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ETHICS AND GOVERNANCE OF AI IN HEALTHCARE: CASE INDONESIA, EU, AND THE US

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ABSTRACT
Artificial Intelligence (AI) is fundamentally changing healthcare systems worldwide, enhancing diagnostics, personalized treatment, and health management, yet it introduces ethical and governance complexities related to privacy, fairness, accountability, and equitable access. This study explores the ethics and governance of AI in healthcare by comparing Indonesia, the European Union (EU), and the United States (US) through a qualitative comparative methodology that includes policy analysis, legal review, and literature synthesis. It examines national laws, regulatory frameworks, ethical guidelines, and institutional practices to identify normative foundations and regulatory mechanisms, alongside challenges and best practices. Findings reveal that the EU employs a rights-based, precautionary approach with enforceable legal frameworks and robust institutional oversight, emphasizing privacy and fairness. In contrast, the US favors a decentralized, innovation-driven model with sector-specific regulations, which, while encouraging rapid technological advancement, leads to regulatory fragmentation and health equity issues. Indonesia finds itself in an intermediate position, adhering to global ethical norms through legislation like the Personal Data Protection Law and Digital Health Blueprint, but it encounters challenges with enforcement and capacity. The study suggests that Indonesia could benefit from a hybrid governance model that merges EU-style enforceable ethical standards with US-style flexible regulatory mechanisms and incentives for innovation. Policy recommendations include enhancing legal and ethical frameworks, instituting risk-based oversight, bolstering institutional and technical capacities, promoting equity, and engaging in public-private partnerships to align local AI governance with international best practices and effectively utilize AI in healthcare while maintaining ethical integrity and public trust.

INTRODUCTION

Artificial Intelligence (AI) has rapidly transformed the landscape of healthcare systems across the world (Noorbakhsh-Sabet et al., 2019 ;Hamsal & Binsar, 2025; Esmaeilzadeh, 2024; Roppelt et al., 2024; Alowais et al., 2023). From diagnostic imaging and predictive analytics to telemedicine and drug discovery, AI-driven technologies are reshaping how health services are delivered, managed, and accessed (Rashid et al., 2025; Aparna et al., 2026; Shafique et al., 2025). The promise of AI in

improving clinical accuracy, reducing operational costs, and expanding healthcare access is undeniable (Faiyazuddin et al., 2025; Fahim et al., 2025; Ahmed et al., 2020). Yet, this technological progress brings with it complex ethical dilemmas and governance challenges. Questions concerning data privacy, informed consent, algorithmic bias, transparency, and accountability have become central to debates over the responsible use of AI in health. The convergence of health data, machine learning, and digital platforms thus demands not only technical expertise but also strong ethical and regulatory foundations. In recent years, the global community has witnessed divergent approaches to the governance of AI in healthcare (Taeihagh, 2021; Schwalbe & Wahl, 2020; Monlezun, 2023a; Birkstedt et al., 2023; Chen et al., 2023). The European Union (EU) has pioneered a human-centric, rights-based framework that emphasizes trust, transparency, and accountability, exemplified by the General Data Protection Regulation (GDPR) and the forthcoming EU AI Act (Balcioğlu et al., 2025; Kashyap & Mitra, 2025). The United States, by contrast, adopts a more innovation-driven and market-oriented approach, with governance distributed across agencies such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) (Herzlinger & Walker, 2023; Mei & Sag, 2025). Meanwhile, developing countries like Indonesia are in the early stages of designing national frameworks for AI governance (Wadipalapa et al., 2024; Saragih et al., 2023; Bernot et al., 2024). Indonesia's health transformation agenda and the newly enacted Personal Data Protection Law (*Undang-Undang Perlindungan Data Pribadi*) represent important steps forward, yet the country still faces institutional, ethical, and infrastructural constraints in implementing responsible AI in healthcare.

The ethical governance of AI in health, therefore, is not only a technical or legal issue but also a question of justice, trust, and societal values. The challenge lies in aligning technological innovation with ethical imperatives such as autonomy, beneficence, non-maleficence, and justice principles derived from bioethics that continue to guide medical decision-making in the digital age. However, the translation of these principles into concrete governance mechanisms varies significantly across regions. The EU's strong legal frameworks contrast sharply with the fragmented and sectoral approaches in the United States, while Indonesia's regulatory landscape remains emergent and uneven. These variations reflect broader political, institutional, and cultural differences that shape how societies balance innovation with ethical responsibility.

Existing scholarship on AI governance has primarily focused on advanced economies, with limited comparative analysis that includes developing contexts such as Indonesia. Most studies emphasize either ethical principles or regulatory structures in isolation, rather than examining how both interact in practice across different political and legal systems. As a result, there is a lack of integrative understanding of how ethical frameworks are institutionalized through governance mechanisms in diverse health systems. Addressing this gap requires a comparative perspective that bridges normative ethics, law, and policy analysis. This study aims to examine the ethics and governance of AI in healthcare through a comparative analysis of Indonesia, the European Union, and the United States. It seeks to answer two main research questions: (1) How do ethical principles shape the governance of AI in health across these three regions? and (2) What lessons can Indonesia draw from the EU and US experiences to strengthen its own governance framework? By combining ethical analysis with institutional comparison, this research contributes to a more nuanced understanding of how global norms of responsible AI can be localized in emerging health systems. This research lies in its integrative approach that connects ethical theory, policy design, and regulatory practice across contrasting contexts. Unlike existing studies that focus solely on technological or legal aspects, this paper situates AI in health within broader governance and value frameworks. By highlighting both common challenges and local specificities, it aims to provide insights for developing an ethically robust and context-sensitive governance model for AI in healthcare one that promotes innovation while safeguarding human dignity, rights, and equity.

METHOD

This study adopts a qualitative and comparative research design to analyze how ethical principles and governance structures shape the development and regulation of artificial intelligence (AI) in the healthcare sectors of Indonesia, the European Union (EU), and the United States (US). The methodology integrates normative ethical analysis, comparative policy evaluation, and institutional analysis to provide a holistic understanding of cross-regional differences and commonalities in AI

health governance. The research is based on a qualitative comparative approach that seeks to identify similarities and differences in ethical and governance frameworks across three case studies: Indonesia, the EU, and the US. This design is appropriate for exploring complex social, legal, and institutional processes that cannot be captured through quantitative methods. The comparative framework enables the study to assess how ethical norms are institutionalized within different regulatory and cultural contexts, and how these arrangements influence the implementation of AI in health systems. The study follows a three-stage process. First, it identifies and describes the ethical principles and governance instruments relevant to AI in healthcare in each jurisdiction. Second, it compares their scope, structure, and enforcement mechanisms using a common analytical framework. Third, it synthesizes the findings to highlight best practices and lessons applicable to Indonesia's emerging governance landscape.

RESULT AND DISCUSSION

AI in Healthcare: Ethical Challenges and Global Context

The growing integration of artificial intelligence (AI) into healthcare systems has transformed how medical data are analyzed, diagnoses are made, and treatments are delivered. Machine learning algorithms now assist in interpreting medical imaging, predicting disease progression, and personalizing therapeutic interventions. At the same time, the use of big data and AI introduces profound ethical dilemmas related to privacy, bias, explainability, and accountability. These challenges transcend national boundaries, requiring coordinated global governance frameworks to ensure that innovation aligns with ethical and human rights standards.

Ethical Dilemmas in AI for Health

One of the central ethical concerns surrounding AI in healthcare is data privacy (Bavli et al., 2025). AI systems rely on vast quantities of sensitive health information, often drawn from electronic medical records, genomic databases, and real-time monitoring devices (Rani et al., 2025). The aggregation and analysis of such data can yield powerful insights, yet they also expose patients to risks of unauthorized access, misuse, or reidentification (Abouelmehdi et al., 2018). Inadequate safeguards may lead to violations of confidentiality, eroding the trust that underpins the patient–physician relationship (Pai, 2025). This challenge is particularly acute in developing countries, where data protection laws and cybersecurity infrastructures are still evolving (Bechara & Schuch, 2021). The ethical imperative, therefore, is to ensure that personal health data are processed transparently, with informed consent and robust security measures in place (Lin, 2025). A second major issue concerns bias and discrimination embedded within algorithmic systems (Kordzadeh & Ghasemaghaei, 2022). Because AI models learn from historical data, they often reproduce or amplify existing inequities present in those datasets (Moore, 2022). In healthcare, this can manifest as unequal diagnostic accuracy across populations, particularly affecting minority groups or individuals with underrepresented genetic or demographic profiles. Studies such as Obermeyer et al. (2019) have shown that racial bias in healthcare algorithms can lead to the systematic underestimation of medical needs for certain groups (Obermeyer et al., 2019a). The ethical challenge here lies not only in detecting and correcting bias but also in confronting the structural inequalities that shape the data itself. The third dilemma relates to explainability and transparency. Many AI systems, especially those based on deep learning, operate as "black boxes," (ŞAHiN et al., 2025) producing outcomes that even developers may find difficult to interpret (Hassija et al., 2024). In medical contexts, opacity poses serious risks because healthcare professionals must understand and justify the basis for clinical decisions (Alizadeh et al., 2025). Ethical and legal frameworks increasingly call for "explainable AI" that allows for human understanding of the logic behind algorithmic outputs (Akhtar et al., 2024a). This requirement supports accountability, patient safety, and informed consent but remains technically complex to achieve without compromising model performance (Akhtar et al., 2024b; Kataria & Rani, 2025).

Another critical ethical issue involves consent and autonomy. Traditional models of medical consent assume that patients can understand the procedures and risks associated with a given treatment (Wiertz & Boldt, 2022). However, when AI systems are used in diagnosis or decision support, the mechanisms and implications of data processing are often opaque to both patients and clinicians (Ogut, 2025). Informed consent thus becomes more procedural than substantive, raising

questions about whether patients truly understand how their data are used and how automated systems influence their care (Tarantini et al., 2025; Chau et al., 2025). To uphold autonomy, consent mechanisms must evolve to accommodate the informational complexity of AI technologies, ensuring that patients retain meaningful control over their data (Lu et al., 2024). Finally, accountability remains a persistent ethical and legal challenge. When AI systems make or influence clinical decisions, determining who is responsible for errors becomes difficult (Bleher & Braun, 2022). Is it the physician who relied on the AI's output, the developer who trained the model, or the institution that deployed it? Without clear lines of accountability, affected individuals may struggle to seek redress for harm. Ethical governance requires that responsibility be distributed transparently across actors, supported by traceable documentation and continuous human oversight.

The Role of Big Data and Machine Learning in Diagnosis and Treatment

The ethical challenges of AI are deeply intertwined with the role of big data in modern healthcare (Majnarić et al., 2021). Machine learning models depend on large, diverse datasets to identify patterns and make predictions that exceed human analytical capacities (Najafabadi et al., 2015). In diagnostics, AI assists radiologists in detecting tumors, ophthalmologists in identifying retinal diseases, and pathologists in classifying cell abnormalities (Saleh et al., 2022; Lamba, 2025). In treatment, predictive analytics help clinicians design personalized therapies, anticipate complications, and allocate medical resources more efficiently. However, the scale and sensitivity of health data also magnify ethical and technical risks. Data collected from wearable devices, mobile health apps, and online platforms blur the boundary between medical and non-medical information. Commercial data brokers often possess extensive health-related datasets, raising questions about ownership, consent, and the commodification of personal health information. Furthermore, the global circulation of health data complicates jurisdictional accountability: data stored in one country may be processed in another under different legal and ethical regimes. The use of big data also introduces challenges related to data quality and representativeness. Poorly curated or biased datasets can lead to erroneous predictions, which in healthcare may have life-or-death consequences. Ensuring that AI systems are trained on diverse, high-quality data is therefore an ethical as well as a technical priority. Additionally, the constant updating of algorithms through continuous learning processes demands dynamic oversight mechanisms that traditional regulatory systems are often ill-equipped to handle. In short, the role of big data in healthcare is double-edged: it offers unprecedented opportunities for medical advancement but simultaneously heightens the risks of surveillance, discrimination, and loss of autonomy. Addressing these tensions requires governance frameworks capable of balancing innovation with human rights protection.

International Governance Initiatives

Recognizing the global nature of AI's ethical challenges, several international organizations have developed frameworks to guide responsible AI development and deployment in healthcare. The World Health Organization (WHO) published its Guidance on Ethics and Governance of Artificial Intelligence for Health in 2021, articulating six core principles: protecting human autonomy; promoting human well-being and safety; ensuring transparency, explainability, and intelligibility; fostering responsibility and accountability; ensuring inclusiveness and equity; and promoting responsiveness and sustainability. The WHO framework emphasizes that governments and developers must embed these principles throughout the AI lifecycle from data collection and algorithm design to deployment and evaluation. The Organization for Economic Co-operation and Development (OECD) issued the OECD AI Principles in 2019, which were subsequently endorsed by the G20. These principles call for AI that is inclusive, transparent, robust, and accountable, while upholding human-centered values and fairness. The OECD also promotes international cooperation in AI policy, recognizing that no single jurisdiction can address the global implications of AI alone. UNESCO's Recommendation on the Ethics of Artificial Intelligence, adopted in 2021 (Van Norren, 2023; Ganbaatar, 2025), represents another milestone in global AI governance. It sets out a comprehensive human rights-based framework that emphasizes dignity, equality, and environmental sustainability. The recommendation urges member states to establish ethical impact assessments, independent oversight bodies, and mechanisms for redress and accountability (Stewart, 2014). It also stresses the importance of ensuring that AI development does not exacerbate social inequalities or infringe on

cultural diversity (Mukherjee, 2025). Together, these initiatives mark a significant step toward building a global ethical consensus on AI in health. However, their implementation remains uneven. High-income regions such as the EU have incorporated many of these principles into binding legislation, while developing countries, including Indonesia, are still in the process of adapting them to local contexts. The effectiveness of global frameworks therefore depends on national capacities, institutional commitment, and the extent to which ethical principles are translated into enforceable governance structures. AI technologies hold immense promise for advancing medical science and improving healthcare delivery, but they simultaneously generate new ethical tensions that test the boundaries of existing regulatory systems. Issues of privacy, bias, transparency, consent, and accountability are not confined to individual nations; they are transnational challenges that require coordinated ethical governance. Big data and machine learning, while indispensable for modern health innovation, also magnify the risks of inequity and surveillance. International frameworks by WHO, OECD, and UNESCO provide essential guidance, yet their real impact depends on how effectively individual countries integrate ethical commitments into practical governance mechanisms.

Case Analysis

Indonesia

The integration of artificial intelligence (AI) into Indonesia's healthcare system has expanded rapidly in recent years, reflecting the country's broader push toward digital transformation (Herman et al., 2022). The government's vision, outlined in the Digital Health Blueprint (2021–2024) (Futri & Naruetharadhol, 2025); (McKenna et al., 2025) and the Health Transformation Agenda (*Agenda Transformasi Kesehatan*), seeks to modernize healthcare delivery, strengthen disease surveillance, and promote equitable access to medical services across the archipelago. AI has begun to play an increasingly important role in these initiatives, particularly in public health monitoring, telemedicine, and medical diagnostics. While the potential benefits for improving health outcomes are substantial, Indonesia continues to face significant ethical and governance challenges in ensuring that AI is used responsibly, fairly, and transparently.

Emerging Use of AI in Public Health, Telemedicine, and Diagnostics

AI applications in Indonesia's health sector are emerging in several domains. In public health, machine learning algorithms are being used to analyze epidemiological data and support disease surveillance (Putri et al., 2024; Sakti et al., 2025; Ahmad et al., 2022). AI systems have been applied to predict dengue fever outbreaks (Jaya et al., 2025), monitor the spread of COVID-19, and allocate medical resources more efficiently. These systems help enhance early warning capabilities and enable more data-driven policy responses, particularly in areas with limited medical expertise. In clinical practice, hospitals and technology start-ups have begun integrating AI tools for diagnostic support, especially in medical imaging (Kulkov, 2023; Bellina & Jungmann, 2023; Alexander et al., 2020). AI-assisted radiology is being used to detect tuberculosis (Acharya et al., 2022), pneumonia (Ippolito et al., 2023), and CT scan images (Yan et al., 2022), addressing the shortage of medical specialists in rural regions. Telemedicine platforms such as *Halodoc* and *Alodokter* have also accelerated the use of AI-driven chatbots and virtual assistants for patient triage, symptom assessment, and personalized medical advice developments that expanded rapidly during the COVID-19 pandemic. The Ministry of Health has launched the *SATUSEHAT* platform to integrate patient data from both public and private healthcare providers. This digital infrastructure is intended to create a unified national health database that can support AI analytics and decision-making. However, the growing reliance on digital platforms and AI technologies raises concerns about data quality, cybersecurity, and the uneven distribution of digital infrastructure between urban and rural regions.

Legal and Policy Framework

Indonesia's legal and policy framework for AI in healthcare is still evolving and remains fragmented (Rahman, 2024). A major step forward was the enactment of the Personal Data Protection Law (Undang-*Undang Nomor 27 Tahun 2022 tentang Perlindungan Data Pribadi, or UU PDP*), which provides the first comprehensive legal foundation for data governance in Indonesia. The law incorporates principles such as data minimization, consent, purpose limitation, and the protection of sensitive personal information, including medical data. In healthcare, it mandates that the processing

of patient information requires explicit consent and must adhere to strict security standards. In parallel, the Digital Health Blueprint (2021–2024) provides a strategic vision for transforming Indonesia's health sector through digital innovation. It highlights priorities such as interoperability, cybersecurity, and the establishment of governance mechanisms for new technologies, including AI. Similarly, the Health Transformation Agenda identifies AI as a key enabler across six pillars of reform primary care, referral systems, health resilience, financing, technology, and human resources emphasizing its role in diagnostics, disease prevention, and digital record management. Despite these initiatives, Indonesia still lacks specific regulations or binding ethical guidelines for AI in healthcare. Policies issued by the Ministry of Communication and Informatics (*Kominfo*) and the National Research and Innovation Agency (*BRIN*) encourage responsible AI use but are largely advisory. There is no independent body dedicated to AI ethics oversight, and institutional accountability remains weak. Consequently, the responsibility for managing ethical risks often falls on individual healthcare providers and private technology companies, leading to uneven standards across the sector.

Ethical and Governance Challenges

The integration of artificial intelligence (AI) into Indonesia's healthcare system reflects a complex interplay between technological innovation, regulatory preparedness, and structural inequality. To move beyond descriptive accounts, these challenges can be systematically examined through socio-technical governance theory, which highlights misalignments between emerging technologies and institutional capacities (Choi & Zo, 2019), and through the normative principles of responsible AI, including fairness, accountability, and transparency (Floridi & Cowls, 2019). Situating Indonesia's experience within these theoretical frameworks reveals that the core governance issues data protection, ethical oversight, inequality, and private-sector dominance are manifestations of deeper structural constraints rather than isolated policy failures. Data protection enforcement exemplifies a pronounced regulatory lag, a condition in which technological developments outpace legal and institutional responses (Mance, 2022). Although Indonesia's Personal Data Protection Law establishes a formal rights-based framework, its implementation has been hindered by the delayed formation of an independent supervisory authority and weak institutional capacity among healthcare providers. Empirical evidence of repeated health-data breaches involving major digital platforms underscores the enforcement deficit and its implications for patient autonomy and trust. In settings where public institutions are under-resourced, such symbolic or "paper-based" compliance is common and often leads to performative rather than substantive protections (Scherer, 2015). As a result, the law currently risks functioning more as a normative aspiration than a functional governance mechanism.

A second structural gap lies in ethical oversight of AI systems**,** which requires institutional expertise in algorithmic accountability, bias detection, and model transparency. Most hospital ethics committees in Indonesia remain rooted in the biomedical research tradition and are ill-equipped to assess socio-technical risks embedded in AI systems. This reflects a broader global finding that clinical governance structures lag behind the epistemic challenges posed by AI, including the opacity of algorithmic decision-making ("black box" models) and the difficulty of securing meaningful informed consent for automated decision support (Khatiwada et al., 2024a; Mittelstadt, 2019a). As AI systems become more embedded in diagnostic and triage workflows, insufficient ethical oversight amplifies the risk of unaccountable or biased clinical outcomes. Structural digital inequality further constrains Indonesia's ability to ensure equitable access to AI-enabled healthcare. Applying theories of technological distributive justice (Schroeder, 2018), disparities in broadband access, digital literacy, and facility readiness disproportionately disadvantage rural and remote regions. Empirical studies in Southeast Asia consistently show that digital health innovations tend to concentrate in urban centers, reinforcing existing socioeconomic divides (Khatiwada et al., 2024b). This spatially uneven diffusion of AI risks exacerbating health inequities by restricting the benefits of innovation to populations with existing infrastructural and socioeconomic advantages. A critically underexplored dimension is the dominance of private-sector actors in Indonesia's digital health landscape. Theoretical perspectives on platform capitalism and datafication suggest that when digital health innovation is driven primarily by private platforms, commercial imperatives often shape data governance practices more strongly than public-interest considerations (Longhofer & Winchester, 2023; Dijck et al., 2018). Many widely used AI-driven applications in Indonesia rely on extensive data extraction, yet operate with limited

transparency regarding algorithmic processes, secondary data use, or privacy safeguards. Without strong public oversight, health data risks becoming a commodity rather than a protected public good, creating tensions between corporate innovation and rights-based governance. This dynamic mirrors global concerns that privatized AI ecosystems can magnify asymmetries of power and weaken state capacity to regulate AI in the public interest (Evenett, 2021). Taken together, these challenges illustrate that Indonesia's AI-in-healthcare trajectory is not merely shaped by technological readiness but by broader governance configurations. Ensuring that AI contributes to ethically sound and equitable healthcare transformation requires strengthening regulatory enforcement, institutionalizing AI-specific ethical review processes, imposing clearer accountability obligations on private actors, and closing structural digital gaps. Grounding these reforms in established theoretical frameworks situates Indonesia's experience within global debates on responsible and justice-oriented AI governance, offering conceptual contributions that extend beyond empirical description.

European Union

The European Union (EU) has emerged as one of the global leaders in establishing ethical and regulatory frameworks for artificial intelligence (AI), particularly in the field of healthcare (Meszaros et al., 2022; Schmidt et al., 2024). The EU's approach reflects its broader commitment to human rights, data protection, and technological accountability. Healthcare innovation in the region is deeply intertwined with these principles, combining advanced research and digital infrastructure with strong institutional mechanisms for oversight. However, even within this comprehensive governance ecosystem, ethical challenges persist, especially regarding data sharing, algorithmic bias, and the balance between innovation and regulation.

Development and Application of AI in Healthcare

AI has become a cornerstone of the EU's digital health strategy (Cohen et al., 2020). Member states have adopted AI applications across diverse areas, including medical imaging, clinical decision support, precision medicine, and public health management (Pesapane et al., 2018; Stenzinger et al., 2023; Tang et al., 2025). European hospitals are using AI to detect cancer (Hunter et al., 2022); (Hesso et al., 2024), identify cardiovascular risks (Sau et al., 2024; Romiti et al., 2020; Siontis et al., 2021), and assist in surgical planning (Klumpp et al., 2021). AI-driven platforms also support health system efficiency through predictive modeling of hospital admissions and the optimization of treatment pathways. The European Commission's "European Health Data Space" (EHDS) initiative, launched in 2022 (Marelli et al., 2023; Terzis & Santamaria Echeverria, 2023; Hussein et al., 2024; Hussein et al., 2023), seeks to create a unified digital ecosystem where health data can be securely shared across member states for research, innovation, and policy-making. This initiative underpins the development of AI systems capable of drawing on large, interoperable datasets while ensuring privacy and consent mechanisms consistent with EU law. Several member states have also implemented national strategies that promote AI in healthcare. For example, Germany's "AI Strategy for Health" focuses on clinical data infrastructure and ethical AI research (Radic et al., 2024), while France's "Health Data Hub" supports secure access to aggregated medical datasets for algorithmic development (Szeftel et al., 2025). Collectively, these initiatives illustrate a coordinated European effort to harness AI while embedding strong ethical and legal safeguards.

Legal and Policy Framework

The EU's AI governance is anchored in a robust legal foundation centered on human rights, privacy, and transparency. The General Data Protection Regulation (GDPR), enacted in 2018 (Voigt & Von Dem Bussche, 2017a), remains the cornerstone of data ethics in the European context. The GDPR establishes strict rules for processing personal data, emphasizing informed consent, purpose limitation, and the right to data access, rectification, and erasure. Importantly, it categorizes health data as "special category data," requiring heightened protection and explicit consent for processing. Building on this foundation, the Artificial Intelligence Act (AI Act) expected to take effect in 2025 introduces the world's first comprehensive legal framework for AI regulation (Van Kolfschooten & Van Oirschot, 2024; Rudschies & Schneider, 2025). The Act adopts a risk-based approach, categorizing AI systems into minimal, limited, high, and unacceptable risk tiers. AI applications in healthcare generally fall under the "high-risk" category due to their potential impact on human life

and well-being. High-risk systems will be subject to stringent requirements for transparency, human oversight, data quality, and post-market monitoring. In addition to these binding laws, the Ethics Guidelines for Trustworthy AI, published by the European Commission's High-Level Expert Group on Artificial Intelligence in 2019, outline seven key principles: human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination, and fairness; societal well-being; and accountability. These guidelines have significantly influenced AI policy across member states and serve as a reference point for ethical practice in both public and private sectors. Furthermore, the EU's Digital Europe Programme and Horizon Europe research funding initiatives provide financial and institutional support for the ethical development of AI technologies in healthcare. These programs encourage the creation of human-centered AI systems, integrating ethical assessment mechanisms throughout the research and innovation process.

Ethical and Governance Challenges

Artificial intelligence has become an integral part of the European healthcare landscape (Lampreia et al., 2024), offering the promise of enhanced diagnostic accuracy (Khalifa & Albadawy, 2024), personalised treatment (Beccia et al., 2022), predictive analytics (Mehta et al., 2019), and system-wide efficiency (Basile et al., 2025). Despite these benefits, its rapid expansion raises deep ethical and governance challenges that the European Union must address carefully. Existing regulatory frameworks such as the General Data Protection Regulation (GDPR) (Tamburri, 2020), the forthcoming EU AI Act, and sector-specific health regulations provide a foundation for responsible AI development. However, these frameworks also reveal persistent gaps concerning data protection, transparency, accountability, fairness, and cross-border data governance, all of which shape the broader debate about trustworthy and ethical AI in healthcare. A central challenge concerns the protection of personal data and patient privacy. AI depends heavily on large volumes of sensitive health information, including genomic profiles, electronic health records, and behavioural data. GDPR classifies such information as special category data requiring strict safeguards and lawful bases for processing (Voigt & Von Dem Bussche, 2017b). Although GDPR aims to empower individuals with rights related to access, consent, and data portability, the regulation encounters difficulties in the context of AI systems that rely on secondary use of data for purposes beyond those originally communicated. This complicates long-term informed consent, especially as algorithms are continually updated, retrained, or used in new clinical contexts without direct patient involvement (Floridi et al., 2021). Additionally, differences in how EU member states interpret GDPR provisions often hinder cross-border data flows, producing bureaucratic obstacles that slow scientific collaboration and medical research (Thorogood & Chokoshvili, 2023).

Equity and fairness are also significant governance concerns. AI systems trained on incomplete or demographically skewed datasets risk producing biased predictions that disproportionately affect minority or underserved populations. Studies show that algorithms trained primarily on European-descendant populations may underperform when diagnosing diseases in diverse groups, thereby exacerbating existing health inequalities (Rajkomar et al., 2018). Although the EU AI Act designates medical AI systems as high-risk and requires rigorous dataset quality controls, continuous monitoring, and documentation, scholars argue that technical requirements alone cannot correct deeper structural inequalities embedded in health systems (Mittelstadt, 2019b). Addressing fairness therefore requires governance approaches that incorporate social, institutional, and ethical considerations beyond narrow technological fixes. Transparency and explainability represent another major area of concern. Machine-learning models, particularly deep neural networks, often function as opaque systems whose internal logic is not easily interpretable by clinicians or patients. This lack of clarity challenges clinician autonomy and undermines the patient's ability to make informed decisions. Debates surrounding the right to explanation under GDPR highlight the need for meaningful insight into how AI-generated clinical recommendations are produced (Goodman & Flaxman, 2017). The EU AI Act attempts to address this by mandating traceability, technical documentation, and oversight mechanisms. Nevertheless, experts argue that strict explainability requirements may conflict with the performance of highly complex models, suggesting an unresolved tension between accuracy and interpretability (Castelvecchi, 2016).

Questions of responsibility and liability further complicate the integration of AI into healthcare. Determining who is accountable when AI-supported clinical decisions lead to harm is

challenging because of the distributed nature of AI development and deployment. Traditional laws such as the Product Liability Directive and the Medical Device Regulation were not designed for adaptive AI systems that evolve beyond their initial programming (Schuilenburg & Peeters, 2020; Ebers & Cantero Gamito, 2021). As AI becomes more autonomous, the boundaries between developer responsibility, clinical judgment, and institutional oversight become increasingly blurred. The European Commission's proposed AI Liability Directive seeks to clarify fault and burden-of-proof standards, but significant uncertainties remain, particularly for self-learning systems or situations involving shared responsibility. Cross-border data sharing and interoperability present additional governance challenges within the EU. Effective AI applications require harmonised infrastructures, standardized data formats, and reliable cybersecurity measures across member states. However, the EU still experiences wide disparities in the digital maturity of national health systems, complicating efforts to build integrated datasets or implement uniform AI solutions (Carvalho & Kazim, 2022). Initiatives such as the European Health Data Space aim to address these challenges by creating a more coherent framework for data sharing, research access, and patient rights. Yet concerns persist regarding data sovereignty, secure information exchange, and the involvement of private technology companies, particularly non-EU actors, in handling European health data.

Underlying all these issues is the challenge of sustaining public trust. European citizens generally support the use of AI in healthcare but remain cautious about privacy risks, commercial exploitation of health data, and broader concerns related to algorithmic surveillance (Fritsch et al., 2022). Ethical guidelines developed by bodies such as the European Group on Ethics emphasise human dignity, solidarity, and social justice, but critics argue that such guidelines often lack enforceability and function more as aspirational standards than operational governance tools (Jobin et al., 2019). Translating high-level ethical principles into concrete practices such as algorithmic impact assessments, independent audit mechanisms, or participatory decision-making remains an ongoing challenge. Overall, while the European Union has positioned itself as a global leader in promoting trustworthy and human-centered AI, healthcare presents a uniquely sensitive domain requiring continuous regulatory evolution. The governance gaps identified in data protection, bias mitigation, transparency, liability, interoperability, and societal trust illustrate that technological advancement must be matched with robust ethical oversight. The combination of GDPR, the AI Act, and the European Health Data Space provides a strong normative foundation; however, effective and ethical integration of AI into healthcare will require ongoing coordination among policymakers, clinicians, patients, industry actors, and researchers to ensure that innovation serves public welfare while upholding fundamental rights.

United States

The United States represents a distinctive model of AI governance in healthcare one characterized by strong innovation capacity, decentralized regulation, and an active private sector. Unlike the European Union's centralized and principle-based approach, the U.S. system relies on a patchwork of federal and state-level frameworks, combined with sector-specific oversight and industry-driven standards. This fragmented structure has allowed rapid technological advancement and commercialization but has also created gaps in ethical and regulatory accountability, particularly concerning health data, algorithmic fairness, and corporate influence.

Development and Application of AI in Healthcare

AI has become deeply embedded in the U.S. healthcare landscape, driving innovation in diagnostics, personalized medicine, and clinical decision support. Hospitals and biotechnology companies employ machine learning to analyze medical imaging, predict disease progression, and optimize treatment regimens. Major institutions such as the Mayo Clinic, Cleveland Clinic, and Johns Hopkins University have partnered with technology firms like Google Health and IBM Watson to develop AI-powered diagnostic and analytics tools (Gupta et al., 2025a; Tyagi & Sharma, 2021). The U.S. also leads in precision medicine and genomic research, where AI is used to process massive datasets linking genetic information to clinical outcomes (Prosperi et al., 2018; Abbas et al., 2025). AI-driven drug discovery platforms, predictive health analytics, and virtual assistants are being adopted widely in both clinical and consumer health contexts. Telehealth platforms such as Teladoc and Amwell integrate AI algorithms for symptom triage and patient engagement, especially after the

COVID-19 pandemic accelerated digital healthcare adoption. At the same time, these advances have heightened ethical concerns around data security, patient privacy, and algorithmic accountability. Because most innovation is driven by private corporations, data ownership and access often remain in the hands of technology firms rather than patients or healthcare institutions, raising questions about transparency and the commodification of health information.

Legal and Policy Framework

The regulatory landscape for AI in healthcare in the United States is decentralized, reflecting the broader structure of the American legal system (Pesapane et al., 2021). Several key federal institutions play central roles in establishing ethical and technical standards for AI. The Food and Drug Administration (FDA) serves as the primary regulator for AI-based medical devices and software as a medical device (SaMD) (Mahler et al., 2021; Shah et al., 2025). The FDA's 2019 framework for AI and machine learning–based medical devices introduced a "total product lifecycle" approach, emphasizing premarket review, algorithmic transparency, and ongoing post-market monitoring (Benjamens et al., 2020). This adaptive regulatory model allows for continuous learning systems while ensuring patient safety and performance reliability. However, the FDA's oversight applies mainly to products categorized as medical devices, leaving many AI health applications such as wellness apps or administrative tools outside its jurisdiction. The Department of Health and Human Services (HHS) oversees broader health technology governance, including the protection of patient information under the Health Insurance Portability and Accountability Act (HIPAA). HIPAA provides rules for the collection, storage, and sharing of personal health data but was originally designed before the rise of large-scale digital analytics (Estrada-Galiñanes & Wac, 2020). As a result, it does not adequately address new forms of data generated by wearable devices, health apps, or non-traditional providers, leaving regulatory blind spots. The National Institutes of Health (NIH) also plays a role in promoting ethical AI research. Through its "Bridge2AI" initiative, the NIH funds projects that integrate ethical principles, data diversity, and interdisciplinary collaboration in AI development (Clark et al., 2024; Pacia et al., 2024). These initiatives aim to ensure that AI tools are not only technically sound but also socially and ethically responsible.

Ethical Frameworks and National Initiatives

In addition to agency-specific policies, the U.S. has introduced national frameworks to guide the ethical use of AI. The National Institute of Standards and Technology (NIST) released the AI Risk Management Framework (AI RMF) in 2023, providing a voluntary yet influential structure for identifying, assessing, and mitigating AI-related risks. The framework emphasizes transparency, fairness, accountability, and privacy protection, promoting responsible innovation across industries, including healthcare. Complementing this, the White House introduced the Blueprint for an AI Bill of Rights in 2022, outlining five key principles for the responsible use of AI: (1) protection from unsafe or ineffective systems, (2) algorithmic discrimination protections, (3) data privacy, (4) notice and explanation, and (5) human alternatives and fallback options. Although non-binding, this framework signals a normative commitment to human-centered AI governance and provides a reference point for both public agencies and private corporations developing AI technologies in healthcare.

Ethical and Governance Challenges

Artificial intelligence (AI) has become a central component of contemporary health-system innovation in the United States (Monlezun, 2023b), promising greater diagnostic accuracy, improved efficiency, and more personalized clinical decision support (Monlezun, 2024). Its rapid diffusion across hospitals, insurers, digital health companies, and public-health agencies reflects not only technological enthusiasm but also structural pressures to reduce costs and increase productivity. Yet, the deployment of AI in the U.S. healthcare landscape raises a complex web of ethical and governance challenges that call for rigorous examination. These challenges do not arise from technological shortcomings alone; rather, they emerge from the interaction between proprietary algorithms, fragmented health governance, uneven regulatory capacity, and longstanding structural inequalities. Understanding these dynamics is crucial for ensuring that AI contributes to equitable, trustworthy, and clinically meaningful healthcare delivery. One of the most widely recognized ethical concerns in the U.S. context is the reproduction of racial and socioeconomic bias through algorithmic

decision-making (Véliz, 2023). AI systems trained on historical clinical and billing data are susceptible to encoding patterns of discrimination that have long characterized American healthcare (Thesmar et al., 2019). The widely cited study by Obermeyer and colleagues (2019) reveals how a prominent commercial risk-prediction algorithm disproportionately underestimated the health needs of Black patients because it relied on healthcare expenditures as a proxy for illness severity (Obermeyer et al., 2019b). Since Black patients historically receive less care and have lower spending despite higher disease burdens, the algorithm inadvertently labeled them as "lower risk," thereby limiting their eligibility for targeted interventions (Haider et al., 2024). This case is emblematic of a broader pattern: proxies used for AI development often mask structural inequities, allowing algorithms to appear neutral while producing unequal outcomes. Such findings challenge the notion that technical optimization alone can rectify systemic disparities and underscore the ethical imperative of scrutinizing model assumptions, training data provenance, and embedded value judgments.

Beyond bias, issues of transparency and explainability remain central to ethical governance. Many state-of-the-art AI models, especially deep-learning systems used in diagnostic imaging or predictive analytics, operate as "black boxes" whose internal logic is opaque to both clinicians and patients (Nazir et al., 2024). In a healthcare environment that relies on informed consent and shared decision-making, opacity undermines the epistemic authority of clinicians and erodes patient trust. The National Academy of Medicine stresses that meaningful explainability is not merely a technical preference but an ethical requirement when AI informs high-stakes medical decisions (Matheny et al., 2022). Clinicians must be able to understand, challenge, and contextualize algorithmic outputs to maintain accountability and avoid uncritical automation bias. Without interpretability, AI risks becoming a source of epistemic asymmetry, concentrating knowledge within technology vendors rather than clinical professionals, and potentially reducing clinical autonomy. Data privacy represents another foundational challenge in the U.S. governance landscape. Unlike many other high-income countries, the United States lacks a comprehensive national data-protection law, instead relying on a patchwork of sector-specific regulations such as the Health Insurance Portability and Accountability Act (HIPAA). While HIPAA provides protections for identifiable health information handled by "covered entities," AI development frequently involves actors who fall outside HIPAA's scope, including technology companies, app developers, data brokers, and cloud-computing firms. The U.S. Department of Health and Human Services has repeatedly warned that common tracking technologies and third-party analytics tools may unintentionally disclose sensitive health information, even when organizations believe such data are "de-identified" (Gupta et al., 2025b). Moreover, advances in re-identification techniques challenge the assumption that data can ever be fully anonymized, raising concerns about consent, secondary use, and commercial exploitation. The ethical question extends beyond privacy alone: control over health data increasingly determines who can shape AI development, whose health needs are prioritized, and who benefits from algorithmic innovation.

Regulatory oversight continues to evolve but remains fragmented and, at times, lagging behind technological change. The Food and Drug Administration (FDA) has taken significant steps to regulate AI- and machine-learning-based software as medical devices (SaMD) (Gerke et al., 2020), acknowledging that adaptive algorithms require a lifecycle approach rather than a traditional one-time premarket evaluation. The FDA's 2021 Action Plan outlines intentions for real-world performance monitoring, transparency, and good machine-learning practices (Thakkar et al., 2023). Yet, practical implementation remains challenging. Adaptive systems that update continuously blur the boundary between development and deployment, complicating regulatory review and accountability. Furthermore, the rapid expansion of non-SaMD AI tools such as clinical decision support integrated into electronic health records or proprietary large language models used for documentation operates largely outside narrow device regulations. As a result, significant governance gaps persist, particularly regarding post-deployment monitoring, reporting obligations for failures, and liability in cases where AI-supported decisions cause harm. The legal ambiguity surrounding responsibility in AI-mediated care further complicates governance. Traditional malpractice frameworks assume clear lines of responsibility between clinician judgment, medical devices, and institutional obligations. AI disrupts this model by introducing probabilistic recommendations, automated suggestions, and vendor-controlled systems whose inner operations may not be fully disclosed to clinicians. Determining liability when an algorithm contributes to misdiagnosis becomes a complex negotiation between hospitals, AI developers, and clinicians. Without clearer standards for documentation, validation, and

human-oversight requirements, malpractice disputes may deter clinicians from integrating innovative AI tools or, conversely, encourage over-reliance on algorithmic recommendations as a form of defensive medicine.

Workforce dynamics also raise important ethical considerations. AI tools will inevitably redistribute clinical labor, automating administrative tasks and influencing diagnostic processes. While some commentators anticipate increased efficiency and reduced burnout, others warn of potential deskilling if clinicians become overly dependent on algorithmic suggestions. The American Medical Association has emphasized the need for "physician-led oversight of augmented intelligence" to ensure that AI supplements rather than supplants clinical expertise. Ethical deployment requires robust training, participatory design involving clinicians, and institutional support structures that allow professionals to critically engage with AI rather than passively accept its recommendations. If workforce adaptation is neglected, AI may deepen professional hierarchies or erode trust between clinicians and patients. The governance environment is further shaped by political and market dynamics. The U.S. government has sought to coordinate national AI policy through executive orders outlining principles of trustworthy AI and risk-management mandates, yet political transitions often introduce uncertainty about regulatory priorities. Private-sector actors, including major technology companies and health-tech startups, exert substantial influence on the pace and direction of AI adoption, sometimes pushing tools into clinical environments faster than institutions can rigorously evaluate them. This creates a tension between innovation and precaution: a rapid "deploy now, fix later" ethos may expose patients to untested or biased tools, while overly restrictive policies could hinder beneficial innovation. Balancing these competing imperatives requires governance mechanisms that prioritize public accountability, independent evaluation, and inclusive stakeholder engagement. In addition to institutional-level challenges, societal equity concerns remain paramount. AI has the potential either to mitigate or magnify health disparities depending on how it is designed, deployed, and governed. Ensuring equitable outcomes requires not only technical bias-mitigation strategies but also structural reforms addressing uneven data quality, differential access to digital health tools, and historical underrepresentation of marginalized communities in clinical datasets. Ethical AI governance therefore cannot be separated from broader debates about social justice, access to care, and community participation in health decision-making. Public-trust frameworks must go beyond compliance checklists and actively involve affected communities to legitimize AI use in clinical settings. The ethical and governance challenges of AI in U.S. healthcare arise from the interplay between sophisticated algorithms, fragmented regulation, structural inequities, and shifting professional norms. Addressing these challenges requires a comprehensive, multi-layered strategy: rigorous bias audits, transparent model documentation, adaptive regulatory strategies, clearer liability frameworks, robust privacy protections, clinician education, and meaningful public engagement. AI holds enormous potential to improve healthcare, but its benefits will only be realized if governance systems prioritize equity, accountability, and patient trust. The United States stands at a pivotal moment; the decisions made now will shape whether AI becomes a tool for health equity or a mechanism that reinforces existing disparities.

Indonesia's Position in the Global AI Governance Spectrum

Artificial Intelligence (AI) has become one of the most significant technological transformations influencing governance, economy, and social life across the globe (Abbas Khan et al., 2025; Kumar et al., 2024). The term AI governance spectrum refers to the diverse range of regulatory, ethical, and institutional frameworks that countries adopt to balance innovation, public trust, and accountability (Calo et al., 2017; Floridi, 2023). Within this global landscape, Indonesia's position remains emergent and adaptive, shaped by its developmental priorities, institutional capacities, and socio-cultural contexts. By comparing Indonesia to the European Union (EU) and the United States (US), one can identify how these different models of AI governance embody distinct philosophical orientations ranging from the EU's human-centric and precautionary approach to the US's innovation-driven and market-oriented framework and how Indonesia situates itself between these two poles. The European Union's approach to AI governance is characterized by a strong emphasis on ethical and legal safeguards designed to protect fundamental rights. The EU Artificial Intelligence Act (AIA), first proposed in 2021 (Neuwirth, 2023), introduces a comprehensive regulatory framework that classifies AI systems based on risk levels and mandates compliance standards for transparency,

accountability, and data protection (European Commission., 2021). This approach aligns with the EU's broader normative framework on digital rights, notably the General Data Protection Regulation (GDPR), which prioritizes citizen protection over market flexibility (Wagner, 2018). The EU's philosophy reflects a precautionary principle where technological innovation must proceed within clearly defined ethical boundaries (Floridi, 2023).

Conversely, the United States employs a more decentralized and innovation-centric governance model. Rather than a single, comprehensive federal law, the US relies on sector-specific regulations and voluntary frameworks, allowing industries to self-regulate under general guidance provided by federal agencies such as the National Institute of Standards and Technology (NIST) (Bryson et al., 2017; NIST, 2023). The US model embodies what scholars describe as experimentalist governance, in which flexibility, market dynamism, and technological advancement take precedence over preemptive regulation (Calo et al., 2017). This model has enabled rapid AI innovation, particularly in Silicon Valley, but has also raised concerns regarding bias, surveillance, and the erosion of privacy rights (Zuboff, 2023). Indonesia's approach to AI governance is situated within this global spectrum as an emerging and hybrid framework. The Indonesian government launched the National Artificial Intelligence Strategy 2020–2045 (*Strategi Nasional Kecerdasan Artifisial, STRANAS KA*) (Mardila, 2025), which identifies five strategic sectors: education, research, health, bureaucratic reform, and industrial innovation (Kemenristek/BRIN, 2020). The strategy emphasizes principles of ethical AI, digital literacy, data sovereignty, and human resource development. However, the implementation of these principles remains uneven due to institutional fragmentation, limited coordination among agencies, and infrastructural constraints. While the policy ambition seeks to position Indonesia as a regional leader in AI innovation, its regulatory mechanisms are still underdeveloped compared to the EU's legally binding approach or the US's robust innovation ecosystems.

Indonesia's institutional and regulatory landscape also reveals the complexities of aligning national strategies with global governance norms. The country operates under a decentralized administrative system, where regional governments possess significant autonomy but often lack digital governance capacity (Pratiwi, 2021). This decentralization creates discrepancies in policy execution, particularly in AI adoption within local governance, education, and healthcare sectors. Moreover, Indonesia's engagement in multilateral forums such as UNESCO's Recommendation on the Ethics of Artificial Intelligence (2021) and ASEAN's Guide on AI Governance and Ethics (ASEAN Secretariat, 2023; Tun et al., 2025) demonstrates its intention to integrate international ethical standards while localizing them within national and cultural contexts (Nugroho, 2025). When compared to the EU and the US, Indonesia occupies a transitional position in the AI governance spectrum. The EU represents a "compliance-first" model rooted in normative regulation, while the US follows a "market-first" model emphasizing innovation and competition. Indonesia, on the other hand, can be described as pursuing an adaptive governance model, seeking to balance national digital transformation goals with ethical and human-centered principles (Keith, 2024). This balancing act reflects Indonesia's developmental status: as a middle-income country, it aims to harness AI for economic growth and efficiency while preventing the social inequalities and ethical risks that accompany unregulated technological expansion. However, Indonesia's efforts face several structural challenges. These include limited research funding for AI innovation, a shortage of skilled digital labor, and the absence of comprehensive data protection legislation equivalent to the EU's GDPR or the US's sectoral privacy laws (Intani & Annisa, 2024). Furthermore, institutional capacity-building and inter-ministerial coordination remain crucial to transforming Indonesia's AI vision into effective governance practice (Holzhacker et al., 2016). Addressing these challenges requires not only technical and legal reform but also the cultivation of policy capacity defined as the institutional ability to anticipate, adapt, and respond to complex technological changes (Wu et al., 2015). Indonesia's position in the global AI governance spectrum can be described as emergent, hybrid, and adaptive. While the EU and the US represent two mature but contrasting poles ethical regulation versus market innovation Indonesia is still constructing its own AI governance pathway, informed by national priorities and global normative trends. The country's ability to build institutional resilience, policy capacity, and cross-sectoral coordination will determine whether it can evolve from a policy follower into a normative contributor within the global AI governance landscape. This comparative understanding not only highlights Indonesia's developmental trajectory but also reflects the broader

global tension between technological sovereignty, innovation, and ethical responsibility in the age of artificial intelligence.

CONCLUSION

The rapid integration of artificial intelligence into global healthcare systems illustrates a profound transformation in how medical knowledge is produced, interpreted, and operationalized. Across contexts from Indonesia to the European Union AI promises enhanced diagnostic accuracy, strengthened public health surveillance, and more efficient clinical decision-making. Yet these advancements unfold alongside complex ethical dilemmas that expose the fragility of existing governance structures. Core challenges such as data privacy, algorithmic bias, transparency, informed consent, and accountability reflect not merely technical shortcomings but deeper socio-institutional tensions that must be addressed to safeguard patient rights and public trust. The centrality of big data in AI-driven healthcare amplifies these concerns, revealing structural risks associated with data commodification, unequal distribution of digital infrastructure, and cross-border disparities in regulatory oversight. Indonesia's experience demonstrates how regulatory lag, weak institutional capacity, and private-sector dominance shape the governance landscape, leaving ethical safeguards unevenly implemented. While national initiatives such as the Personal Data Protection Law and the Digital Health Blueprint signal progress, the absence of AI-specific oversight bodies and persistent digital inequality constrain equitable and accountable AI deployment. Conversely, the European Union has established one of the world's most comprehensive AI governance frameworks, anchored in GDPR, the forthcoming AI Act, and extensive ethical guidance. Nevertheless, even this sophisticated ecosystem faces unresolved issues regarding cross-border data sharing, long-term consent, algorithmic transparency, and liability in adaptive AI systems. Taken together, these cases underscore that the ethical governance of AI in healthcare is inherently global, requiring alignment between national policies, international principles, and evolving technological realities. Frameworks introduced by the WHO, OECD, and UNESCO provide crucial normative foundations, but their effectiveness ultimately depends on how nations institutionalize oversight, enforce accountability, and ensure that innovation remains consistent with human rights, fairness, and social justice. As AI continues to permeate healthcare, its transformative potential must be matched by equally transformative regulatory commitments ones that embrace interdisciplinary expertise, protect the most vulnerable populations, and recognize that ethical governance is not a barrier to innovation but its necessary condition.

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