RAIS Journal for Social Sciences | VOL. 9, No. 2, 2025
ISSN 2574-0245 (Print) | ISSN 2574-1179 (Online) | DOI: 10.5281/zenodo.17649370

Artificial Intelligence and Medicine in the Old Continent: How Europe is Trying to Define an Ethical Application of this New Technology

Emanuela MIDOLO[1], Rosangela BARCARO[2]

[1,2]*Interdepartmental Center for Research Ethics and Integrity (CID Ethics), CNR, Rome, Italy*
emanuela.midolo@ethics.cnr.it

Abstract: Artificial Intelligence is a powerful and transformative force in medicine, offering unprecedented capabilities in diagnostics, drug discovery, and patient care. However, this transformation is not without significant challenges. The AI-driven paradigm introduces complex ethical and systemic risks, including privacy vulnerabilities amplified by the perpetuation of health inequities through algorithmic bias, and the erosion of trust and professional competence due to opaque "black box" systems. The current regulatory and governance landscape in Europe is in a state of flux, attempting to manage a fast-moving technology with traditional frameworks not designed for its iterative nature. The authors, in this work, aim to define an ethical and legal common framework to support the ethical application of AI in the field of medicine.

Keywords: Artificial Intelligence, Medical Ethics, Ethics dilemma, New Technologies, European AI Act, European Health Data Space (EHDS), GDPR

Introduction

The rapid integration of artificial intelligence (AI) has become increasingly embedded in medical systems, shaping diagnostics, personalized therapy, and hospital management. From AI-driven imaging analysis to predictive analytics for patient outcomes, these tools promise greater efficiency and precision. However, this progress raises complex ethical, legal, and social questions, particularly in Europe, where robust data protection and human rights frameworks shape technological development. Indeed, the European context is particularly significant, given its strong normative traditions of human dignity and data protection, enshrined in the Charter of Fundamental Rights of the European Union (CFR EU, 2000) and the General Data Protection Regulation (GDPR, 2016).

The European ethical tradition in science and technology is rooted in post–World War II humanism and the Nuremberg Code (1947), emphasizing human rights, autonomy, and social responsibility. These principles are embedded in the Charter of Fundamental Rights of the European Union and inform modern regulatory efforts. European bioethics, particularly in healthcare, emphasizes the precautionary principle. Technological innovation should proceed only when potential harms are understood and mitigated. This framework ensures that medical AI is developed not merely for efficiency or profit, but for the enhancement of human well-being and justice in the medical field, maintaining a fundamentally human-centered approach. The European Union introduced the Artificial Intelligence Act (AI Act) in 2021, which is the first comprehensive attempt to regulate AI across Member States. It classifies AI systems by risk level and imposes the strictest requirements on high-risk applications, which include most medical AI systems. Core

obligations include rigorous data quality, clear human oversight mechanisms, transparency, and ongoing post-market evaluation. The General Data Protection Regulation (GDPR) complements the AI Act by providing a robust legal framework for data processing, ensuring personal health data are collected and used lawfully and with explicit consent.

This paper examines the ethical dimensions of AI in medicine across Europe, focusing on principles of safety, transparency, justice, autonomy, and accountability. It analyzes European regulatory responses—including the EU Artificial Intelligence Act (AI Act, 2021) and the European Health Data Space (EHDS, 2024)—and contrasts these with the comparatively market-driven, innovation-first approach in the United States. Drawing upon recent literature, policy frameworks, and ethical theory, this study argues that Europe's rights-based governance offers a model of "trustworthy AI," yet also faces challenges in innovation speed, interoperability, and equitable implementation.

While the United States has prioritized innovation and commercial development in AI, the European Union (EU) has sought to integrate ethics into regulation through a precautionary, rights-based model. This paper explores how these differing philosophical foundations manifest in practice. It aims to identify how Europe addresses ethical concerns surrounding medical AI—such as bias, transparency, data governance, and accountability—and what lessons may be drawn from comparison with the U.S.

Background: AI in Medicine

AI applications in medicine encompass a broad range of technologies, including machine learning algorithms for diagnostic imaging, natural language processing for clinical documentation, predictive modeling for risk assessment, and robotics for surgery and patient care. These systems depend heavily on data, especially sensitive health information, creating tension between innovation and privacy. The potential benefits are substantial. AI can reduce timeline for diagnostic exams, identify disease patterns undetectable by human clinicians, and improve resource allocation. However, medical AI also introduces risks: data bias, opaque decision-making, errors and shifting professional responsibilities. In both Europe and the United States, such issues are increasingly seen not merely as technical flaws but as ethical and societal challenges that require governance frameworks to ensure trust and safety.

Ethical Principles and Challenges in the European Context

Despite progress, significant ethical challenges remain, such as algorithmic bias, opacity, liability gaps, and issues related to cross-border data use. AI ethics encompasses a framework of values, principles, and techniques that apply moral standards to the development and use of artificial intelligence. Within the medical field, these ethical considerations are closely aligned with the four foundational principles of medical ethics established by Beauchamp and Childress (2019): autonomy, nonmaleficence, beneficence, and justice. Autonomy emphasizes respect for patients' rights to make informed decisions. In AI-driven medicine, this involves designing technologies that enhance decision-making transparency and ensure that outputs are comprehensible to both patients and clinicians. Nonmaleficence, or the obligation to avoid harm, necessitates rigorous safety testing and vigilance against algorithmic bias. Bias in machine learning models, particularly when training data lack diversity, can lead to unequal diagnostic accuracy and perpetuate disparities across patient populations.

Beneficence requires that AI systems prioritize patient welfare by improving clinical outcomes and care quality. Justice demands fairness and equal access to AI's benefits, independent of patients' socioeconomic or demographic backgrounds. The ethical responsibility of developers is therefore pivotal. They must integrate ethical principles

throughout all stages of AI development, ensuring that technological progress aligns with moral and professional standards. However, the literature reveals a gap in understanding how developers perceive and operationalize ethical considerations. Addressing this gap is essential to foster the responsible, equitable, and value-driven application of AI in medicine.

European researchers and policymakers advocate participatory models involving clinicians, patients, and citizens in shaping AI governance, thus reinforcing legitimacy and social trust (Morley, Luciano, & Cowls, 2020). This paper explains the fundamental ethical principles involved in the application of AI technologies in medicine.

Patient Safety and Nonmaleficence

Ensuring that AI systems do not harm patients is a central ethical requirement. The European Medicines Agency (EMA) and the European Parliament have identified patient safety as the foremost concern in medical AI. The risk of automation bias—clinicians over-trusting algorithmic outputs—can lead to diagnostic or therapeutic errors. Europe's regulatory framework thus mandates clinical validation, continuous monitoring, and post-market surveillance for AI-based medical devices, emphasizing a "human in the loop" model.

Bias, Fairness, and Justice

Bias in AI systems arises when training data do not reflect demographic diversity and age. In healthcare, such bias can reinforce existing inequalities, for example, by under-diagnosing diseases in disadvantaged populations or by creating difficulties for older patients to have an efficient interface with these technologies. European ethics guidelines for a "Trustworthy AI," developed by the EU High-Level Expert Group on Artificial Intelligence, explicitly include fairness and non-discrimination as core principles. These are further supported by legal mandates under the GDPR and the proposed Artificial Intelligence Act (AI Act), which classify most medical AI systems as "high-risk" and subject them to strict oversight.

Transparency and Explainability

Opacity in AI decision-making jeopardizes both clinical accountability and patient autonomy. European frameworks demand explainability, so that patients and clinicians should understand how and why an AI system reached a conclusion. This is grounded in the ethical principle of respect for persons and in legal provisions under the GDPR's "*right to explanation*" (Goodman & Flaxman, 2017). While full algorithmic transparency may be technically difficult, European initiatives encourage the use of interpretable models and documentation of data provenance. Several studies are being conducted in the EU on Large Language Models (LLMs) that could interact and communicate with patients in an empathetic mode (de O Campos et al., 2024).

Data Protection and Privacy

Data governance is a defining ethical concern in Europe. The GDPR, effective since 2018, sets global standards for lawful, fair, and transparent data processing. Medical AI depends on vast datasets that may contain genetic, biometric, or behavioral data, raising questions about informed consent, data minimization, and secondary use (Jasanoff & Hurlbut, 2018). The forthcoming European Health Data Space (EHDS) aims to enable health-data sharing for research while safeguarding individual rights, a distinctive European attempt to reconcile innovation with ethical oversight.

One of the major risks highlighted today concerning the use of AI technologies in healthcare is the data breach of patient information. A data breach represents a problematic violation of human rights that impacts various ethical principles. Personal health data represent a fundamental asset for biomedical research and the advancement of clinical knowledge. Beyond their primary use in patient care and clinical trials, the secondary use of health data, or purposes different from those originally intended, has gained increasing significance in the healthcare domain. Nevertheless, the sharing and reuse of such sensitive data raises substantial ethical and legal concerns that extend beyond traditional privacy risks. Health information can reveal aspects of an individual's current and future condition, potentially influencing other personal rights and interests, including non-discrimination in employment, credit, insurance, and intimate life decisions such as reproductive choices. Consequently, the ethical implications of a data breach transcend issues of confidentiality, engaging the core principles of bioethics and the inherent dignity of the human person. Indeed, from an ethical standpoint, the improper management of health data poses a serious threat to public trust in healthcare systems and may undermine the fundamental right to care and safety (Alder, 2025). Professional responsibility in this context extends beyond mere legal compliance; it embodies a moral and ethical commitment to the protection of patients as individuals (Mittelstadt, 2022). Guided by the principles of beneficence and non-maleficence, healthcare professionals are ethically obliged to safeguard the dignity and integrity of those they serve, ensuring that data management practices uphold both patient welfare and societal confidence in medical institutions.

Accountability and Human Oversight

The diffusion of responsibility between developers, healthcare providers, and institutions complicates accountability. If an AI system misdiagnoses a patient, determining liability becomes ethically and legally fraught. The European Commission's approach embeds human oversight as a non-negotiable principle: AI should support, not replace, clinical judgment. This aligns with the European conception of technology as a tool for human flourishing, rather than as autonomy-reducing automation.

Equity of Access and Solidarity

An often-overlooked ethical issue is the unequal distribution of AI benefits across Europe. High-resource hospitals in Western Europe can afford advanced AI systems, whereas institutions in Eastern or rural regions may face significant adoption delays. The EU's commitment to social justice and solidarity requires policies that ensure equitable access and avoid a "two-speed" digital health landscape.

The European Regulatory-Ethical Framework: The EU Artificial Intelligence Act

The AI Act, signed in 2021 but truly enforced in 2024, represents the first comprehensive legislative framework for AI worldwide. It introduces a risk-based approach: prohibited, high-risk, limited-risk, and minimal-risk categories. Medical AI systems classified as high-risk applications necessitate rigorous requirements for transparency, data quality, and human oversight. Ethically, the AI Act operationalizes the principle of precaution—preventing harm before it occurs, trying to contribute to ethical programming and application of AI across EU Member States.

The Ethics Guidelines for Trustworthy AI

Issued in 2019, these guidelines articulate seven key requirements: human agency, technical robustness, privacy, transparency, diversity, societal well-being, and accountability. Though

non-binding, they provide a moral compass for developers and institutions, reflecting Europe's rights-based orientation. One of the critical aspects of AI application in healthcare is the patient-physician relationship. As affirmed in a Report of the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO, 2021) of the Council of Europe on AI on the doctor-patient relationship, the integration of AI into healthcare is transforming how medical care is delivered and may significantly affect the traditional doctor-patient relationship. The same Committee in 2024 affirmed the importance of the patient-doctor relationship due to the humanistic approach between these two, in contrast to the Artificial Intelligence systems which are static and do not automatically interact in a human way (CDBIO, 2024). While AI has the potential to enhance clinical expertise through advanced data analytics, its impact depends on how it is implemented. If AI serves mainly to support doctors, rather than replace them, it may have minimal effect on the trust, empathy, and moral integrity central to good medical practice (Mittelstadt, 2010). However, if AI increasingly replaces human expertise, the nature of "good" care could change, potentially creating new norms in clinical relationships. Although a complete shift toward AI-driven diagnosis and treatment remains distant, pressures such as those seen during the COVID-19 pandemic have already accelerated trends like remote care delivery (Keskinbora, 2019).

Major obstacles to full AI adoption include proving clinical efficacy, ensuring safety and fairness, and addressing implicit biases. As AI becomes more integrated into healthcare systems worldwide, it is essential to maintain the moral and fiduciary foundations of the doctor-patient relationship (Floridi & Cowls, 2019). Policymakers and regulators must establish strong standards to ensure that AI enhances rather than undermines patient trust, care quality, and the ethical foundations of medicine.

The European Health Data Space: The risks of an increase in Data Breach and European Initiatives

The EHDS, under negotiation since 2022, seeks to harmonize access to health data for research and innovation while ensuring strong ethical safeguards. It exemplifies Europe's attempt to balance the utilitarian value of data with the deontological imperative to protect individual rights. The EHDS, which entered into force on March 26, 2025, represents a major milestone in the European Union's effort to establish a secure and interoperable framework for health data management and sharing (European Commission, 2025). The regulation aims to empower citizens with direct control and access to their electronic health records (primary use) while enabling the secondary use of health data for research, innovation, and public health purposes (Mancini & Midolo, 2024). Through a cross-border digital infrastructure, the EHDS seeks to foster scientific progress and improve healthcare outcomes across the EU. To safeguard individuals' fundamental right to privacy, the regulation mandates the implementation of Secure Processing Environments (SPE) that prevent unauthorized access and direct data downloads. Nevertheless, challenges persist regarding the harmonization of national legislations, the risk of data breaches due to system interoperability, and the varying levels of citizens' willingness to engage in data altruism—the voluntary sharing of personal health data for the common good (Davidovics, Kovács & Gaál, 2024). Despite these challenges, the EHDS constitutes a significant step toward a unified European digital health ecosystem, enhancing access, research, and innovation while reinforcing data protection and ethical responsibility in the use of sensitive medical information. The EHDS initiative aims to create a cross-border health data ecosystem under strict ethical standards. There are also several projects, such as AI4Health (2022), HumanE-AI-Net (2020), and ETHICAL AI (2025), that promote trustworthy, explainable, and human-centered AI. Member States such as France, Germany, and Italy have established

bioethics guidelines emphasizing physician oversight and transparency. In particular, the Italian Agenzia per l'Italia Digitale (AGID) (2024) had approved the *Italian Strategy for Artificial Intelligence 2024-2026*.

Comparative Perspective: Europe and the United States

The European and American approaches to AI in medicine reflect two distinct philosophical traditions. In the United States, innovation is primarily driven by market dynamics and private investment. Indeed, the ethical and regulatory landscapes of AI in medicine diverge significantly between Europe and the United States. In the European Union, ethics and law are deeply intertwined. Regulation precedes or accompanies innovation, embodying a "precautionary governance" model rooted in human rights. The guiding assumption is that public trust, grounded in transparency and fairness, is a prerequisite for innovation.

In contrast, the United States has adopted a more market-driven, innovation-first philosophy. The Food and Drug Administration (FDA) regulates AI-enabled medical devices but focuses primarily on safety and efficacy rather than broader ethical dimensions such as bias or explainability. Privacy is governed by a fragmented framework (notably the Health Insurance Portability and Accountability Act, HIPAA 1996), which lacks the comprehensive reach of the GDPR. Ethical oversight tends to be institutional (e.g., hospital review boards) rather than systemic.

Ethically, the European model emphasizes trustworthiness; the American model emphasizes progress. While the U.S. approach can accelerate innovation, it risks ethical blind spots, including unaddressed bias and opaque algorithmic processes. Conversely, Europe's rigorous oversight may slow innovation but offers a more ethically sustainable foundation for public trust.

Discussion: A European Model of Trustworthy Medical AI, Between Ethics and Innovation

Europe's approach represents a deliberate balance between innovation and ethical responsibility. By anchoring AI governance in human rights and data protection, the continent promotes a vision of trustworthy AI that safeguards individuals and collective welfare. The European approach to medical AI demonstrates that ethical governance is not an obstacle to innovation but a condition of legitimacy. However, practical challenges remain. Compliance with the AI Act and GDPR can be costly, particularly for small and medium-sized enterprises. Moreover, achieving meaningful explainability in deep learning remains technically elusive (Veale & Edwards, 2018).

There is also tension between individual rights and collective benefits. Ethical frameworks emphasizing consent and data minimization may limit the scope of data-driven research. To reconcile these aims, Europe must continue to develop technical solutions such as federated learning and privacy-preserving computation, alongside robust ethical oversight. A balanced model may lie in transatlantic cooperation—combining Europe's rights-based governance with America's innovation dynamism. Shared ethical standards and interoperable regulatory mechanisms could enhance global trust in medical AI while maintaining competitiveness.

Conclusion

AI technologies are redefining the practice and ethics of medicine. In Europe, ethical reflection and legal regulation are intertwined, reflecting deep cultural commitments to human dignity, privacy, and social justice. The EU's emerging governance architecture—

the AI Act, GDPR, and Health Data Space (2025)—embodies a comprehensive attempt to make medical AI "trustworthy by design." Yet the ethical task is ongoing. Ensuring equitable access, maintaining public trust, and reconciling innovation with precaution require continuous dialogue between technologists, clinicians, ethicists, and policymakers. The comparison with the United States underscores that neither ethics without innovation nor innovation without ethics is sustainable. Europe's model offers a compelling, though imperfect, example of how to embed moral responsibility at the heart of technological progress.

Artificial Intelligence is transforming medicine, but its benefits can only be realized through ethical foresight and legal rigor. The ethical deployment of artificial intelligence in healthcare relies on a principled framework that upholds the core tenets of medical ethics. The ethical framework guiding AI applications in healthcare must be grounded in the principles of autonomy, nonmaleficence, beneficence, and justice (WHO, 2021). Ensuring autonomy requires that AI systems remain transparent and support informed decision-making by patients and healthcare professionals. Nonmaleficence emphasizes the prevention of harm through rigorous validation, bias mitigation, and accountability mechanisms. Beneficence demands that AI be designed to enhance patient outcomes and the overall quality of care, while justice requires equitable access and fair treatment across all demographic groups. Integrating these principles into AI development transcends mere ethical compliance—it establishes a foundation for trust, safety, and social responsibility (Mittelstadt, 2010). Europe's commitment to embedding moral reflection in technological governance represents a distinctive path — one that prioritizes human dignity, justice, and transparency. Ultimately, embedding this ethical framework demands continuous collaboration among developers, clinicians, ethicists, and policymakers (Weidener & Fischer, 2024). Ethical principles must be integrated not as afterthoughts but as foundational design requirements from the earliest stages of AI conception to deployment. By doing so, healthcare AI can progress responsibly balancing innovation with moral accountability and ensuring that the pursuit of technological advancement remains firmly rooted in the protection of human dignity and the equitable promotion of health for all.

References

Alder, S. (2025, October 26). Healthcare Data Breach Statistics. *The HIPAA Journal.* https://www.hipaajournal.com/healthcare-data-breach-statistics/

AI4health. (2022). PNRR Project. Society of Information Technology, Consulting and System Integration. https://www.ai4health.ai/brochure-informative/brochure-commerciale-2022.pdf

Beauchamp, T. L., & Childress, J. F. (2019). *Principles of biomedical ethics* (8th ed.). Oxford University Press.

Council of the European Union. (2025, January 21). European Health Data Space: Council adopts new regulation improving cross-border access to EU health data. https://www.consilium.europa.eu/en/press/press-releases/2025/01/21/european-health-data-space-council-adopts-new-regulation-improving-cross-border-access-to-eu-health-data/

Davidovics, K., Kovács, R., & Gaál, P. A. (2024). Secondary use of helath data in EU: Exploring the legal challenges of the upcoming European Health Data Space Regulation in light of the findings of the TEHDAS project. *IME Innováció Menedzsment Egészségügy, 23*(KSZ 1), 5-15.

de O Campos, H., Wolfe, D., Luan, H., & Sim, I. (2025). Generative AI as Third Agent: Large Language Models and the Transformation of the Clinician-Patient Relationship. *Journal of Participatory Medicine*, 17(1), e68146. https://jopm.jmir.org/2025/1/e68146

ETHICAL AI. (2025). Educate and Innovate - Shaping the University Future with Responsible Artificial Intelligence Erasmus+ Programme. https://www.pixel-online.net/project.php?id=201

European Union (2000), Charter of Fundamental Rights of the European Union, Official Journal of the European Communities. https://www.europarl.europa.eu/charter/pdf/text_en.pdf

European Parliament and of the Council (2016), REGULATION (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Official Journal of the European Union. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

European Commission. (2019). *Ethics Guidelines for Trustworthy AI.* Brussels. https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai.

European Commission. (2021). *Proposal for a Regulation Laying Down Harmonized Rules on Artificial Intelligence (Artificial Intelligence Act).* Brussels: COM (2021) 206 final. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52021PC0206.

European Commission. (2025). *Regulation on the European Health Data Space.* https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en.

European Group on Ethics in Science and New Technologies. (2023). *Ethics of AI in Healthcare: Challenges and Policy Recommendations.* European Commission. https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics_en.

European Medicines Agency. (2023 April). *Artificial Intelligence in Medicine Regulation*. EMA News Release. https://www.ema.europa.eu/en/news/artificial-intelligence-medicine-regulation.

European Parliament. (2016). General Data Protection Regulation (GDPR). *Official Journal of the European Union*. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679.

European Parliament. (2022). *Artificial Intelligence in Healthcare.* Study Panel for the Future of Science and Technology. Research Service Scientific Foresight Unit (STOA) PE 729.512. https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729512/EPRS_STU(2022)729512_EN.pdf.

European Parliamentary Research Service (2022). Ethical and Legal Challenges. European Parliament. https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729543/EPRS_STU(2022)729543(ANN1)_EN.pdf.

European Union. (2012a). Treaty on European Union (Consolidated version). *Official Journal of the European Union,* C 326, 13–390. https://eur-lex.europa.eu/resource.html?uri=cellar:2bf140bf-a3f8-4ab2-b506-fd71826e6da6.0023.02/DOC_1&format=PDF

European Union. (2012b). Treaty on the Functioning of the European Union (Consolidated version). Official Journal of the European Union, C 326, 47–390. https://eur-lex.europa.eu/EN/legal-content/summary/treaty-on-the-functioning-of-the-european-union.html

Floridi, L., & Cowls, J. (2019). A unified framework of five principles for AI in society. *Harvard Data Science Review, 1*(1). https://hdsr.mitpress.mit.edu/pub/l0jsh9d1/release/8

GDPR. (2016). *Legal foundations and main obligations for the processing by IRCCS of personal data collected for healthcare purposes for further research purposes.* https://www.garanteprivacy.it/temi/sanita-e-ricerca-scientifica/irccs.

Goodman, B., & Flaxman, S. (2017). European Union regulations on algorithmic decision-making and a "right to explanation." *AI Magazine, 38*(3), 50–57.

HealthDataSpace.eu. (2025). *Data Protection and Security, 2025.* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

Health Insurance Portability and Accountability Act (1996) Pub. L. No. 104-191, 110 Stat. 1936. https://aspe.hhs.gov/reports/health-insurance-portability-accountability-act-1996

High-Level Expert Group on AI. (2020). *Policy and Investment Recommendations for Trustworthy AI.* European Commission. https://digital-strategy.ec.europa.eu/en/policies/expert-group-ai

HumanE AI Net (2020). HumanE-AI-Net - Rete HumanE AI, CNR. https://www.cnr.it/en/research projects/project/41208/humane-ai-net-humane-ai-network-dit-ad004-120

Italian Agenzia per l'Italia Digitale (AGID). (2024). *Italian Strategy for Artificial Intelligence 2024-2026*. https://www.agid.gov.it/sites/agid/files/2024-07/Italian_strategy_for_artificial_intelligence_2024-2026.pdf

Jasanoff, S., & Hurlbut, J. B. (2018). A global observatory for gene editing. *Nature, 555*(7697), pp.435–437.

Keskinbora, K.H. (2019). Medical ethics considerations on artificial intelligence. *Journal of Clinical Neuroscience, 64, 277-282.*

Mancini, E., & Midolo, E. (2024). "You Could Have Asked Me First": Potential and Limits of Consent to Secondary Use of Genetics Data and Biological Samples in Healthcare for Scientific Research Purposes. *notizie di POLITEIA*, XL, 155, 20-38.

Mittelstadt, B. (2010). Principles Alone Cannot Guarantee Ethical AI. *Nature Machine Intelligence 1*(11), 501–507.

Mittelstadt, B. (2022). Principles alone cannot guarantee ethical AI. *Nature Machine Intelligence, 4*(1), 1–7.

Mittelstadt, B. (2023). *The Impact of Artificial Intelligence on the Doctor-Patient Relationship: Report of the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO).* Council of Europe. https://www.coe.int/en/web/human-rights-and-biomedicine/report-impact-of-ai-on-the-doctor-patient-relationship

Morley, J., Luciano, F., &Cowls, J. (2020). From What to How: An Initial Review of Publicly Available AI Ethics Tools, Methods and Research to Translate Principles into Practices. *Science and Engineering Ethics 26(*4), 2141–2168.

Nuremberg Code. (1947). British Medical Journal, No 7070 Volume 313, Page 1448, 7 December 1996. https://media.tghn.org/medialibrary/2011/04/BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf

Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO). (2024). *Application of AI in healthcare and its impact on the 'patient-doctor' relationship.* Council of Europe. https://rm.coe.int/cdbio-2023-7-rev3-ai-report-new-banner-e/1680b1bfe4

U.S. Food and Drug Administration. (2023). *Artificial Intelligence and Machine Learning in Software as a Medical Device.* FDA, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-software-medical-device

Veale, M., & Edwards, L. (2018). Clarity, Surprises, and Further Questions in the GDPR's 'Right to Explanation.' *Computer Law & Security Review 34*(2), 398–404.

Weidener, L., & Fischer, M. (2024). Role of Ethics in Developing AI-Based Applications in Medicine: Insights from Expert Interviews and Discussion of Implications. *JMIR AI, 3*(1), e51204. doi:10.2196/51204

World Health Organization. (2021). *Ethics and Governance of Artificial Intelligence for Health*. https://www.who.int/publications/i/item/9789240029200