Stance on the Proposal for Artificial Intelligence Act in summer 2021.

Whereas KInIT has publicly communicated the Stance on the Regulation of generative AI in autumn 2023.

We are presenting our position on Healthcare Innovation: Aligning Goals with Societal Benefits Across Emerging Sectoral Frameworks.

Executive summary

The document discusses the implications of the Artificial Intelligence Act (AI Act), Medical Devices Regulation (MDR), and European Health Data Spaces (EHDS) regulation for healthcare innovation. Our findings are generally applicable, however specifics for SMEs and startups are explicitly acknowledged. It highlights the challenges posed by regulatory compliance costs, the need for data governance, and the importance of risk management systems. The document suggests that financial support for compliance and audit for SMEs and startups in the healthcare sector might be of a great benefit for the society and sector development, on top of the existing sandboxes. It emphasizes the need for a single audit body to simplify the process. It also proposes an "anticipatory CE conformity assessment" for continuous learning AI systems. The document calls for local engagement in implementing regulatory frameworks. It concludes by suggesting that local associations could drive AIA and EHDS adoption and that the EU should ensure the acts are adopted based on their merits.

- **Advocating for coherent framework for AI in healthcare**

  Medical devices using AI systems shall be considered high-risk and subject to requirements of MDR and AIA simultaneously. According to both regulations, a conformity assessment procedure is required before attributing CE marking on a device or system. The content of conformity assessment as part of a broader risk management system differs based on the classification of a medical device and AI system due to the substantive obligations discussed below. Risk management systems according to the MDR and AIA may be combined. However, it needs to be emphasized that risks connected to AI systems might differ from risks relevant to the use of medical devices and these shall be evaluated in the specific context of AI being used in the healthcare sector. We recommend the Commission to provide additional specification of how such a risk management system shall be approached to delineate efficient and effective processes to comply with both regulations. Additionally, further guidance from the European Commission on how to implement data and data governance including new requirements stemming from EHDS regulation proposal in practices in the AI medical sector is essential.

  New regulations like the MDR, AI Act, and EHDS are a positive step towards safer and more effective healthcare solutions. They provide a clear roadmap for innovation, prioritizing patient and overall system safety. However, these regulations can be complex and challenging to navigate, especially for smaller players like SMEs and startups. **Regulators should scrutinize per-project budgets to ensure adequate funding for translating research into applications. This minimizes time spent on fragmented funding applications, aiding innovation.**

- **Supporting innovation and responsibility through sandboxes and financial support**

  Regulatory sandboxes have emerged as a practical tool for fostering innovation in highly regulated sectors, such as fintech. They allow for testing innovative products, services, and business models in a live environment, with regulatory oversight but without the need for full regulatory compliance during the testing phase.

  Given the challenges faced by providers, especially SMEs and startups in navigating the complex regulatory landscape of the EU, particularly in the healthcare sector, the introduction of regulatory sandboxes and financial support to undergo audit by notified bodies could be a significant investment for the agile businesses, especially in the area of health-care. This approach would allow providers to validate their innovative solutions in real-world settings, with real users, while mitigating potential risks. Regulatory sandboxes would also provide valuable insights to regulators, helping them understand the practical implications of their regulatory frameworks and adjust them if necessary.

  The AI Act incorporates regulatory sandboxes as a mechanism to balance fostering innovation in AI with ensuring public safety. Each member state is obliged to establish at least one national regulatory sandbox. Therefore, we call upon the EU member states to consider the introduction of regulatory sandboxes for healthcare innovation with priority access for SMEs and startups to strengthen the competitive advantage of the EU and foster innovation in healthcare. Furthermore, we argue that support of SMEs and startups shall be connected to tangible financial assistance for regulatory compliance.

- **Auditing and regulatory oversight**

  The current regulatory landscape requires providers to engage with multiple regulatory bodies, each with its own set of requirements and procedures. This not only increases the complexity of regulatory compliance but also the associated costs.To simplify this process and reduce that burden, especially on SMEs and startups, we suggest the establishment of a single audit body for regulatory compliance. This body would be responsible for conducting audits for compliance with the AI Act, MDR, and EHDS, among others. It would provide a one-stop-shop for regulatory compliance, making the process more efficient and less costly for providers.

- **Anticipatory CE conformity assessment for continuous learning AI systems**

  Continuous learning AI systems pose a unique challenge to the current regulatory frameworks, as they evolve and improve over time. Although the AI Act provides wider flexibility, under the MDR, AI systems would need to undergo a new conformity assessment every time they are updated, which is impractical and costly.

We propose an "anticipatory" CE conformity assessment for continuous learning AI systems. This would involve assessing the AI system's learning algorithms and data governance practices, rather than the specific outputs of the system at a given point in time. This approach would ensure that the AI system continues to meet the necessary regulatory standards as it evolves and improves, without the need for repeated conformity assessments.

While the AI Act, MDR, and EHDS present significant opportunities for healthcare innovation in the EU, they also pose challenges, particularly for SMEs and startups. We believe that with the right support and adjustments to the regulatory frameworks, these challenges can be addressed, fostering a vibrant and diverse ecosystem of healthcare innovators in the EU.

- **Local engagement and implementation of AIA and EHDS**

  To ensure the successful implementation of the European Health Data Space (EHDS) and AI Act across all EU countries, it's crucial to support local engagement and adoption. Local associations and non-political bodies can be officially recognized and approved by the European Commission for aid with EHDS adoption locally, focusing on ensuring the sector gets the necessary tools. Ensuring acts are adopted based on their merits will be vital in realizing their benefits across the EU.

Introduction

Small and medium-sized enterprises (SMEs) and startups are the backbone of the European Union's economy, fostering innovation and job creation.[1] However, navigating the complex regulatory landscape of the EU, particularly regarding medical devices (MDR), Artificial Intelligence (AIA), and health data (EHDS), can be a significant challenge for these agile businesses operating in the area of health-care.

It is of particular essence to understand the complex nature of providing and deploying AI systems in the healthcare industry. On one hand, enhancing citizens' quality of life, including those with chronic and terminal illnesses, shall be stimulated by economic growth of market players through increased productivity and taxpayer contributions. On the other hand, easing the professional duties of medical staff by eliminating unnecessary bureaucratic burdens unrelated to their expertise, as well as reducing misdiagnoses and the wastage of resources on unnecessary tests and treatments.

Taking into account benefits and risks of using AI in healthcare, we shall also not ignore that the EU should remain as a competitive and innovative territory on a global scale.

This stance examines the compliance obligations imposed by these regulations on providers, especially SMEs and startups, exploring the specific hurdles they face and proposing potential solutions to ensure a regulatory environment that fosters both innovation and safety.

We provide a brief analysis of how these regulations, while essential for ensuring safety and health considerations, can create compliance burdens that hinder the development and commercialization of new technologies. The stance identifies specific challenges encountered by SMEs and startups, such as limited resources for compliance expertise, navigating complex legal frameworks, and adapting to evolving regulatory requirements. We also propose solutions to address these identified challenges.

By fostering a regulatory environment that supports SMEs and startups, the EU can ensure that its businesses remain at the forefront of technological innovation while upholding the highest standards of safety and ethical considerations in the development and deployment of new technologies.

[1] See e.g. EUROSTAT. Large businesses generated half of EU's net turnover. Available at: https://ec.europa.eu/eurostat/en/web/products-eurostat-news/w/ddn-20231212-1.

1. Coherent framework for AI in healthcare

The recently adopted AI Act is the first general and comprehensive regulation of AI systems in the EU. It establishes specific requirements for high-risk AI systems, bans certain AI practices and also sets forth rules for general-purpose AI models. Especially, the protection of health is recognized as one of the core subjects being protected by the AI regulation in the EU.[2]

On the other hand, MDR has a slightly different scope. It regulates the placing on the market, making available on the market or putting into service medical devices for human use and accessories for such devices in the EU.[3] But in general AIA and MDR are both product-based regulations.[4]

Specific requirements for AI systems are relevant mostly for high-risk AI systems. How to evaluate if the AI system in question is high-risk is covered in Article 6 of the AIA. The AI systems shall be classified as high-risk if:

- the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the EU harmonisation legislation listed in Annex I of the AIA, and
- the product whose safety component pursuant to the previous point is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the EU harmonisation legislation listed in Annex I of the AIA, or
- the AI system is referred to in the Annex III of the AIA.[5]

It has to be mentioned that Annex III does not contain high-risk areas relevant to healthcare. What is relevant in terms of medical devices is that these devices are regulated by the product EU harmonisation legislation. MDR is explicitly recognized in the point 11 of the Annex I. This in practice means that **medical devices using AI systems shall be considered high-risk and subject to requirements of MDR and AIA simultaneously**, including the obligation of undergoing the conformity assessment procedure.[6]

Providers of a product that contains high-risk AI systems, to which the requirements of AIA or the EU harmonisation legislation, including MDR, apply, should be flexible. In order to ensure consistency and avoid an unnecessary administrative burden or unnecessary costs,[7] operational decisions on how to ensure compliance of a product with all applicable requirements of the EU harmonisation legislation optimally are required. Because the risks

[2] AI Act, Article 1 (1).
[3] MDR, Article 1 (1).
[4] See European Commission. Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016, C/2016/1958. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0726%2802%29.
[5] AI Act, Article 6.
[6] AI Act, Recital 50 explicitly mentioning medical devices.
[7] AI Act, Recital 46.

associated with AI systems that the AI Act addresses are different from those covered by the current body of EU harmonisation acts including MDR, the provisions of AIA supplement them. Sectoral laws do not address concerns particular to AI systems including medical devices as they may pose dangers not covered by the necessary health and safety requirements outlined in the applicable EU harmonised legislation.[8]

According to both regulations, a conformity assessment procedure is required before attributing CE marking on a device or system. The content of conformity assessment differs based on the classification of a medical device and AI system due to the substantive obligations discussed above. Examination of the quality management system and the technical documentation is part of the conformity assessment.

In general, requirements for quality system management are, with certain exceptions, different. This is mainly due to the focus on the healthcare industry or AI systems in general. **Similar requirements presented in both regulations are highlighted.**

Table n. 1.
Requirements for quality management systems according to the MDR and AI Act.

MDR	AI Act
a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the devices covered by the system	**a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system**
identification of applicable general safety and performance requirements and exploration of options to address those requirements	techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system
responsibility of the management	techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system
resource management, including selection and control of suppliers and sub-contractors	examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;
product realisation	technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full or do not cover all of the relevant requirements set out in Section 2 of the AIA, the means to be used to ensure that the high-risk AI system complies with those requirements
processes for reporting of serious incidents and field safety corrective actions in the context of vigilance	**procedures related to the reporting of a serious incident**
risk management	**the risk management system**

[8] AI Act, Recital 64.

setting-up, implementation and maintenance of a post-market surveillance system	the setting up, implementation and maintenance of a post-market monitoring system
verification of the UDI assignments	systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems
handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders	
clinical evaluation	
management of corrective and preventive actions and verification of their effectiveness	
processes for monitoring and measurement of output, data analysis and product improvement	

Considering **risk management systems**, AIA provides explicit possibility to combine risk management procedures according to relevant EU law with the AI Act: *"For providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under other relevant provisions of Union law, the aspects provided in paragraphs 1 to 9 [of the Article 10 AIA] may be part of, or combined with, the risk management procedures established pursuant to that law."*[9] This in practice means that risk management according to the MDR and AIA may be combined. However, it needs to be emphasized that risks connected to AI systems might differ from risks relevant to the use of medical devices and these shall be evaluated in the specific context of AI being used in the healthcare sector.

We recommend the Commission to provide additional specification of how such a risk management system shall be approached to delineate efficient and effective processes to comply with both regulations.

Data and data governance practices are extensively covered by the AI Act, but not by MDR. This is especially relevant in the case of clinical evaluations and the provision of clinical evidence to demonstrate the safety, performance and clinical benefit of a medical device.[10] This might be challenging in the context of requirements of the AI Act to assess the availability, quantity and suitability of the data sets, their original purpose or examination in view of possible biases. Further guidance from the European Commission is essential.

While the EHDS and the AI Act aim to address distinct areas, they converge at a critical juncture – the responsible development and deployment of AI systems that leverage quality health data. Within the adopted AI Act, there is a recital that explicitly mentions the European common data spaces and how they can be utilized by actors whose activities are covered by the Act. According to the recital, providers and other actors should be able to **access and use high-quality datasets** for the development and assessment of high-risk AI systems. There is also an explicit mention of the EHDS, stating that it will "*facilitate non-discriminatory access to health data and the training of AI algorithms on those data sets, in a privacy-preserving, secure, timely, transparent and trustworthy manner*".[11]

[9] AI Act, Article 10 (9).
[10] MDR, Articles 61 and 62.
[11] AI Act, Recital 68.

The EHDS Provisional agreement also introduces a **data quality and utility label** that can be applied to datasets containing electronic health data by health data holders.[12] This label can, in our opinion, significantly aid high-risk AI system providers in fulfilling their data-related obligations mandated by Article 10 of the AI Act.

The EHDS presents a remarkable opportunity to democratize data access for R&D purposes, assuming its full and equitable implementation across EU member states. However, potential pitfalls include the emergence of a black market for high-quality data, insufficient political will at the local government level, and bureaucratic obstacles hindering easy access to EHDS nodes for startups.

The AI Act is clear on drafting **technical documentation**. *"Where a high-risk AI system related to a product covered by the Union harmonisation legislation listed in Section A of Annex I is placed on the market or put into service, a single set of technical documentation shall be drawn up containing all the information set out in paragraph 1* [of the Article 11 AIA], *as well as the information required under those legal acts."*[13] MDR is part of section A. Therefore, only a single technical documentation will suffice to comply with these requirements according to MDR and AIA.

MDR does not include specific provisions related to the use of a medical device and **human oversight**. However, these requirements are one of the cornerstones of the AI Act to emphasize the role of a human-in-the-loop. Detailed requirements in the AIA foresee the capacity of a person working with the AI system. In case of an AI system as a medical device, doctor or other responsible personnel shall:

- Understand the system's capabilities and limitations well enough to monitor its operation and identify any problems or unexpected behavior.
- Be aware of the potential for "automation bias," where people rely too heavily on the system's output, especially when it provides information or recommendations for important decisions.
- Be able to interpret the system's results correctly, considering available tools and methods.
- Have the authority to decide not to use the system altogether, or to disregard, override, or reverse its output in specific situations.
- Have the ability to intervene or even shut down the system safely if necessary.[14]

Further guidance shall be provided on how these aspects are applicable in the healthcare sector and if practitioners themselves shall adhere to these requirements.

The MDR, AI Act and EHDS bring clarity and direction for creating high-quality, innovative healthcare solutions, emphasizing patient and system safety. However, this clarity comes with its set of challenges for providers in general, particularly for SMEs and startups. The substantial cost associated with regulatory compliance, such as establishing a quality

[12] EHDS Provisional agreement, Article 56.
[13] AI Act, Article 11 (2).
[14] AI Act, Article 14 (4).

management system and acquiring CE marking, creates a significant obstacle for smaller entities. This cost is in addition to the product development expense. The minimum viable product often falls short due to quality requirements that are commonplace in other sectors. Furthermore, the venture capital landscape, which often seeks revenue-generating, market-ready products before investment, doesn't align well with the medtech sector's regulatory prerequisites for product implementation.

The regulator may need to dive further into the per-project budget allocated, to ensure that innovative companies can obtain sufficient funds for translating their research into applications and for taking them to industry without having to dedicate large amounts of time and resources in multiple funding application processes.

On top of them, the discrepancy among Member States which are mostly receiving EU funds for innovation and R&D and those who are historically having very low percentage of fund allocation shall be addressed.

2. Responsibility for innovation in healthcare

Europe is on its mission towards healthcare innovation in the region, but what are our true goals when innovating the healthcare sector? What do we want to achieve, as a society and as an economy?

Currently, the innovation landscape is dominated by large corporations, thanks to their financial capabilities and vast resources. These resources may be decisive,for instance, to manage regulatory requirements such as Quality Management Systems (QMS), CE marking, and other regulatory compliance costs, not to mention the access to extensive datasets.

According to Study Report on eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the European Union[15], in countries where the number of patent applications is significantly higher, certain companies are causing the distinction. For instance, in Germany, approximately 96% of total AI in healthcare patents are owned by Siemens Healthcare GMBH, where only 4% of the patents are owned by other companies. Likewise, in the Netherlands, approximately 92% of the total patents are owned by Koninklijke Philips and only 8% are owned by other companies. It is a deciding factor of commercialisation potential and long-term viability of companies working on the development of AI and other innovative solutions in the sector of healthcare in the EU.

However, the financial advantage of big corporations in the healthcare sector does not necessarily translate into better innovation outcomes compared to what smaller entities like SMEs and startups could achieve and propose to the market and industry.[16]

As per OECD Report, we can see that large corporations can engage in monopolistic practices, reducing competition and innovation. Their significant market power allows them to set high entry barriers for new players, which can prevent innovative startups from entering the market.[17]

Investing in market diversification by supporting SMEs and startups is vital for fostering a competitive and innovative MedTech ecosystem. Diversification helps ensure that no single entity has undue control over the market, which can lead to more balanced and widespread technological advancements.

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[15] Publication office of the European Union. Study on eHealth, interoperability of health data and artificial intelligence for health and care in the European Union. 2021. Available at: https://op.europa.eu/en/publication-detail/-/publication/fb8d8ec2-55a0-11ed-92ed-01aa75ed71a1.

[16] OECD (2019). "Competition and Innovation: A Theoretical Perspective". OECD Report.
McKinsey & Company (2021). "Innovation in Healthcare: Perspectives from Leading Companies".
European Commission (2020). "Study on eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the EU". European Commission Report.

[17] OECD Report, 2019. Competition and Innovation: A Theoretical Perspective

Thus, we must ponder: What aims are we striving to fulfill by nurturing innovation in healthcare? And how should emerging regulations like the EHDS, AI Act, and MDR support these goals?

The AI Act provides specific exemptions to ease compliance for SMEs and startups. Specifically, it allows for derogations from certain requirements. This is relevant mainly in the case of drafting technical documentation pursuant to Article 11.

The question remains if such an approach is sufficient. The rationale is that smaller entities often have quicker R&D cycles and concept validations. This is due to leaner communication channels, the absence of internal politics found in larger organizations, and less cumbersome procedural frameworks. These factors could otherwise delay innovation and increase its cost. This scenario underscores why large corporations might establish legally separate but closely aligned smaller entities to tackle these challenges. Nevertheless, it is critical to view these entities through a realistic lens, recognising their inherent ties to parent corporations.

Furthermore, the AI Act foresees a specific role of SMEs, including startups, in the case of **AI regulatory sandboxes**. The Act incorporates regulatory sandboxes as a mechanism to balance fostering innovation in AI with ensuring public safety. These sandboxes will function as controlled environments where businesses, particularly SMEs, can experiment with and test their AI products and services under the supervision of regulatory authorities.[18] AI systems as medical devices are specifically recognized as an appropriate candidate for their use.[19] In practice, this should encourage startups, including med-tech startups, to apply for the opportunity to test their devices in the AI regulatory sandboxes.

Therefore we propose that SMEs shall have priority access and the EU member states shall comply with this obligation.[20] Furthermore, we argue that support of SMEs and startups shall be connected to tangible financial assistance for regulatory compliance. With the specific role of SMEs and startups acknowledged by the AI Act, financial support through tailored grant schemes for businesses testing AI systems in regulatory sandboxes may be provided. Tangible financial support for regulatory compliance costs is crucial for further innovation incentives in the healthcare sector under MDR and AIA, namely, in MedTech, as well as in market diversification, in addition to existing sandbox initiatives. However, such an approach shall be non-discriminate and subject to oversight mechanisms.

[18] See AI Act, Article 57.
[19] AI Act, Recital 147.
[20] AI Act, Article 62 (1) (a).

3. Auditing and regulatory oversight

The AI Act establishes robust oversight structures on the EU and national levels. In general, the **European Commission** oversees the overall implementation and enforcement of the AIA. This includes establishing an **EU Artificial Intelligence Board** composed of representatives from member states and setting up a central **EU AI Office** within the Commission to provide administrative and technical support. Each member state appoints a competent authority responsible for overseeing the application of the AIA within their territory, supervising the market for compliance with the AIA or investigating and addressing potential breaches. Furthermore, notified bodies shall be designated to verify the conformity of high-risk AI systems in accordance with the conformity assessment procedures.[21]

However, MDR similarly requires a similar process with a notified body. Such a situation is foreseen by Article 43 (3) of the AI Act: "For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. … For the purposes of that assessment, **notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Section 2**, provided that the compliance of those notified bodies with requirements laid down in Article 31(4), (10) and (11) has been assessed in the context of the notification procedure under those legal acts."

Therefore, it may be presumed that the verification of conformity with the MDR and the AI Act can be conducted **by a single notified body** who will verify all applicable requirements. Simplifying the audit process through a single regulatory body could alleviate some bureaucratic challenges, especially when faced by SMEs and startups. That means, that when a medical device has to undergo the audit under AI Act and MDR, and potentially, comply with EHDS requirements on data interoperability, the one single audit body shall be assigned. However, as the cost for conformity assessment for both, AIA and MDR compliance, might be increased due to unification of AIA and MDR audit by one notified body, the whole financial burden shall not be borne by the SMEs and startups due to lack of personal capacities of notified bodies to assess AI systems. Such an approach would significantly harm the innovative potential of many market players. **Therefore, financial support can be provided to the SMEs and startups, based on its financial situation and projected potential of the innovation.**

Additionally, MDR requires a new conformity assessment to be conducted in case of significant changes to the Software as a Medical Device (SamD), with or without an AI component in it, whereas, when an SaMD has as its component a high-risk AI system, a new conformity assessment is required as well under AIA. Although the threshold for substantial modification according to the AI Act may not be high, whereas this is not the case of MDR.[22] **These approaches shall be aligned.**

[21] AI Act, Article 34.
[22] See AI Act, Article 3 (23) and Recital 128; MDR Annex IX and X.

We recommend adopting a market access process to the realities of innovative solutions development, such as AI, software and other applications which are based on fast changing components. Transferring the two regulatory approaches, AIA and MDR, a so-called "anticipatory CE conformity assessment"[23] for continuous learning AI systems in medicine could be introduced in Europe as part of the current regulatory framework. The anticipatory CE conformity assessment would be characterized by the fact that it is carried out in advance, including intended changes during putting into service. For subsequent changes that are within the scope of the anticipated, further conformity assessment could be waived. Changes that cannot be foreseen and cannot necessarily be anticipated would then have to be subjected to a new conformity assessment procedure and subsequently certified.

[23] Market access of continuous learning AI systems in medicine, VDE DGBMT: https://www.vde.com/resource/blob/2270412/118ee15da5cc1e03dcce229950bc109c/market-access-of-continuous-learning-ai-systems-in-medicine-data.pdf

4. Local engagement when implementation is not the state's priority

Local engagement and implementation of regulatory frameworks is another important issue in the context of SMEs and startups. How can the EU facilitate the effective local implementation of EHDS and the AI Act in countries where these initiatives may not currently be prioritized in local sectoral strategies on a governmental level?

After several discussions with EU Commission representatives, it's clear that each country has an officially appointed person from the government to lead the implementation of new legislative acts, specifically the EHDS.

We urge EU representatives to adopt a more realistic approach. Otherwise, the divide between EU countries will only widen. Countries like Finland and France may thrive due to the benefits of implementing the AIA and EHDS. Meanwhile, others might merely acknowledge the acts' implementation on paper.

It's easy to foresee that in such a scenario, the primary mission of these acts could be undermined, as participation in rich healthcare data lakes may not materialize as some Member States would have acts being implemented only on paper and not in practice.

To support the implementation of the EHDS Act, the establishment of the TEHDAS[24] initiative and later the involvement of SITRA[25], an independent non-governmental foundation, was intended to assist Member States in integrating the EHDS into their local legislative frameworks. However, the current approach mandates that only approved by local government representatives from Member States can lead the TEHDAS/SITRA project participation. This restriction has led to varying levels of engagement, as some representatives are unable to prioritize the EHDS agenda due to other priorities.

The success of EU policies, such as the EHDS, heavily depends on effective national implementation. Studies indicate that involving non-governmental organizations (NGOs) and other non-political entities can enhance the implementation process. For example, in Hungary and Croatia, dedicated government offices and councils for NGO cooperation have shown positive results in policy implementation.[26]

Reports from TEHDAS and SITRA reveal that the participation and engagement levels of Member States are inconsistent, leading to a slower and less effective implementation of the EHDS framework. Some countries are active and progressing, others are lagging behind, causing a disparity in the overall implementation of the EHDS across Europe.

[24] https://tehdas.eu/tehdas1/
[25] https://www.sitra.fi/en/
[26] INCL Report on Good Governance. Available at: https://www.icnl.org/resources/research/ijnl/a-comparative-analysis-of-european-policies-and-practices-of-ngo-government-cooperation-2.

The EIT Health Report, “Implementing European Health Data Space Across Europe” also highlights that several Member States have not made substantial progress in digital health advancements due to low engagement levels as well as varying infrastructure readiness.[27]

This low engagement undermines the collective benefits and advancements in healthcare innovation that the EHDS aims to achieve. The core philosophy of the EHDS framework is based on the union of data sharing among all Member States, not just a few active ones. Consequently, the lack of engagement from certain countries results in an obvious loss in healthcare advancements and innovation across Europe, as the framework's success relies on broad and consistent participation.

By ensuring that the implementation support for the EHDS Act is more inclusive and extends beyond government representatives, we can enhance engagement levels, promote broader participation, and realize the full potential of the EHDS framework to drive healthcare innovation and advancements across Europe.

According to the European Commission White Paper[28], the Union must renew the Community method by following a less top-down approach and complementing the EU's policy tools more effectively with non-legislative instruments.

For instance, **local associations can be given a mandate to foster, and potentially, push, the innovative acts and policies implementation into the local regulatory frameworks as well as into the practice.** Such an approach would be also in line with the obligation for the EU member states to organise specific awareness raising and training activities on the application of newly adopted regulations tailored to the needs of SMEs including startups, deployers and, as appropriate, local public authorities, utilise existing dedicated channels and facilitate the participation of SMEs and other relevant stakeholders in the standardisation development process.[29]

We recommend establishing a mechanism where local associations and non-political bodies can be officially recognized and approved by the European Commission directly, for aid with EHDS adoption locally, focusing on ensuring the sector gets the tools entitled in order to adopt the novel acts adoption on their merits, equally across Member States.

[27] Implementing EHDS Across Europe, EIC Health Report. Available at: https://eithealth.eu/wp-content/uploads/2024/04/EIT_Health_ThinkTank_Implementing_the_EHDS_across_Europe_23.04.24.pdf.
[28] European Governance. Available at: https://ec.europa.eu/commission/presscorner/detail/en/DOC_01_10.
[29] See AI Act, Article 62.

Conclusion

By adhering to principles discussed above and addressing the outlined challenges, we believe that we can foster a healthcare innovation environment that truly benefits society, encouraging a diverse range of contributors to participate in shaping the future of healthcare.

The potential of AI, as well as overall technological advancement in the sector, to revolutionize healthcare is undeniable. However, harnessing this power responsibly requires a collaborative effort. We invite all stakeholders – healthcare providers, researchers, industry leaders, policymakers, and patient advocates – to join us in our effort to foster safe healthcare innovation for everyone.

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About us

AI:Dental (AID) is a startup working on educational and clinical solutions in dentistry by providing high quality Artificial Intelligence for students training, clinical diagnostics and treatment planning in dentistry. AI:Dental aims to democratise dental health through AI by enhancing precision, affordability and accessibility in education and patient care. For more information, please, visit: https://www.aidental.ai/.

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