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The EU AI Act's Impacts on Digital Health

Regulatory Challenges and Future Directions for Medical and Healthcare Innovation

https://doi.org/10.1515/cdbme-2024-2046

Abstract: The European Artificial Intelligence Act (AI Act) has profound implications for technological innovation in the medical and health care sector, transcending the boundaries of existing legal frameworks such as the Medical Device Regulation (MDR) and the General Data Protection Regulation (GDPR). This paper examines basic regulatory choices of the AI Act relevant for the field of digital health innovations by contextualizing its main goals, key obligations, and addressed actors. In light of these considerations, we present a scoping literature review that identifies potential regulatory challenges for stakeholders engaged in research, innovation and healthcare. Building on this, we point to concepts and methodologies to overcome such challenges in a way fostering innovation while realizing key constitutional and societal interests at the same time.

Keywords: EU Artificial Intelligence Act, Regulation, Innovation, Digital health, Healthcare innovation, Regulatory challenges

1 AI and Health: Between Innovation and Regulation

The digital health sector is currently navigating a complex landscape characterized by two seemingly contradictory trends: the imperative for rapid innovation across all facets of healthcare, and the necessity for comprehensive regulatory oversight. As emerging technologies, particularly Artificial Intelligence (AI), drive unprecedented advancements in healthcare delivery and outcomes, there is a growing consensus that this technological transformation must be guided by societal considerations from its inception.

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AI, a transformative force in contemporary healthcare, holds immense potential that permeates both popular discourse and academic literature. As of 2022, AI in healthcare commands the largest market share among AI applications [1], a testament to its growing influence. Its impact is far-reaching, with applications in diverse areas such as image recognition in radiology or gastroenterology, predicting guide-RNA activity in CRISPR-based gene-editing, and monitoring systems for intraoperative hypotension [2]. The innovation facilitated by AI spans the entire healthcare ecosystem, from drug discovery and medication management to the creation of virtual clinical environments, painting a promising picture of the future of healthcare [3].

Healthcare professionals, researchers, and patients alike anticipate myriad benefits from AI integration, including faster and more secure diagnosis [3], a better patient journey, cost reduction, and new treatment options. However, the transformative potential of AI in healthcare is accompanied by a unique set of challenges. These include common concerns associated with data-intensive technologies, such as cybersecurity, privacy, transparency, self-determination, safety, diversity, equality, fairness and sector-specific issues, such as the need for rigorous clinical trials and the paramount importance of maintaining patient trust [4].

In response to these challenges and opportunities, the European Union has enacted the Artificial Intelligence Act (AI Act), which is scheduled to enter into force on 12 July 2024. This legislation is designed to complement the existing Medical Device Regulation (MDR), creating a comprehensive regulatory framework for AI-based medical technologies. The AI Act's stated objectives are to promote human-centric and trustworthy AI while ensuring a high level of protection of health, safety, and fundamental rights against the harmful effects of AI systems. The AI Act adopts a risk-based approach to regulation, categorizing AI systems mainly into the following categories:

1. AI systems that pose unacceptable risks are prohibited;
2. High-risk AI systems are subject to detailed regulation and
3. Other AI systems remain largely unregulated but are subject to voluntary codes of conduct.

Given the critical nature of healthcare applications, most AI-based innovations in the medical field, particularly those

classified as medical devices under the MDR, will likely fall into the high-risk category [5,6]. Consequently, these systems will be required to demonstrate compliance with the stringent requirements outlined in the AI Act before they can be introduced to the market.

This regulatory framework represents a significant development in the governance of AI in healthcare, aiming to strike a balance between fostering innovation and safeguarding core constitutional values such as human rights. The following analysis will explore the implications of the AI Act for the digital health sector, examining its potential impact on innovation, patient care, and the broader healthcare ecosystem.

2 The EU AI Act in the Health Space

2.1 General Regulatory Choices

The AI Act represents a transformative shift in the regulatory landscape for digital health, transcending the boundaries of existing frameworks such as the MDR and the GDPR [7]. This groundbreaking legislation exemplifies a holistic approach to regulating AI systems, with profound implications for technological innovations in the medical and health sectors. A comparative analysis between the AI Act and other instruments unveils four pivotal trends.

Firstly, the AI Act expands the scope of regulatory objectives beyond the traditional realm of product safety regulations. While sharing the MDR's foundational focus on performance and safety [8], the AI Act's ambitions encompass according to Art. 1 (1) “enhancing the internal market, promoting human-centric and trustworthy AI adoption, ensuring robust protection of health, safety, fundamental rights, democratic principles, the rule of law, and environmental protection, as well as fostering innovation in AI technologies”. This multifaceted approach is evident in the explicit goal of the regulation, which includes innovation and the uptake of technologies. Furthermore, the regulatory purview is extended to encompass fundamental rights. In the field of health, this will necessitate the consideration of rights like patient autonomy, equality and non-discrimination at the stage of conformity assessment of these technologies. Therefore, the AI Act seeks to balance the seemingly conflicting goals of technological advancement and rights protection under a single legislative umbrella.

Secondly, the AI Act introduces an enhanced regulatory framework with a more comprehensive set of obligations than previous digital health regulations. For high-risk AI systems, these include obligations to ensure its goals through extensive data governance measures, requirements for accuracy and robustness, and mandatory implementation of risk management systems to identify, evaluate, and mitigate risks to fundamental rights and other concerns. Concurrently, the Act promotes innovation through a mandated establishment of regulatory sandboxes by Member States and provisions for real-world testing. The AI Act even lifts data protection constraints inter alia for health-focused applications. The AI Office, as the primary regulatory body on the European stage, fulfills a dual mandate: it oversees compliance and enforcement issues while simultaneously coordinating and facilitating innovation measures for research and development in digital health [8,9].

Thirdly, the AI Act's scope encompasses a broader range of actors in the AI ecosystem, extending beyond the traditional boundaries of technology regulation, which mainly focused on producers. New obligations apply e.g. to distributors and professional deployers of AI systems. This shift will have serious repercussions for actors in healthcare, including healthcare organizations and medical professionals. Whereas previously such actors mainly had to adhere to the instructions of use, stakeholders are required to employ personnel with requisite AI literacy, communicate potential risks to regulators and relevant actors, and maintain ongoing risk assessments. This expanded scope represents a departure from traditional technology regulation, directly addressing stakeholders previously outside the regulatory ambit.

Finally, the AI Act adopts a flexible, design-based regulatory approach, eschewing rigid prescriptions in favor of adaptable principles [10]. This “by-design-methodology” necessitates the translation of general objectives, such as transparency and human oversight, into sector-specific requirements, the development of a dynamic knowledge ecosystem to provide guidance in specialized domains, and the continuous evolution of regulatory standards in response to technological advancements and emerging challenges.

The AI Act's ambitious expansion of regulatory scope, encompassing broader goals, novel instruments, and a wider range of actors, coupled with its design-based approach, has inevitably engendered specific concerns and challenges within the digital health sector. In order to scope hurdles to the AI Act's effective implementation and to mitigate any unintended consequences in this critical field, we have collected and synthesized challenges flagged in the literature.

2.2 Regulatory Challenges for Innovation

A review of scholarly publications about the AI Act was conducted with a focus on medical and health innovation. Only publications whose points of critique in relation to previous versions of the draft have not been rendered moot by the final version were included. This resulted in the following four main areas of concern.

2.2.1 Compatibility – (Mis)alignments with Existing Legal Frameworks?

The AI Act does not stand in isolation but is embedded into the broader European Regulatory Framework, which raises challenges related to the interplay and compatibility of different legal acts. As a horizontal regulation targeting AI systems, the AI Act is designed to be closely interlinked with sector-specific product regulations like the MDR or data protection regulations like the GDPR. Such links necessitate the simultaneous and complementary application of various laws, which is seen as a risk factor for misalignments and norm conflicts, potentially resulting in critical areas, such as medical AI, "doubly, ineffectively, or even conflictingly regulated" [11].

For project teams, these interrelations are deemed to increase complexity, ultimately demanding considerable personal, temporal, and financial resources to ensure compliance [11,12]. Where processes and requirements – such as conformity assessment procedures, risk management obligations, or post-market monitoring activities – are mandated by different legal acts, developers may leverage synergies by integrating the necessary information and documentation into a single, combined format (Art. 8 (2) AI Act). However, innovators raise practical challenges of resolving conflicts when different regulations use inconsistent terminologies, follow varying timelines, or assign responsibilities to different stakeholders [13,14].

Such challenges are particularly highlighted regarding conformity assessments, where duplications may occur when AI systems are integrated into products governed by sector-specific regulations like the MDR and market entrance is planned in different timelines or with multiple stakeholders involved along the value chain [13]. Similar issues are anticipated with regard to risk management obligations and impact assessments, which exemplarily are also required by GDPR but there fall into the responsibility of controller of the data, which is in effect the deployer and not the developer, who is mainly addressed in the AI Act [13,14]. Lastly, in the context of post-market monitoring, there are concerns about conflicts resulting from diverging competencies and interferences of market surveillance authorities under different regulations [5].

2.2.2 Openness – A Gateway for Legal Uncertainties and Liability Risks?

Beyond potential conflicts arising from the interaction with other legal sources, commentators expect further challenges in interpreting the AI Act itself. Resulting from AI´s nature as general-purpose technology, AI regulation necessitates flexible and value-based regulatory approaches. However, the openness of the AI Act may pose challenges to project teams when wording leaves considerable discretion for varying interpretations, ambiguous formulations are used or definitions and sector-specific guidelines are not available yet [13,15].

For innovators, such ambiguities and legal uncertainties may manifest in significant liability risks, which, particularly for SMEs, are considered to impose burdens on innovation [12,16]. These risks are expected to be fuelled by the AI Act´s heavy reliance on self-certification by the developers of AI systems [14,17]. Although third-party conformity assessment is comparably prevalent for medical AI-based technologies, providers still enjoy a broad margin of discretion regarding "(i) whether the used software is an AI system; (ii) whether the system may likely cause harm; and (iii) how to comply with the mandatory requirements of Title III, Chapter 2 AI Act, which are not laid down in detail in the proposal" [13]. Considerable uncertainties are already highlighted with regard to the definition of "AI systems" and "high-risk AI systems", the two central criteria to determine the scope and applicability of the AI Act. [11,13]. Similar concerns are raised with a view to open terminologies like "transparency", "interpretability" or "explainability" [13]. Some provisions, such as Art. 10 (3) AI Act, which requires data sets to be "relevant, sufficiently representative, and to the best extent possible, free of errors and complete", are even criticized as "utopian" [14] and "practically impossible" [18] to fulfil.

2.2.3 Over-regulation – A Burden to Innovation?

Rules and requirements that force organizations to allocate significant resources to compliance may hamper innovation in disproportionate way. In a competitive environment, such over-regulation might hinder the development of such technologies in Europe.

Given the AI Act´s broad scope and applicability to AI systems in the medical field, commentators expect increased compliance costs [11], potentially resulting in reduced competitiveness and deceleration of growth. These costs are said to disproportionately affect SMEs, which are crucial drivers of the innovation ecosystem, yet face disadvantages compared to well-equipped larger players [12]. Some claim that this will result in many regulatory burdens without improving the overall effects of AI in the health and medical sector. [19].

Beyond challenges for individual organizations, the implications of AI regulation may affect the EU innovation ecosystem as a whole. The previously established European approach, considered relatively open and liberal in comparison to other jurisdiction like in the US, fostered the EU´s reputation as an innovation hub for medical technologies [20]. However, at the same time, the EU is considered to have fallen behind the US and China in the race for AI development [1].

2.2.4 Human Factors – Insufficient Safeguards to Protect Fundamental Rights?

Despite the wide-spread fear of over-regulation across the innovation ecosystem, the AI Act is simultaneously criticized for being too narrowly scoped to effectively protect the rights and freedoms of those exposed to and affected by technologies [11,17,21]. Due to its nature as a product safety regulation, the AI Act focuses on the economic actors developing AI systems rather than on the 'end users' [21]. Even though affected individuals are equipped with selective rights to remedies (Art. 85 f. AI Act), their status is considered comparably weak [11].

In the medical and health field, this position of individuals is perceived as contradictory to innovators' obligation to protect patients' rights by responding to existing sensitivities and vulnerabilities accordingly and ultimately designing human-centered and trustworthy technologies [22]. During the AI development phase, stakeholder participation is not a mandatory requirement (Art. 95 AI Act). With a view to the deployment of AI in the medical and health sectors, the AI Act is evaluated as insufficient to promote trust in various relationships. While requirements concerning human oversight and transparency provide a first step in the right direction, further measures like education on AI for medical practitioners, robust educated consent rules and the possibility of requesting a human in the loop have been proposed to create trust [23] beyond what Arts. 4 and 14 prescribe.

3 Future Directions

The EU AI Act introduces both significant opportunities and challenges for the digitization of healthcare. On the one hand, it aims to promote trustworthy and human-centric AI, ensuring robust protection of health, safety, and fundamental rights. On the other hand, it also brings new regulatory complexities and potential hurdles for AI innovation in the medical and health field, which need to be carefully navigated. These challenges are not unique to the health sector. Across domains, policymakers and innovators must grapple with questions how to achieve critical constitutional principles and goals while still enabling and encouraging technological progress that also furthers such constitutional precepts such as the human right to health and well-being. Sector-specific standards, guidelines, and best practices can help translate the AI Act's broad principles into actionable requirements for healthcare AI development.

However, optimizing the performance of such a comprehensive regulatory framework within a complex innovation ecosystem is also an interdisciplinary research task that needs to push beyond ordinary mechanisms like standardisation. Existing discourses around human-centered engineering, responsible research and innovation [24], integrated research [25], and legal design [26] offer valuable models for understanding and improving the balance between innovation and regulation. Nevertheless, even these approaches must adapt to the novel challenges of a transformative wave of legislation like the AI Act, which simultaneously present challenges and opportunities for the ecosystem. As the AI Act reshapes the regulatory landscape, stakeholders across the healthcare research and development pipeline should actively contribute to ongoing research efforts. By surfacing tensions, highlighting potential adverse effects, and proposing constructive solutions, the digital health community can help ensure effective, context-appropriate implementation of the AI Act, ultimately advancing both innovation and the public good. Continued interdisciplinary collaboration will be vital to realizing the immense potential of AI in healthcare while proactively mitigating risks and pitfalls along the way.

Author Statement

Research funding: This research was financially supported by the German Federal Ministry of Education and Research (BMBF) within the "Cluster Integrierte Forschung", Project "RechTech", funded between 2021 and 2024.

Conflict of interest: Authors state no conflict of interest.

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