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Research Article

LEGAL ANALYSIS OF EU ARTIFICIAL INTELLIGENCE ACT (2024): INSIGHTS FROM PERSONAL DATA GOVERNANCE AND HEALTH POLICY

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ABSTRACT

Background: *This study correlates the up-to-date ethical, functional and legal evaluations related to the management and governance of artificial intelligence (AI) under European Union (EU) law, particularly impacting the health data sector and medical standards as provided by the Artificial Intelligence Act within the Regulation adopted by the European Council in May 2024. The initial proposal for the management and governance of the AI sector was submitted in April 2021. Three years later, on 13 March 2024, the European Union Artificial Intelligence Act (EU AIA) was adopted by the European Parliament. Subsequently, on 21 May 2024, the Council adopted an innovative legislative framework that harmonises the standards and rules for AI regulation. This framework is set to take effect in May 2026, with the central objective of stimulating and motivating a fair, safe, legal single market that respects the principles of ethics and the fundamental rights of the human person.*

Methods: *The current legal analysis focuses on the European Union's new institutional governance involving a multistage approach to managing health data, ethical artificial intelligence, generative artificial intelligence and classification of types of AI by considering the degree of risk (e.g. artificial intelligence systems with limited risk and systems with high risk) and medical devices. It outlines the legal framework for AI regulation and governance in the EU by focusing on compliance with the previously adopted legislation in the Medical Devices Regulation (2017) and the In-Vitro Diagnostic Regulation (2017). The paper also examines the application of the newly adopted EU Artificial Intelligence Act in relation to national justice systems, previous EU regulations on medical devices and personal data protection regulation, and its correlation with the European Court of Human Rights jurisprudence. This opens up complex discussions related to judicial reform and access to justice. For this purpose, as a research objective, the legal analysis includes an innovative perspective following an integrative*

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discussion on the latest legal reforms and regulations of the AI sector in Eastern Europe launched in 2024 with a special focus on the latest developments in the EU Candidate Countries namely Ukraine and the Republic of Moldova.

Results and conclusions: *The present research facilitates the exploration of the real benefits of managing innovative AI systems for medical data, research, and development, as well as within the medical technology industry.*

1 INTRODUCTION

The regulation of the artificial intelligence (AI) sector by the European Parliament on 13 March 2024, along with the approval of the Act on Artificial Intelligence by the Council of the European Union (EU), laid the groundwork for the harmonisation of legal provisions regarding the EU's unitary regulation of AI sector.[1] The Act was adopted on 21 May 2024, with plans for its publication in the Official Journal of the EU, to enter into force twenty days from the moment of publication (Figure 1).[2] Recently, in July 2024, the final version of the EU Artificial Intelligence Act was published in the Official Journal, solidifying the harmonised provisions for the AI sector.[3]

The new legal framework outlines the key definitions applied to AI systems in the European Union in Article 3. Specifically, the first paragraph of Article 3 defines an "AI system" from two functional and operational perspectives, namely (1) as "a machine-based system" characterised by autonomy and (2) "the exercise of adaptiveness of such system".[4]

Moreover, the act adopted in May 2024 legally regulates the framework of the EU institutional governance and data in the AI sector and aims to delineate a uniform framework for the AI application at the level of the community market. This framework is centred on the human person, aiming to safeguard individual health, ensure the safety of citizens, and protect fundamental rights and freedoms. However, recent debates among

1 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 Harmonized Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)) <https://www.europarl.europa.eu/doceo/document/TA-9-2024-0138_EN.html> accessed 20 June 2024.

2 European Council and Council of the EU, 'Timeline - Artificial Intelligence' (*European Council and Council of the European Union*, 21 May 2024)' <https://www.consilium.europa.eu/en/policies/artificial-intelligence/timeline-artificial-intelligence/> accessed 22 June 2024.

3 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 Laying Down Harmonised Rules on Artificial Intelligence and Amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance), PE/24/2024/REV/1 [2024] OJ L 1689/1 <http://data.europa.eu/eli/reg/2024/1689/oj> accessed 12 July 2024.

4 ibid, art 3, para 1.

experts and in specialised literature have emerged regarding the ethical framework of the Artificial Intelligence Act. This new evidence-based legislation encompasses a new management system in the health sector, procedures, health data, standards and tools of assurance and quality assurance.[5]

The EU Artificial Intelligence Act is the first globally adopted legal framework regulating the field of AI in the EU. For the medical sector, the regulation applies in all areas: manufacturers of medical devices and developers' sector of consumer applications, concerning both AI systems and their results.[6] In addition to these provisions, Recital 51 deduces the structural-functional framework of Artificial Intelligence systems based on previous legislation provided by the Medical Devices Regulation and In-Vitro Diagnostic Regulation concerning medical devices incorporating an AI system.

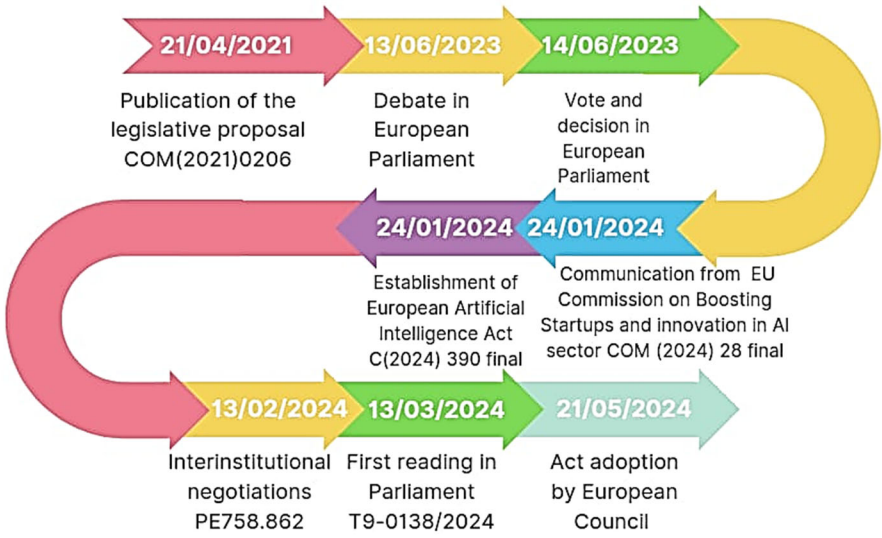

Figure 1. Timeline of the adoption of the EU Artificial Intelligence Act (2021–2024)[7]

The new regulation sets mandatory deadlines for application and implementation as follows: 12 months for providers of AI systems of general purpose,[8] 24 months for member states to ensure the institutional mechanisms to establish a regulatory sandbox,[9] and 36 months for high-risk AI systems.[10]

5 Arian Ranjbar and others, 'Managing Risk and Quality of AI in Healthcare: Are Hospitals Ready for Implementation?' (2024) 17 Risk Manag Healthc Policy 877, doi:10.2147/RMHP.S452337.

6 Artificial Intelligence Act (n 3) recital 50.

7 Systematized by the authors based on: European Council and Council of the EU (n 2).

8 Artificial Intelligence Act (n 3) recital 179.

9 ibid, recitals 57, 60.

10 ibid, art 111(1).

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2 LITERATURE REVIEW ON EU POLICY REGARDING PERSONAL DATA AND HEALTH POLICY IN ARTIFICIAL INTELLIGENCE (AI) MANAGEMENT AND GOVERNANCE

The literature on AI management and governance has acclaimed EU policy-making momentum while also acknowledging the definitions, obstacles, loopholes and limitations in regulating AI systems. These concerns are especially significant as professionals, industry holders, and academics have expressed their concerns regarding the misuse of AI across different fields of activity, including the economy, finances, entrepreneurship and marketing,[11] rule of law,[12] democracy and elections,[13] healthcare, social innovation, and professional life.[14]

Though developed to provide the security and control of AI development, the operationalisation of concepts like "human oversight"[15] and "human-centred"[16] in the EU Artificial Intelligence Act and AI governance has raised several questions and complexities adjudged in the literature.[17] Researchers have thus discussed how well the recitals of the EU Artificial Intelligence Act[18] align with the development and construction of machine learning[19] and AI systems.[20]

Through its scope and complexity, establishing "regulatory sandboxes"[21] through the EU Artificial Intelligence Act has also raised questions surrounding innovation and safety in

11 Alejo Jose G Sison and others, 'ChatGPT: More Than a "Weapon of Mass Deception" Ethical Challenges and Responses from the Human-Centered Artificial Intelligence (HCAI) Perspective' [2023] International Journal of Human-Computer Interaction 1, doi:10.1080/10447318.2023.2225931.

12 Roger Brownsword, 'Law, Authority, and Respect: Three Waves of Technological Disruption' (2022) 14(1) Law Innovation and Technology 5, doi:10.1080/17579961.2022.2047517.

13 Jelena Cupać and Mitja Sienknecht, 'Regulate Against the Machine: How the EU Mitigates AI Harm to Democracy' (2024) 31(5) Democratization 1067, doi:10.1080/13510347.2024.2353706.

14 Marta Cantero Gamito, 'The Role of ETSI in the EU's Regulation and Governance of Artificial Intelligence' [2024] Innovation: The European Journal of Social Science Research 1, doi:10.1080/13511610.2024.2349627.

15 Lena Enqvist, '"Human Oversight" in the EU Artificial Intelligence Act: What, When and by Whom?' (2023) 15(2) Law, Innovation and Technology 508, doi:10.1080/17579961.2023.2245683.

16 Ozlem Ozmen Garibay and others, 'Six Human-Centered Artificial Intelligence Grand Challenges' (2023) 39(3) Journal of Human-Computer Interaction 391, doi:10.1080/10447318.2022.2153320.

17 Araz Taeihagh, 'Governance of Artificial Intelligence' (2021) 40(2) Policy and Society 137, doi:10.1080/14494035.2021.1928377.

18 Nicola Fabiano, 'AI Act and Large Language Models (LLMs): When Critical Issues and Privacy Impact Require Human and Ethical Oversight' (31 March 2024) arXiv preprint arXiv:2404.00600 [cs.CY] <https://arxiv.org/html/2404.00600v1> accessed 05 July 2024.

19 Raphaële Xenidis, 'Beyond Bias: Algorithmic Machines, Discrimination Law and the Analogy Trap' (2023) 14(4) Transnational Legal Theory 378, doi:10.1080/20414005.2024.2307200.

20 Paul Friedl, 'Dis/similarities in the Design and Development of Legal and Algorithmic Normative Systems: The Case of Perspective API' (2023) 15(1) Law, Innovation and Technology 25, doi:10.1080/17579961.2023.2184134.

21 Thomas Buocz, Sebastian Pfotenhauer and Iris Eisenberger, 'Regulatory Sandboxes in the AI Act: Reconciling Innovation and Safety?' (2023) 15(2) Law, Innovation and Technology 357, doi:10.1080/17579961.2023.2245678.

different industries and EU markets, health policy and medical technologies and devices.[22] In line with these issues, the literature raises the issue of "explainability in artificial intelligence" and the concerns induced by EU legislation[23] focusing on medical diagnostic technologies and the issues surrounding patients' rights.[24]

Moreover, the literature connects the EU Artificial Intelligence Act, the European Convention on Human Rights (ECHR) and the General Data Protection Regulation (GDPR) in a complex discussion on the issues raised by anti-deep fake legislation,[25] democratic values and human rights.[26]

3 METHODOLOGY AND RESEARCH METHODS

The current legal analysis centres on the European Union's new institutional governance. The methodology involves a multistage legal approach and content analysis of EU regulation of the management of health data, ethical artificial intelligence, generative artificial intelligence and classification of types of artificial intelligence by considering the degree of risk (e.g. artificial intelligence systems with limited risk and systems with high risk) and medical devices.

This analysis considers the current framework for European Union artificial intelligence regulation and governance by focusing on compliance with the previously adopted legislation, such as the Medical Devices Regulation (2017) and the In-Vitro Diagnostic Regulation (2017). The hypothesis posits that aligning the new legal framework within EU AI regulations with these previously adopted regulations in the Medical Devices Regulation (2017) and the In-Vitro Diagnostic Regulation (2017) enhances the protection of human rights and safety within the healthcare system, with particular emphasis on safeguarding patients' rights.

22 Jonathan McCarthy, 'From Childish Things: The Evolving Sandbox Approach in the EU's Regulation of Financial Technology' (2023) 15(1) Law, Innovation and Technology 1, doi:10.1080/17579961.2023.2184131.

23 George Pavlidis, 'Unlocking the Black Box: Analysing the EU Artificial Intelligence Act's Framework for Explainability in AI Law' (2024) 16(1) Innovation and Technology 293, doi:10.1080/17579961.2024.2313795.

24 Daria Onitiu, 'The Limits of Explainability & Human Oversight in the EU Commission's Proposal for the Regulation on AI- a Critical Approach Focusing on Medical Diagnostic Systems' (2022) 32(2) Information & Communications Technology Law 170, doi:10.1080/13600834.2022.2116354.

25 Felipe Romero-Moreno, 'Generative AI and Deepfakes: A Human Rights Approach to Tackling Harmful Content' [2024] International Review of Law, Computers & Technology 1, doi:10.1080/13600869.2024.2324540.

26 Hendrik Schopmans and Irem Tuncer Ebeturk, 'Techno-Authoritarian Imaginaries and the Politics of Resistance against Facial Recognition Technology in the US and European Union' (2023) 31(1) Democratization 1, doi:10.1080/13510347.2023.2258803.

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4 RESULTS AND DISCUSSIONS

4.1. EU new legal trilogue (2024): Generative AI, European Artificial Intelligence Office (EU AIO) and Council Regulation (EU) 2024/1732

In early 2024, the EU Commission launched three new provisions for the health sector and the implementation framework of the Artificial Intelligence Act:

(i) Communication COM(2024) 28 final: This legislative act regulates new forms and models of content known as "Generative AI". It encompasses a wide range of technologies associated with the health sector, such as the use of health data, health services, personalised services and facilities, and regulatory frameworks for biotechnologies.[27] It also integrates the framework of applications based on an AI system in areas such as support services and personalised health. Additionally, it incorporates the common European data space for AI start-ups, covering sectors such as health, research and innovation.

(ii) Commission Decision C(2024) 390 final: Adopted on 24 January 2024, this decision establishes the European Artificial Intelligence Office (EU AIO). The EU AIO is tasked with applying and implementing EU regulations in the AI sector through collaboration with public and private partners, as well as professionals from the scientific community, developers and experts in the AI sector.[28]

(iii) Council Regulation (EU) 2024/1732: Adopted on 17 June 2024, this regulation focuses on innovative European start-ups in the AI sector.[29] For the health sector, it introduces new legal provisions based on ethical AI, confirming the character of strategic sectors for the health sector and healthcare domains. The new regulation aims to support and facilitate the development of AI-based models and applications in strategic areas,[30] such as health[31] and support services.[32]

27 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, on Boosting Startups and Innovation in Trustworthy Artificial Intelligence, COM/2024/28 final of 24 January 2024 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52024DC0028 > accessed 10 July 2024.

28 Commission Decision of 24 January 2024 Establishing the European Artificial Intelligence Office, C/2024/390 [2024] OJ C 1459/1 <http://data.europa.eu/eli/C/2024/1459/oj> *accessed* 10 July 2024.

29 Council Regulation (EU) 2024/1732 of 17 June 2024 amending Regulation (EU) 2021/1173 as Regards a EuroHPC Initiative for Start-Ups in Order to Boost European leadership in Trustworthy Artificial Intelligence, ST/10109/2024/INIT [2024] OJ L 1732/1 <http://data.europa.eu/eli/reg/2024/1732/oj> accessed 10 July 2024.

30 Liubov Maidanyk, 'Artificial Intelligence and Sui Generis Right: A Perspective for Copyright of Ukraine?' (2021) 4(3) Access to Justice in Eastern Europe 144, doi:10.33327/AJEE-18-4.3-n000076.

31 Urs Gasser, 'An EU Landmark for AI Governance' (2023) 380(6651) Science 1203, doi:10.1126/science.adj1627.

32 Laura Ervo, 'Debtors Protection and Enforcement Efficiency According to Finnish Law' (2020) 3(4) Access to Justice in Eastern Europe 265, doi:10.33327/AJEE-18-3.4-a000039.

4.2. General Overview of the Artificial Intelligence Act

The regulatory framework of the Artificial Intelligence Act encompasses three fundamental characteristics:[33] legality, convergence and flexibility to adapt to processes and developments in the technological spectrum.[34] It defines AI models for general use, distinguishing them from AI systems (AIS)[35] based on their functional nature, generality and the typology of their assigned tasks.[36]

The Artificial Intelligence Act, therefore, sets three objectives through which the new regulation ensures the correct and safe development and use of AI systems: (*a*) the classification of AI systems based on the risk and the associated typology: minimal, limited, high and unacceptable; (*b*) the financial sanctions in case of non-compliance with the legal framework; (*c*) from the perspective of institutional governance, the creation of an artificial intelligence office at the EU level to order, supervise and to harmonise the legislative framework at the level of the member states.

The approach to ethical principles within the Artificial Intelligence Act brings a consistent contribution to the regulation of the AI and personal data protection sector at the EU level considering the case law retrieved from the European Court of Human Rights (ECtHR) in the following areas: (*a*) human rights and private life;[37] (*b*) protection of personal data and data collection in professional activities;[38] (*c*) health care and protection of health data[39] and (*d*) respect of health record and human rights.[40] This type of multi-principle approach is consistently related to (*i*) social existence and functioning;[41] protection of the fundamental rights and freedoms of the natural person;[42] (*ii*) protection of private life and guaranteeing the confidentiality of the information and communication space;[43] (*iii*) supporting the innovation framework, respecting and guaranteeing freedom of science, concerning the

33 Stephen Gilbert and others, 'Learning From Experience and Finding the Right Balance in the Governance of Artificial Intelligence and Digital Health Technologies' (2023) 25 Journal of Medical Internet Research e43682, doi:10.2196/43682.

34 Stephen Gilbert, 'The EU Passes the AI Act and its Implications for Digital Medicine are Unclear' (2024) 7(1) NPJ Digital Medicine 135, doi:10.1038/s41746-024-01116-6.

35 Artificial Intelligence Act (n 3) recital 12.

36 ibid, recital 97.

37 *S and Marper v the United Kingdom* App nos 30562/04, 30566/04 (ECtHR, 4 December 2008) paras 30, 31 <https://hudoc.echr.coe.int/eng?i=001-90051> accessed 24 June 2024.

38 *Bărbulescu v Romania* App no 61496/08 (ECtHR, 12 January 2016) paras 70–72 <https://hudoc.echr.coe.int/eng?i=001-159906> accessed 24 June 2024.

39 *LH v Latvia* App no 52019/07 (ECtHR, 29 April 2014) paras 28–30 <https://hudoc.echr.coe.int/fre?i=001-142673> accessed 24 June 2024.

40 *KH and Others v Slovakia* App 32881/04 (ECtHR, 28 April 2009) paras 35, 36, 46, 49 <https://hudoc.echr.coe.int/eng?i=001-92418> accessed 24 June 2024.

41 Artificial Intelligence Act (n 3) recital 4, 9, 16.

42 ibid, recital 22.

43 ibid, recital 10.

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need to ensure development, as well as supporting research activity and the development of the scientific activity.[44]

This approach objectively appeals to the legal processing of personal data, considering both personal information and data and the non-personal data processing framework.[45]

Being the first regulatory legal act with horizontal mandatory character,[46] the Artificial Intelligence Act establishes a system of guarantees by adhering to a set of principles of social and biomedical ethics. Although expressly mentioned by Recital 27, a fair analysis of the ethical and principled framework is necessary, starting from the consistent and common application of these principles in the new regulation and AI legal safety and safety regulation.[47]

4.3. Ethical AI

In a first acceptance of the principle related to the human-centred approach, the content of Recital 8 states "ethical AI" and "protection of ethical principles". Recital 25 further defines and operationalises important distinctions regarding scientific reality, highlighting the need for research and development activity to conform to ethical and professional standards and principles relevant to scientific research. In this context, the relevant interpretations of the ECtHR regarding the protection of biometric data and ethical principles explore legal and conceptual developments focusing on (*a*) retention and processing of DNA samples and biometric data;[48] (*b*) risk of data and regulation of respect of fundamental freedoms[49] and (*c*) ethical norms and standards for protection of health, rights and freedoms.[50]

Recital 27 reflects on the ethical principle of technical robustness and the safety assurance framework, focusing on the development and resilience of AI systems to ensure protection against illegal use by third parties.

44 ibid, recital 25.

45 ibid, recital 10.

46 Tambiama Madiega, 'Artificial Intelligence Act: Briefing EU Legislation in Process' (*EPRS European Parliamentary Research Service*, June 2023) <https://superintelligenz.eu/wp-content/uploads/2023/07/EPRS_BRI2021698792_EN.pdf> accessed 24 June 2024.

47 Sofia Palmieri and Tom Goffin, 'A Blanket That Leaves the Feet Cold: Exploring the AI Act Safety Framework for Medical AI' (2023) *30*(4) *European Journal of Health Law* 406, doi:10.1163/15718093-bja10104.

48 *Gaughran v The United Kingdom* App no 45245/15 (ECtHR, 13 February 2020) paras 19–21 <https://hudoc.echr.coe.int/eng?i=001-200817> accessed 24 July 2024.

49 *Wilhelmus Paulus Willems v the Netherlands* App no 57294/16 (ECtHR, 9 November 2021) paras 55–57 <https://hudoc.echr.coe.int/eng?i=001-214169> accessed 24 July 2024.

50 *Tuleya v Poland* App nos 21181/19, 51751/20 (ECtHR, 6 July 2023) paras 366, 456 <https://hudoc.echr.coe.int/eng?i=001-225672> accessed 24 July 2024.

According to the third principle of the Artificial Intelligence Act, data protection, confidentiality and governance are established as systematised principles within the new legal framework.[51] This principle addresses the condition of the human being while also considering the broader social context. It encompasses a constative-causal perspective that outlines the conditions for the development and use of AI systems in compliance with norms and rules designed to maintain confidentiality, ensure proper data processing, and protect data quality and integrity throughout its handling.[52]

The fourth principle of transparency, as outlined in Recital 9, emphasises distinct concepts and the the complex legal operationalisation of technical documentation and requirements related to the status of AI systems records. Deriving from the initial provisions of Recital 9, other mentions refer strictly to high-risks AI systems for which the EU Artificial Intelligence Act requests transparency and clear instructions regarding the system's capacities and capabilities, as well as precise mentions regarding its limitations and other categories of potentially associated risks.[53]

In Article 13, the creation of terminology to approach ethical principles is based on rigour, with a specific inventory of terms and an empirical approach centred on transparency, access, and the provision of information. From a second perspective, the mechanism and process of designing, using, and deploying AI systems are designed to ensure a transparent operation and a transparent analysis and evaluation of the results of high-risk AI systems. A third consideration regarding the transparency of high-risks AI systems engages compliance with the obligations set forth by the EU Artificial Intelligence Act for providers and deployers.[54] On the other hand, we must note a degree of generality for the mentions in Section 3, only the minimum mentions for the instructions for use being specified, namely the criteria and status of operation and use, identification and contact data of the high risks AI systems supplier, characteristics and capabilities of high risks AI systems. Article 13 also comes with a limiting-descriptive exploration of the performance limitations of high risks AI systems considering the forms of use, the role of internal factors or external factors, the dynamic realities of activities and the evolutionary dynamics of the level of accuracy, the security of high risks AI systems, the robustness and the purpose of using the high risks AI systems, any known or potentially anticipated uses of the high risks AI systems.

The principle of diversity is widely exposed in the EU Artificial Intelligence Act, the initial focus being initially highlighted in Recital 27. Starting from the principle of diversity, we distinguish in the same recital the associated principle of non-discrimination, but also of fairness, which operates as a complex of associations and criteria perceived at the level of development and use of an AI system. Thus, Recital 27 describes and characterises the

51 Artificial Intelligence Act (n 3) recital 27.

52 ibid, recital 27.

53 ibid, recitals 17, 59, 60, 68, 72, 74, 94.

54 ibid, s 3, arts 16–25, 27.

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development and use of AI systems, operationalises the role of various factors and promotes the principle in the sphere of gender equality and equal access by excluding any discriminatory consequences contrary to the previously adopted EU legislation.

The last principle focuses on a structural-functional approach based on social well-being and environmental sustainability as elements associated with the development and use of AI systems. In this framework, this principle allows clear observation of the principled and functional variety of EU legislation oriented towards social life, protection of rights, health or environment.[55]

4.4. Legal Areas and High-Risk AI Systems

The Artificial Intelligence Act establishes a stricter regulation system in critical areas for the life of the citizen, as well as that of the community. Thus, the new provisions regulate defining sectors such as health, transport and public safety, areas for which six fundamental compliance requirements are provided for: (*1*) the management, assessment and risk management framework of high-risk AI systems; (*2*) data management and governance; (*3*) regulations and provisions regarding the documentation and the technical framework; (*4*) system functionality and compliance with EU requirements; (*5*) compliance and transparency regarding the operating framework, capacity and functionality of the AI system; (*6*) a set of criteria and obligations necessary to be admitted to the EU market. These criteria are centred on the management associated with the risk, being prohibited systems that employ cognitive-behavioural manipulation.[56] The same set of restrictions also includes AI systems that employ social scores that generate discriminatory effects of excluding certain social groups, but also unfavourable consequences related to personal characteristics or some social groups.[57]

4.5. Medical Devices Regulation and Artificial Intelligence Act: Legal and Policy Considerations

In this innovative context of harmonisation of rules in the AI sector at the European level, the legislator followed a framework of rules intended to encourage the functioning of internal markets, the common and uniform legal and regulatory spectrum and the principles and values of the EU respecting the rights and freedoms of the individual.[58] The new legislation facilitates and guarantees the protection of the rights and data of natural persons and the protection of health by requiring a common and functional legal framework for the use of AI systems,[59] as well as compliance with the previously adopted legislation of

55 *Wilhelmus Paulus Willems v the Netherlands* (n 49) paras 58, 59.
56 Ranjbar and others (n 5).
57 Artificial Intelligence Act (n 3) recital 31.
58 *Gaughran v The United Kingdom* (n 48) paras 22, 23.
59 Artificial Intelligence Act (n 3) recital 1.

the European Union regarding the Medical Devices Regulation (2017)[60] and In Vitro Diagnostic Medical Devices Regulation (2017).[61] In this context, it is important to mention that the Artificial Intelligence Act does not limit the regulatory framework only to the medical devices sector but regulates a wider framework referring to any product or result that meets the definition of AI systems.

Concerning the AI systems classified and categorised by the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation, the legal provisions of the new regulation refer to the conformity assessment ordered by a third party. The AI systems approach from the regulatory scope of the two previous provisions indicates that the EU Artificial Intelligence Act envisages a double regulation opposing the AI system, namely compliance with the requirements of the previous legislation as well as the new legal requirements provided by the Artificial Intelligence Act. The Artificial Intelligence Act's approach to previous European legislation (the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation) brings necessary clarifications regarding compliance with the previously adopted regulations. A close examination of Recital 64 illustrates the linkage between the newly adopted legislation and the previous regulations of the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation, observing the clear formulation of the references to medical devices, the health risks of these products and the typology of security requirements.

(a) Risk Classes and Assessment

The Medical Devices Regulation primarily governs operational and technical standards in the scope of risk assessments related to physical safety rather than addressing potential malfunctions in the operation and use of medical devices. In contrast, the Artificial Intelligence Act regulates and guarantees better protection of patients' rights in a special section in Annex III of measures specific to the health sector. However, it does not include details about specific measures. Moreover, Annex III does not have a particular list of measures for the healthcare sector. Thus, the Medical Devices Regulation classifies medical devices into four class categories based on varying levels of risk and intended use: Class I – low-risk devices; Class IIa and Class IIb – medium-risk devices; and Class III - all high-risk devices. Similarly, the Artificial Intelligence Act regulates four categories of risks: unacceptable risk,[62] high risk,[63] limited risk,[64] and minimal or no risk.[65]

60 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 (Text with EEA relevance) [2017] OJ L 117/1 <http://data.europa.eu/eli/reg/2017/745/oj> accessed 10 July 2024.

61 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in Vitro Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2017] OJ L 117/176 <http://data.europa.eu/eli/reg/2017/746/oj> accessed 10 July 2024.

62 Artificial Intelligence Act (n 3) recitals 26, 31, 46, 179.

63 ibid, recitals 48, 52, 58; art 59(c).

64 ibid, recital 53.

65 ibid, art 36.

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(b) Criteria for Classifying Medical Devices

The first observation highlights that under the Medical Devices Regulation, many AI applications in the healthcare sphere are not legally regulated. This regulatory gap in the Artificial Intelligence Act particularly concerns high-risk AI systems. In this context, the regulatory deficit is compensated by the legislative framework of the Medical Devices Regulation that classifies medical devices according to the following criteria: (*a*) Chapter I, Annex VIII of the Medical Devices Regulation - duration of use which categorises three levels: transitory (with use for less than 60 minutes); in the short term - use between 60 hands and 30 days and in the long term - for extended use that exceeds 30 days, as well as invasive and active devices; (*b*) Chapter II, Annex VIII of the Medical Devices Regulation - implementation rules; (*c*) Chapter III – classification rules (non-invasive devices, invasive devices and active devices).[66] The Artificial Intelligence Act specifies in Article 6 a double condition for classifying and evaluating high-risk medical devices. The first condition aims to be used as a safe component or is already a product. In this case, it is necessary to operationalise the conformity assessment procedure of a third party.

A recent analysis of the scientific literature in the field reveals explorations of the regulatory framework of medical AI, as well as data confidentiality, health data governance,[67] risk management and AI sector, ethical aspects and risk assessment,[68] regulation of medical devices, healthcare generative AI and AI cycle.[69]

(c) Conformity Assessment and Certification Requirements

In accordance with the final adopted version, the Artificial Intelligence Act states that medical devices regulated by the Medical Devices Regulation are high-risk medical devices. Considering this regulation, the Artificial Intelligence Act has two preconditions in the evaluation procedure for high-risk medical devices. The first condition refers to the use and use as a safety component of a product, or even a product; according to the new legal provisions of the Artificial Intelligence Act, a third-party evaluation is needed within the Medical Devices Regulation. Within the regulations provided by the Medical Devices Regulation, an important regulatory differentiation is provided for medium and high-risk devices, as the Medical Devices Regulation requests a conformity assessment from the manufacturers. Conformity assessment is an audit procedure that requires an audit of a

66 Regulation (EU) 2017/745 (n 60) annex VIII.

67 Hannah van Kolfschooten, 'The AI Cycle of Health Inequity and Digital Ageism: Mitigating Biases Through the EU Regulatory Framework on Medical Devices' (2023) 10(2) *Journal of Law and the Biosciences* lsad031, doi:10.1093/jlb/lsad031.

68 Johann Laux, Sandra Wachter and Brent Mittelstadt, 'Trustworthy Artificial Intelligence and the European Union AI Act: On the Conflation of Trustworthiness and Acceptability of Risk' (2024) 18(1) Regulation & Governance 3, doi:10.1111/rego.12512.

69 Sandeep Reddy, 'Generative AI in Healthcare: An Implementation Science Informed Translational Path on Application, Integration and Governance' (2024) 19(1) Implementation Science 27, doi:10.1186/s13012-024-01357-9.

notified institution or body. Thus, Chapter 4, Article 30 and subsequent articles perform the conformity assessment procedure with the express mention that only conformity assessment bodies that meet the legality criteria provided for in Article 31 can be notified.

The Artificial Intelligence Act also provides for conformity assessment, which includes three procedural stages: examination, training, testing and validation mechanisms and procedures.[70] The most relevant regulatory differentiation concerns the periods in which conformity assessment is carried out. In the new regulatory context provided by the Artificial Intelligence Act, all the periods before, during and after the development of a high-risk AI system are available.

(d) Human Supervision

Under the Medical Devices Regulation, human oversight is not a legal requirement, and legal mentions regarding data quality control are limited to the post-market clinical phase. Unlike the Medical Devices Regulation, the EU Artificial Intelligence Act explicitly mandates human oversight within the risk management procedure, as outlined in Article 14. The Artificial Intelligence Act further operationalises data quality management by acknowledging three principles of assurance: data relevance, data representativeness, lack of errors and completeness. In such a regulation, we observe EU legal provisions becoming the referential subject for data management and governance.[71]

A similar approach to fundamental rights is reflected in the decisions of the Inter-American Court of Human Rights (IACtHR), which emphasises the protection of rights such as freedom of expression[72], the right to informed decision-making,[73] access to information and data,[74] freedom of speech, and freedom of information and communication.[75]

4.6. Research and Development (R&D) in the Artificial Intelligence Act

Regarding the ethical principles and standards, the Artificial Intelligence Act has seven particular references to the ethical framework of AI systems in Recital 27 and Recital 7 (ethical guidelines), Recital 8 (ethical AI in the regulations of the European Council), Article 95 and Recital 165 (the need to implement a framework just, correct and transparent in the field of AI systems), Recital 25 (provisions regarding ethical, legal and professional

70 Artificial Intelligence Act (n 3) recitals 67, 68, 71, art 10.

71 *Tuleya v Poland* (n 50) para 457.

72 *Ivcher-Bronstein v* Peru Ser C no 75 (IACtHR, 14 March 2001) paras 146–148 <https://www.corteidh.or.cr/tablas/fichas/ivcherbronstein.pdf>accessed 22 June 2024.

73 *Ricardo Canese v Paraguay* Ser C no 111 (IACtHR, 31 August 2004) paras 95–98 <https://www.corteidh.or.cr/tablas/fichas/ricardocanese.pdf> accessed 22 June 2024.

74 *Claude-Reyes et al v Chile* Ser C no 151 (IACtHR, 19 September 2006) paras 77, 86–92 <https://www.corteidh.or.cr/tablas/fichas/claudereyes.pdf> accessed 22 June 2024.

75 *Rios et al v Venezuela* Ser C no 194 (IACtHR, 28 January 2009) paras 105–108 <https://www.corteidh.or.cr/tablas/fichas/rios.pdf> accessed 22 June 2024.

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standards and regulations in the field of scientific research), and Article 60 (ethical guidelines and the testing of high risks AI systems).

The Artificial Intelligence Act regulates, with exception, the AI systems whose exclusive purpose focuses on scientific research and development, as specified in Article 2(6)(8). Under a strict interpretation of Article 2, AI systems or AI models, including their results, are exempt from the regulations if their primary purpose is scientific research and development.[76]

4.7. Latest Legal Reform and Regulations of the AI sector: Case-Law in Ukraine (2024) and Republic of Moldova (2024)

The legislative reform of the AI sector was centred both at the level of the EU internal market space and at the level of the Candidate Countries, namely the Republic of Moldova and Ukraine. In this sense, two documents with major legal relevance were recently adopted by the Government of the Republic of Moldova[77] and the Government of Ukraine[78] to establish a framework for the compatibility of national legislation with legal regulation at the EU level.

4.7.1. Legal Provisions of Non-Original Objects and Sui Generis Right in Law of Ukraine "On Copyright and Related Rights" (2022)

In this context, it is important to note that on 1 December 2022, Ukraine adopted the Law of Ukraine "On Copyright and Related Rights," which addresses the legal regulation of non-original objects, including those generated by AI.[79] The innovative Ukrainian legal framework first adopted two years ago engages two important perspectives related to the legal regulation of non-original objects generated by computer programs, which includes objects or products produced by AI.

The 2022 Ukrainian legal framework also introduces in its first paragraph the regulation of "sui generis right", referring to "non-original objects generated by a computer program"[80] and stating the "non-direct participation of a person in the creation of the object".[81] The new

76 ibid, art 2 para 6.

77 Government of Republic of Moldova, *White Book on Data Governance and Artificial Intelligence* (Ministry of Economic Development and Digitalization of Republic of Moldova 2024) <https://particip.gov.md/ro/download_attachment/22059> accessed 28 July 2024.

78 Government of Ukraine, *White Paper on Artificial Intelligence Regulation in Ukraine: Vision of the Ministry of Digital Transformation of Ukraine: Version for Consultation* (Ministry of Digital Transformation of Ukraine 2024) <https://www.kmu.gov.ua/en/news/rehuliuvannia-shtuchnoho-intelektu-v-ukraini-mintsyfry-prezentuie-bilu-knyhu> accessed 28 July 2024.

79 Law of Ukraine no 2811-IX of 1 December 2022 "On Copyright and Related Rights" [2023] Official Gazette of Ukraine 3/196 <https://zakon.rada.gov.ua/laws/show/2811-20#Text> accessed 28 July 2024.

80 ibid, art 33.

81 ibid, art 33 para 1.

legal context further addresses the holders (persons) of this sui generis right, the scope and aims of their property rights, and the validity of these rights, which is capped at 25 years from the year following the creation of the non-original object.[82]

In this context, two legal provisions address (1) the moment when the sui generis right is generated and operates[83] and (2) the level of effectiveness of the special type of sui generis right.[84] The Ukrainian legal framework is harmonised with the EU's main legal provisions adopted in the intellectual property field, referring to both the "exercise of intellectual property rights"[85] and the "agreement on the transfer of intellectual property rights."[86]

4.7.2. Scope of Application and Regulation of AI in the Republic of Moldova (2024)

The document adopted by the Government of the Republic of Moldova in 2024 centres on two important dimensions of regulation of the AI sector: engaging a performant digital sector and management of data governance by focusing on a policy framework to promote and guarantee human rights and international cooperation.[87]

Considering the reform and regulatory framework of the AI sector at international and European levels, the document recently launched by the Government of Moldova in 2024 frames a functional and structural point of view by presenting a set of twelve recommendations regarding the implementation of a uniform legislative framework. The first three recommendations include protecting personal data and guaranteeing human rights and decision-making transparency in the artificial intelligence sector.[88] The following four recommendations provide a framework for legal reforms and sectoral policies to facilitate access to data and technological development. The document focuses on the institutional role of the government authority, as well as the beneficiaries from the public and private sectors.[89]

A defining element of the document adopted by the Government of the Republic of Moldova focuses on the need to identify and implement national standards to ensure and guarantee data interoperability.[90] A concrete reform initiative in this regard is MCloud, aimed to administer AI models at the national level and align the country's legislation with international standards in AI.

82 ibid, art 33 para 6.
83 ibid, art 33 para 5.
84 ibid, art 33 para 6.
85 ibid, art 453.
86 ibid, art 1113.
87 Government of the Republic of Moldova (n 77) 6-9.
88 ibid.
89 ibid.
90 ibid.

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The last five recommendations employ a triple dimension of legal regulation of the AI field: (1) the need to create a meta-data catalogue including data sets from the public and private sectors to facilitate the access of companies as well as the educational and research environment; (2) implementing a mechanism for monitoring and evaluating AI projects at the national level; (3) promoting and respecting a set of ethical principles in the process of creating, developing and implementing AI projects focusing on human rights, democratic norms, the non-discriminatory approach.[91]

4.7.3. Scope of Application and Regulation of AI in Ukraine (2024)

In Ukraine this year, an important regulation in a consultative version was adopted at the governmental level.[92] The new document in the consultative version integrates a trivalent framework for the assumption of goals and legislative implementation as follows: (1) promoting a competitive space in the business sector; (2) promoting, guaranteeing and protecting human rights; (3) accessing European integration and adopting of a national legislative framework compatible and harmonised with European and international norms and values.[93]

The document sets four dimensions of reform of the Ukrainian institutional system focusing on the collective functionality at the organisational level by introducing and implementing AI as follows: (1) attracting investments through the use of mechanisms, products and services based on AI; (2) new opportunities for the labour market using AI systems; (3) improving organisational management in the public and private sector; (4) competitive, structural and professional advantages for the domestic market sector and the educational space.[94]

Another relevant aspect of the document focuses on the stages of development and implementation of the future regulation regarding AI in Ukraine, underpinning both the objective of international cooperation and compliance and compatibility with the European legislative framework. The document reflects the role of the regulatory sandboxes, pointing to the relevance of a national legal advisory platform aimed at monitoring the respect and protection of human rights and the impact of engaging and implementing AI products and services.[95]

In this context, the document developed by the Ukrainian authorities this year conceptualises and operationalises a broader framework to manage functional and institutional needs. Also, the document highlights the role of financial resources and the human factor, as well as the importance of social relations and public relations in

91 ibid 11-2.
92 Government of Ukraine (n 78).
93 ibid 23-5.
94 ibid 4-8.
95 ibid 19-20.

future AI regulation. In this context, the authorities reflect several sectoral recommendations regarding the system labelling concerning AI systems engaging data governance, algorithms, personal data and data privacy, organisational decisions, evaluation and monitoring.[96]

5 CONCLUSIONS

The current research explored the new regulatory framework proposed by the European Commission, focusing on its ethical and professional implications for the healthcare sector. The analysis of this European-level legal framework reveals that it is built on standardised variables (e.g. conformity assessment) while also emphasising the importance of harmonising with previous legislation, including the Medical Devices Regulation and the In-Vitro Diagnostic Regulation. Additionally, the study considered the recent legal developments, such as the generative AI framework, the establishment of the European Artificial Intelligence Office (EU AIO), and the Council Regulation (EU) 2024/1732.

The paper discussed the correlation of the newly adopted EU Artificial Intelligence Act to previous EU regulations on medical devices and personal data protection, as well as with the European Court of Human Rights jurisprudence. This alignment raises complex issues regarding implementing the Artificial Intelligence Act within the national justice systems, referring to judicial reform and access to justice considerations.

The paper was methodologically centred on the hypothesis that questions whether the legal framework embedded in the European Union's artificial intelligence regulations is consistent with the previously adopted legislation, specifically the Medical Devices Regulation (2017) and the In-Vitro Diagnostic Regulation (2017). The analysis aimed to determine whether the EU's Artificial Intelligence Act enhances the protection of human rights and safety within the healthcare system in general and, specifically, whether it strengthens the safeguarding of patients' rights. Additionally, the research explored whether the legislator intended to align the Artificial Intelligence Act with the aforementioned regulations.

Consequently, we can appreciate that although the Artificial Intelligence Act engages, protects and guarantees the exercise and security of fundamental human rights, the devices mentioned in Annex III do not include precise references or regulations for all areas of public health. In this context, criteria and principles such as transparency and data accuracy are necessary for medical devices based on AI due to their direct interaction with individuals. Another criterion that validates the regulation and the improved protection offered by the EU Artificial Intelligence Act is the responsibility of various entities and institutions at the national or European level, such as the EU and Member States (Recital 24

96 ibid 21-2.

and Article 100), providers of AI models for general use (Recital 101), authorities (Article 59), importers (Article 23). Respect for public order and the role of national authorities represent two other important criteria revealed and focused on by the Artificial Intelligence Act to protect personal data.

Prior to the adoption of this regulation, the Ukrainian legislator adopted the "Law on Ukraine on Copyright and Related Rights" on 1 December 2024. These legislative reforms have enhanced the possibility of solving technology litigation, including disputes related to AI use. Thus, the analysis envisaged the interpretation of EU regulations managing innovative Artificial Intelligence systems for medical data, research and development, and the medical technology industry. Thus, the Medical Devices Regulation and the In-Vitro Diagnostic Regulation will continue to apply once the EU Artificial Intelligence Act is adopted. Our research validates the legislative progress proposed by the new EU Artificial Intelligence Act regulations, illustrating the need for the horizontal regulation assumed by the new legal framework to be accompanied by a subsequent sectoral approach and regulation. Moreover, we can conclude that medical devices and technology need a new management and quality control system. This system, already regulated by the previous legal order provided by the Medical Devices Regulation, must complement the rules and provisions related to the use of AI within the application of the Artificial Intelligence Act, especially in the management and governance of the data used in the previous stage, but also to introduce it to the market.

In conclusion, while the Medical Devices Regulation primarily addresses risks associated with safety, the Artificial Intelligence Act provides a more complex and extensive level of safeguarding human rights and safety. The paper explored the latest legal reforms and regulations of the AI sector in Eastern European countries, with a special focus on Ukraine (2024) and the Republic of Moldova (2024). An innovative aspect of this research is its interpretation of the legal perspective brought by the documents released by the two governments of these candidate countries.

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RIGHTS AND PERMISSIONS

АНОТАЦІЯ УКРАЇНСЬКОЮ МОВОЮ

Дослідницька стаття

ПРАВОВИЙ АНАЛІЗ ЗАКОНУ ЄС ПРО ШТУЧНИЙ ІНТЕЛЕКТ (2024): ПЕРЕВАГИ В СФЕРІ УПРАВЛІННЯ ПЕРСОНАЛЬНИМИ ДАНИМИ ТА ПОЛІТИКИ ОХОРОНИ ЗДОРОВ'Я

Анка Пармена Олімід*, Кетеліна Маріа Джеорджеску та Даніель Алін Олімід

АНОТАЦІЯ

Вступ. *Це дослідження зіставляє сучасні етичні, функціональні та правові оцінки, пов'язані з управлінням і регулюванням штучного інтелекту (ШІ) відповідно до законодавства Європейського Союзу (ЄС), зокрема з впливом на медичні стандарти та сектор медичних даних, як це передбачено Законом про штучний інтелект в межах*

Регламенту, прийнятого Європейською Радою в травні 2024 року. Початкову пропозицію щодо управління та керування сектором штучного інтелекту було подано в квітні 2021 року. Через три роки, 13 березня 2024 року, Європейський парламент ухвалив Закон Європейського Союзу про штучний інтелект (EU AIA). Згодом, 21 травня 2024 року, Рада прийняла інноваційну законодавчу базу, яка гармонізує стандарти і правила регулювання ШІ. Вона має набути чинності в травні 2026 року, головною метою якої є стимулювання та мотивація чесного, безпечного, законного єдиного ринку, який поважає принципи етики та фундаментальні права людини.

Методи. *Здійснений правовий аналіз зосереджується на новому інституційному управлінні Європейського Союзу, що передбачає багатоступеневий підхід до керування даними про стан здоров'я, етичний штучний інтелект, генеративний штучний інтелект, класифікацію типів штучного інтелекту з урахуванням ступеня ризику (наприклад, системи штучного інтелекту з обмеженим ризиком і системи з високим ризиком) і медичне обладнання. У ньому окреслено законодавчу базу щодо регулювання та управління штучним інтелектом у ЄС, зокрема зосереджено увагу на дотриманні раніше прийнятих нормативно-правових актів у Регламенті MDR (The Medical Devices Regulation) (2017) та Регламенті IVDR (The In Vitro Diagnostic Medical Devices Regulation) (2017). У статті також досліджується застосування нещодавно ухваленого Закону ЄС про штучний інтелект щодо національних систем правосуддя, попередні нормативні акти ЄС щодо медичних пристроїв і регулювання захисту персональних даних, а також здійснюється їх зіставлення з практикою Європейського суду з прав людини. Це відкриває складні дискусії щодо судової реформи та доступу до правосуддя. Відповідно до мети дослідження, правовий аналіз містить інноваційну перспективу, що ґрунтується на інтегративному обговоренні останніх правових реформ і нормативно-правових актів у сфері штучного інтелекту в Східній Європі, які були впроваджені у 2024 році, з особливим акцентом на останні події в країнах-кандидатах на вступ до ЄС, а саме в Україні та Республіці Молдова.*

Результати та висновки. *Ця стаття сприяє вивченню реальних переваг управління інноваційними системами ШІ для медичних даних, досліджень і розробок, а також у галузі медичних технологій.*

Ключові слова: *штучний інтелект, ШІ, етичний ШІ, законодавство ЄС, генеративний ШІ, медичні дані.*