# Between Hard and Soft Law in AI and Healthcare

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***Abstract***

*The present article scrutinises the potential benefits that can be gained from progress in artificial intelligence for revolutionising public health in terms of efficiency, accessibility, and economic sustainability. The primary objective of the study is to examine how artificial intelligence can enhance public health systems while analysing the regulatory challenges associated with its fast development. To achieve these objectives, the study employs a qualitative methodological approach, including a comparative analysis of international soft law instruments, policy documents, and institutional guidelines developed by major global actors such as the UN, UNESCO and others. International soft law in relation to artificial intelligence usually refers to initiatives at the UN, OECD, UNESCO, G20, ISO/IEC, etc. The results of the study indicate that while soft law provides flexibility, adaptability, and rapid responsiveness to technological change, it also suffers from limitations such as a lack of enforceability, accountability gaps, and uneven implementation across jurisdictions. The implications of the study highlight the need for policymakers to integrate soft law principles into formal legal systems, foster international cooperation, and ensure that ethical considerations, transparency, and accountability remain central in the deployment of AI technologies in public health.*

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## 1. Introduction

Just a few years ago, scientists around the world were discussing the future of artificial intelligence (AI), while today we can say that the phenomenon of AI has already become a tangible reality, increasingly penetrating various spheres of public life. In addressing the complex challenges of global health[3], artificial intelligence is

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[3] Teodora Kiryakova-Dineva and Ruska Bozhkova, "Public Health Risk Environment for Bulgarian SMEs (Guest Houses and Family Hotels) in the COVID-19 Pandemic," in *Risk, Crisis, and Disaster Management in Small and Medium-Sized Tourism Enterprises*, ed. Diego R. Toubes and Noelia Araújo-Vila (IGI Global, 2021), 77–102, https://doi.org/10.4018/978-1-7998-6996-2.ch004. For the discussion of AI in healthcare,

emerging not just as a tool, but as a transformative force that is changing a plethora of areas, including the provision of healthcare.

At this time, as the collection, storage and processing of data is becoming cheaper, most companies are trying to implement platforms in their traditional activities. The most famous of these attempts come under the title of artificial intelligence, the Internet of Things (IoT), Big Data and Industry 4.0[4]. In the management of platform business models, the processing and rearrangement of information flows is usually carried out by a person who is associated with artificial intelligence.

In this sense, the current task facing lawyers is to develop and test the legal module of cyberspace[5], composed of a number of different concepts: cyber law, the so-called platform law and internet law[6]. The vast number of international digital transactions are carried out by clients of platform companies, while legal science tries to make sense of the legal transition triggered by the new technological paradigm[7].

Advances in artificial intelligence technologies provide unprecedented opportunities to revolutionise public health[8], making it more efficient, accessible and economically sustainable. By promoting the integration of artificial intelligence through appropriate policies, we could improve care, legal access, and ensure that new technologies, treatments and medicines[9] benefit society.

Artificial intelligence could also transform the pharmaceutical sector throughout the entire drug life cycle, from drug discovery and development to pharmacokinetics[10], evaluation, manufacturing, marketing, approval and

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see European Commission, "Artificial Intelligence in Healthcare," accessed October 8, 2026, https://health.ec.europa.eu/ehealth-digital-health-and-care/artificial-intelligence-healthcare_en.

[4] Klaus Schwab, *Четвъртата индустриална революция* [The fourth industrial revolution], Bulgarian reprint (Hermes, 2021), 58, https://ikhermes.bg/blog/blog/ochakvajte-chetvrtata-yndustryalna-revoliucyia-otnovo-v-knyzarnycyte. See also Nick Srnicek, *Капитализм платформ* [Platform capitalism], trans. Maria Dobryakova (Higher School of Economics Publishing House, 2019), https://doi.org/10.17323/978-5-7598-1786-4.

[5] Gabriela Belova et al., "COVID-19, Infodemic and Cyber Security," *Environment. Technology. Resources. Proceedings of the International Scientific and Practical Conference* 5 (2025): 57–61, https://doi.org/10.17770/etr2025vol5.8479.

[6] S. Yu. Kashkin and A. V. Altoukhov, "В поисках концепции правового регулирования искусственного интеллекта: платформенные правовые модели" [The concept of legal regulation of artificial intelligence: Platform legal models], *Courier of Kutafin Moscow State Law University (MSAL)*, no. 4 (2020): 30, https://doi.org/10.17803/2311-5998.2020.68.4.026-040.

[7] Kashkin and Altoukhov, "В поисках концепции," 30.

[8] On AI in contemporary healthcare, see European Commission, "Artificial Intelligence in Healthcare."

[9] Gabriela Belova, "Online Sales of Medicinal Products in the CJEU Case-Law—Between the Free Movement of Goods and Public Health Protection," in *Building an Adapted Business Law*, ed. Sónia de Carvalho and Anton Petričević (ADJURIS, 2022), 271–84, https://adjuris.ro/books/babl/Building%20an%20Adapted%20Business%20Law.pdf.

[10] Pharmacokinetics is a branch of pharmacology that quantitatively studies the processes of movement and fate of drugs in the body. It describes the four main processes, known as ADME: Absorption, Distribution, Metabolism, and Excretion, determining the concentration of the drug over time. See Sean Grogan and Charles V. Preuss, "Pharmacokinetics," in *StatPearls* (StatPearls Publishing), last updated July 30, 2023, https://www.ncbi.nlm.nih.gov/sites/books/NBK557744/. On AI across the medicine life cycle, see

pharmacovigilance.

## 2. Artificial Intelligence and Soft Law

The governance of artificial intelligence has emerged as one of the most serious challenges facing contemporary international law, requiring a careful balance[11] between innovation, human rights and societal impact. The rapid development and deployment of artificial intelligence technologies in various sectors of industry and commerce, ranging from healthcare to finance and from education to the judiciary, has outpaced the creation of binding legal frameworks[12] capable of regulating their widespread adoption and use. In this context, so-called soft law takes on a central role, providing guidelines, principles and standards that, although legally non-binding, have significant normative influence and are likely to contribute to shaping future regulation. Soft law in the field of artificial intelligence usually includes international initiatives under the auspices of the United Nations, the Organisation for Economic Co-operation and Development (OECD), UNESCO, the G20, ISO/IEC[13] standards and other global multi-stakeholder frameworks. This publication explores the nature, usefulness and limitations of so-called soft law in the governance of artificial intelligence, including its interaction with emerging hard law instruments and the continuing need for a hybrid approach that combines adaptability with applicability[14] by many researchers.

Soft law can be defined as a set of non-binding norms, principles and guidelines intended to influence the behavior of certain entities, but which lack direct legal enforcement. In practice, soft law is a relatively widespread instrument of international public law since the end of the Second World War. In terms of the governance of artificial intelligence, soft law instruments have proven to be particularly useful due to

European Commission, "Artificial Intelligence in Healthcare."

[11] Gabriela Belova and Albena Ivanova, "EU Institutions: Revisiting Gender Balance and Women's Empowerment," *Laws* 12, no. 1 (2023): 3, https://doi.org/10.3390/laws12010003.

[12] Nikolay Marin and Diana Kovatcheva, "Legal Problems and Decisions in the Cooperation between National Ombudsmen in South-East Europe," *Balkanistic Forum*, no. 2 (2019): 295–317 (in Bulgarian), https://www.ceeol.com/search/article-detail?id=764870.

[13] ISO/IEC standards are international norms for information technology (IT), cybersecurity and electrical engineering, developed jointly by the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC). They provide frameworks for security, service management and data protection, with the most well-known examples including ISO/IEC 27001 (information security) and ISO/IEC 20000 (IT services). See International Organization for Standardization and International Electrotechnical Commission, *Information Security, Cybersecurity and Privacy Protection—Information Security Management Systems—Requirements*, ISO/IEC 27001:2022 (ISO, 2022), https://www.iso.org/standard/27001. See also International Organization for Standardization and International Electrotechnical Commission, *Information Technology—Service Management—Part 1: Service Management System Requirements*, ISO/IEC 20000-1:2018 (ISO, 2018), https://www.iso.org/standard/70636.html.

[14] Kashkin and Altoukhov, "В поисках концепции," 34–35. For the overview of soft law in AI governance, see Marco Pasqua, "Bridging Soft and Hard Law in AI Governance," British Institute of International and Comparative Law, December 17, 2025, https://www.biicl.org/blog/121/bridging-soft-and-hard-law-in-ai-governance.

their flexibility and responsiveness to (technological) innovations[15]. Their creation typically stems from international organizations, multi-stakeholder initiatives or industry-led consortia that seek to provide guidance in areas where a binding regulatory framework is lacking or underdeveloped. Some of the most typical and frequently cited examples include: The OECD Principles on Artificial Intelligence, adopted in 2019 and updated in 2024 after extensive consultations among policymakers, academia and industry leaders; The UNESCO Recommendation on the Ethics of Artificial Intelligence, adopted on 23 November 2021 within the framework of the United Nations, reflecting broad international cooperation to set ethical standards for the development and deployment of artificial intelligence[16]. In each of these frameworks, "soft law" provides a mechanism to set expectations, guide behaviour and encourage accountability without the delays and rigidity associated with the so-called hard law. None of the "soft law" instruments is anchored by legal sanctions, but they all shape behaviour through consensus and shared commitment(s).

The normative status of soft law instruments is complex and highly context-dependent. Although they are not binding, they carry significant weight in shaping regulatory approaches and influencing policy development at national, European and international levels. For example, the OECD Principles on Artificial Intelligence, adopted in May 2019, have indeed established themselves as the main framework of the so-called soft law for the global governance of AI, having been endorsed by over 47 countries (including all OECD member states) as well as by G20 countries[17]. These principles have a profound, tangible impact on the way AI is regulated around the world, serving as a kind of "DNA" for national AI strategies and policies[18].

Despite these advantages, the main drawback of so-called soft law lies in its implementation options. Compliance is usually voluntary and relies on reputational incentives, public scrutiny or internal corporate governance. For example, the UNESCO Recommendation on the Ethics of Artificial Intelligence requires Member States to submit periodic reports on implementation, promoting accountability without legal sanctions and illustrating how soft law can pave the way for enforceable rules while respecting the autonomy of stakeholders[19]. In situations where soft law exists without an accompanying hard law, implementation gaps can be significant, especially in

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[15] Pasqua, "Bridging Soft and Hard Law."

[16] UNESCO, *Recommendation on the Ethics of Artificial Intelligence*, adopted November 23, 2021, https://www.unesco.org/en/legal-affairs/recommendation-ethics-artificial-intelligence. See also Pasqua, "Bridging Soft and Hard Law."

[17] The G20 was established in 1999 as a forum of finance ministers and central bank governors; leaders have met annually since 2008. Its membership comprises 19 countries, the European Union and the African Union. The EU is represented jointly by the Presidents of the European Council and the European Commission. See Australian Government, Department of Foreign Affairs and Trade, "The G20," accessed October 8, 2026, https://www.dfat.gov.au/trade/organisations/g20. See also Council of the European Union, "International Summits Involving the EU," accessed October 8, 2026, https://www.consilium.europa.eu/en/european-council/international-summits-involving-the-eu/.

[18] OECD, "OECD AI Principles Overview," accessed October 8, 2026, https://oecd.ai/en/ai-principles.

[19] Pasqua, "Bridging Soft and Hard Law." See also UNESCO, *Recommendation on the Ethics of Artificial Intelligence*, sec. V, paras. 131–34.

countries where specific AI legislation is minimal or non-existent. In this context, compliance depends largely on voluntary commitment, which may be insufficient for high-risk AI applications. States or individual companies may ignore voluntary guidance in line with soft law if political[20] or commercial pressure is strong[21]. Therefore, flexible law often serves as a tool for encouragement and promotion: it highlights best practices and reputational risks, but only hard law can enforce them.

### 3. Formation of the So-Called Hoft Law (A Combination of Hard and Soft Law)

In fact, in the field of artificial intelligence, in recent years, more and more researchers have begun to talk about hoft law, which is defined as a hybrid or combination of hard and soft law. In practice, as already indicated in the previous content, soft law in the field of artificial intelligence is a prelude or a kind of bridge to hard law. This intermediate situation can be described by the recently appeared new term in the law of the European Union, namely hoft law or the so-called semi-hard law, a combination of hard and soft law[22].

A number of principles, initially formulated as guidelines, are gradually codified into binding rules. A striking example in this regard is the European Union Artificial Intelligence Act (Regulation (EU) 2024/1689)[23]. This instrument is the first of its kind comprehensive legal framework for artificial intelligence, building on and reflecting many principles originally formulated in soft law acts, establishing a risk-based regulatory framework for high-risk applications of artificial intelligence.

As is known, the aforementioned European Union Artificial Intelligence Act entered into force on 1 August 2024. It aims to promote the responsible development and deployment of artificial intelligence in the EU. High-risk artificial intelligence systems, such as AI-based software intended for medical purposes, must meet several requirements, including risk mitigation systems, high-quality datasets, clear information for users and, last but not least, human oversight.

However, the AI Act will only be fully applicable two years after its adoption, with some exceptions: the bans will enter into force after six months, the governance rules and obligations for general-purpose AI models will become applicable after 12 months, and the rules for AI systems – embedded in regulated products – will apply after 36 months[24].

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[20] Gergana Georgieva, "Challenges in Editing Politically Oriented Articles and Abstracts in Bulgarian Scientific Periodicals," *Orbis Linguarum* 19, no. 2 (2021): 96–102 (in Bulgarian), https://doi.org/10.37708/ezs.swu.bg.v19i2.12.

[21] Pasqua, "Bridging Soft and Hard Law."

[22] Kashkin and Altoukhov, "В поисках концепции," 35.

[23] European Parliament and Council of the European Union, Regulation (EU) 2024/1689 of June 13, 2024, laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), *Official Journal of the European Union* L, 2024/1689 (July 12, 2024), https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng.

[24] European Commission, "Artificial Intelligence in Healthcare." For the applicable statutory timetable, see Regulation (EU) 2024/1689, art. 113, consolidated version of July 27, 2026, https://eur-lex.europa.eu/eli/reg/2024/1689. See also European Commission, "The Enforcement Framework of the AI Act," last updated

The development and deployment of AI in medicine requires access to diverse and high-quality health data to ensure accuracy, reliability and fairness across different populations. The European Health Data Space (EHDS) is expected to play a key role in facilitating this by enabling the secondary use of electronic health data for research and innovation[25].

In this sense, the European Health Data Space will be a fundamental, key pillar of a strong European Health Union[26] and is the first common EU data space in a specific area, stemming from the European Data Strategy. The EHDS entered into force in 2025. The EHDS:

- empowers individuals to take control of their health data;
- facilitates the exchange of data for healthcare provision across the EU (primary data use);
- promotes a true single market for electronic health record systems;
- ensures a consistent, reliable and efficient system for the re-use of health data for research, innovation, policy development and regulatory activities (secondary data use)[27].

The interaction between soft and hard law is therefore mutually reinforcing: soft law allows for experimentation and regulatory piloting, allowing policymakers to test approaches before codifying them, while encouraging the dissemination of best practices that can later be formalised in binding rules.

The integration of national instruments with hard law together with EU secondary law further illustrates this hybrid governance model. Most recently, the Italian Republic adopted Law No. 132 of 23 September 2025 (in force since 10 October 2025), which complements the EU AI Act, demonstrating how domestic legislation can coexist with a supranational regulatory framework. Another national initiative is, for example, the Regulation on Artificial Intelligence in France. The strategy (launched in 2018), which responds to one of the objectives of France 2030, is to make France a pioneer in the field of artificial intelligence. The German draft AI Market Surveillance and Innovation Promotion Act (2025) currently under discussion should not be overlooked, which, like other national regulations, reinforces the idea that the effective management of artificial intelligence should be carried out by multi-level legal coordination, combining "soft" and "hard" law, in order to ensure both adaptability and

October 20, 2026, "AI Act's Enforcement Timeline," https://digital-strategy.ec.europa.eu/en/policies/enforcement-ai-act.

[25] European Commission, "European Health Data Space Regulation (EHDS)," accessed October 8, 2026, https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en. See also European Parliament and Council of the European Union, Regulation (EU) 2025/327 of February 11, 2025, on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, *Official Journal of the European Union* L, 2025/327 (March 5, 2025), https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng.

[26] The European Health Union seeks stronger cooperation on health-crisis preparedness, access to medicines and prevention, treatment and aftercare. See European Commission, "European Health Union," accessed October 8, 2026, https://commission.europa.eu/topics/public-health/european-health-union_en.

[27] European Commission, "Artificial Intelligence in Healthcare." See also Regulation (EU) 2025/327, chap. IV.

applicability[28].

It is obvious that in order to meet the requirements of the time, legal institutions must change – today the management of platform business models creates new legal relations and new institutional and legal mechanisms for regulation. The details of legal regulation[29], which at first glance seem small or unimportant, could have profound systemic consequences in society, the economy, politics, and even in people themselves. Artificial intelligence and platform business models are in a constant dialectical search for a balance between innovative technologies and the economy on the one hand, and their legal regulation on the other, i.e., to these two components, law must be added as well (according to the scheme: technology + economics + law).

## 4. International Perspectives on Healthcare AI Governance

An international perspective shifts the analysis from the adoption of general AI principles to the institutions that make those principles effective in clinical practice. The comparative framework assembled by Solaiman and Cohen examines healthcare AI across jurisdictions, connecting data use, patient protection, liability and governance.[30] The volume edited by Cohen and colleagues similarly situates medical-device regulation within debates in the United States and the European Union, including software, patient safety and post-market oversight.[31] Taken together, these works suggest that international convergence should be assessed through the practical safeguards available to patients and healthcare professionals.

US scholarship on emerging technologies offers a useful starting point for explaining how non-binding instruments acquire practical influence. Hagemann, Huddleston Skees and Thierer describe governance through guidelines, voluntary standards and multistakeholder processes, while examining concerns about legitimacy, transparency and accountability.[32] For healthcare, this supports a qualified view of hybrid regulation: professional guidance and institutional protocols can help specify expected conduct, but their legal significance depends on their relationship with applicable legislation, regulatory powers and rules on liability.

In the more specific field of medical AI, Price proposes an adaptive oversight model in which public regulation is supplemented by disclosures from developers and continuing evaluation by hospitals, clinicians and insurers.[33] This proposal clarifies the

[28] Pasqua, "Bridging Soft and Hard Law."
[29] Gabriela Belova and Gergana Georgieva, "Some Remarks on Legal Education in Bulgaria," *Kutafin Law Review* 8, no. 4 (2021): 713–30, https://doi.org/10.17803/2313-5395.2021.4.18.713-730.
[30] Barry Solaiman and I. Glenn Cohen, eds., *Research Handbook on Health, AI and the Law* (Edward Elgar Publishing, 2024), https://doi.org/10.4337/9781802205657.
[31] I. Glenn Cohen et al., eds., *The Future of Medical Device Regulation: Innovation and Protection* (Cambridge University Press, 2022), https://doi.org/10.1017/9781108975452.
[32] Ryan Hagemann, Jennifer Huddleston Skees, and Adam Thierer, "Soft Law for Hard Problems: The Governance of Emerging Technologies in an Uncertain Future," *Colorado Technology Law Journal* 17, no. 1 (2018): 37–130, https://scholar.law.colorado.edu/ctlj/vol17/iss1/3/.
[33] W. Nicholson Price II, "Regulating Black-Box Medicine," *Michigan Law Review* 116, no. 3 (2017): 421–74, https://doi.org/10.36644/mlr.116.3.regulating.

contribution of soft law: technical guidance and shared evaluation practices can generate evidence that informs regulatory decisions. In our view, such cooperation is especially valuable after deployment, when changing clinical conditions may reveal risks that were not apparent during initial validation.

Comparative analysis must also address the relationship between technical performance and professional responsibility. In a 2026 study centred on English medical negligence law, Berz argues that statistical superiority alone does not establish a duty to adopt or rely on AI; institutional endorsement and meaningful transparency are central to the proposed framework.[34] Applied to the present analysis, this suggests that clinicians need information that makes human oversight possible, while healthcare institutions should define validation, documentation and escalation procedures. Otherwise, responsibility risks being assigned to professionals who cannot adequately assess the tools they use.

These contributions support international cooperation around evidence requirements and patient safeguards. Regulators, healthcare providers and professional bodies could develop common expectations for validation across patient populations, documentation of limitations, monitoring after deployment and reporting harmful incidents. Mutual learning should remain sensitive to differences in healthcare systems and domestic liability rules. The objective should be compatible levels of patient protection, supported by identifiable decision-makers and effective avenues for redress. This gives the hard–soft law relationship a concrete institutional purpose within the human-rights framework developed in this article.

## 5. Conclusion

In conclusion, the integration of AI into healthcare presents significant opportunities, but also complex challenges. The potential of AI to improve health services through improved diagnostics, personalised treatments, and efficient resource management could help address the global public health deficit. From a health law perspective, AI could play a key role in addressing unmet health needs, especially in regions with limited access to health services. Given General Comment No. 14 to the International Covenant on Economic, Social and Cultural Rights (ICESCR)[35], which calls for the use of technology to prevent the spread of disease and increase equitable access to health care, it can be argued that there is a requirement, or at least an endorsement, in human rights law that States should make full use of new technologies

[34] Amelie S. Berz, "Medical Negligence in the Age of Statistically Superior AI," *Medical Law Review* 34, no. 1 (2026): fwag007, https://doi.org/10.1093/medlaw/fwag007.

[35] UN Committee on Economic, Social and Cultural Rights, "General Comment No. 14 (2000): The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)," E/C.12/2000/4, August 11, 2000, paras. 16–17, https://docs.un.org/E/C.12/2000/4. See also International Covenant on Economic, Social and Cultural Rights, adopted December 16, 1966, 993 UNTS 3, art. 12, United Nations Treaty Collection, https://treaties.un.org/Pages/showDetails.aspx?clang=_en&objid=080000028002b6ed. According to the UN Treaty Collection, Bulgaria deposited its ratification on September 21, 1970; the Covenant entered into force for Bulgaria on January 3, 1976.

to achieve the best possible state of health for all individuals in their societies. However, such technological advances need to be implemented within a structured human rights framework to avoid exacerbating existing inequalities or violating fundamental rights such as privacy, dignity and non-discrimination. Relevant legislation on this issue is already being adopted, including the European Health Data Space Regulation[36] to reconcile the opportunities for the right to health provided by access to high-quality personal health data with the right to privacy and personal data. As such legislation is developed, it is important that it takes into account not only the right to privacy but also all other human rights potentially affected.

Any model that takes into account respect for human rights would need to assess the benefits of AI alongside the risks to individual rights posed by these applications. Such a hypothetical model would need to focus both on addressing the tensions between different rights of the same person – e.g. confidentiality in relation to health interventions – and the rights of different individuals, e.g. in the context of triage, the use of data for AI training and digital phenotyping[37]. The specifics of AI models and training methodology are also relevant. Results, epistemology and methodology need to be aligned in determining the right approach to AI and other digital applications in healthcare.

It is undeniable that the digital age provides an unprecedented opportunity for informed and evidence-based decision-making, which by definition is based on multidisciplinary sources of information. These can be applied at every stage of decision-making, from legislation and national budgeting to individual decisions on prioritization, diagnosis, treatment and medication. Relying on the best possible information and information technology in such decision-making not only constitutes a legitimate aim that could justify interferences with certain human rights, but may also be required under the State's positive obligations with regard to the right to health[38]. Human rights therefore appear on both sides of the equation. The same rigor is needed for both negative and positive human rights obligations and, where applicable, for the principle of progressive realisation of human rights, to enable evidence-based reconciliation. Furthermore, a structured assessment of benefits and harms is needed to apply the right tests to the right to equality and non-discrimination. This reliance on

[36] The Commission projects that the EHDS could generate €11 billion in savings over the next decade, improve healthcare efficiency, expand the digital health sector by 20–30 percent, strengthen research and policy development, and support better health outcomes. These are forecasts. See European Commission, "European Health Data Space Regulation (EHDS)," "Transforming Healthcare through Data." For the legal framework and phased application, see Regulation (EU) 2025/327, art. 105.

[37] Digital Phenotyping is an innovative method in medicine and psychology for quantifying human phenotype (behaviour, physiological states) in real time, using data from personal digital devices such as smartphones, wearable technologies (smartwatches) and applications. See John Torous et al., "New Tools for New Research in Psychiatry: A Scalable and Customizable Platform to Empower Data Driven Smartphone Research," *JMIR Mental Health* 3, no. 2 (2016): e16, "Introduction," https://doi.org/10.2196/mental.5165.

[38] Helga Molbæk-Steensig and Martin Scheinin, "Human Rights and Artificial Intelligence in Healthcare-Related Settings: A Grammar of Human Rights Approach," *European Journal of Health Law* 32, no. 2 (2025): 139–64, https://doi.org/10.1163/15718093-bja10146.

real, verifiable and quantifiable data in determining the boundaries of the mandatory or permissible use of AI and other digital applications in health is the epistemic challenge for human rights in the digital age[39]. Ultimately, integrating AI into health requires a nuanced approach that harnesses its potential to improve health outcomes and safeguards against the risks that AI poses to human rights. Governments, healthcare providers and AI developers must work together to ensure that it promotes the right to health while adhering to a comprehensive and principled human rights framework.

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