

## **GDPR AND HEALTHCARE: BALANCING DATA PRIVACY AND ACCESS TO MEDICAL INFORMATION**

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### **Abstract**

*This paper analyses the effect of GDPR on healthcare. The information provided by patients for their healthcare database is a personal information and cannot be made public under normal conditions. However, the regulations regarding the same have not been developed effectively and need a lot of modification. This paper analyses the same challenge. It tries to balance data privacy and data access in a way that artificial intelligence (AI) is allowed to develop in the health care domain while taking care that a patient's data is not exposed to the public. With reference to the General Data Protection Regulation (GDPR) in Europe, it is all the more necessary to consider the ethical concerns of data governance. The paper emphasises the need for an inclusive approach that considers both the benefits of AI and the protection of data privacy. It talks about the necessity of robust government data frameworks, stringent privacy protections, consent procedures, and data anonymization techniques. The rules and regulations applied in this domain need to be extremely clear for collection, storage, and processing of healthcare data. This is necessary to avoid any potential breach of data. This paper compares the various data governance strategies employed by European countries. This includes Germany's cautious approach that prioritises patient consent and Finland's more liberal approach to fostering big data legislation. It explains the difficulty that arises in both such systems while explaining the need for standardized and regulatory framework of healthcare data. The research also discusses privacy issues, the trade-off between data sharing and excessive data protection, and the challenges presented by biases in AI development. It suggests the development of efficient data governance frameworks and regulatory mechanisms to address the privacy issues. It emphasises on equitable resource allocation, evidence-based healthcare practises, and bridging the digital gap.*

**Keywords:** GDPR, Healthcare, Artificial Intelligence (AI), Privacy

### **Introduction**

Healthcare has a lot of prospects thanks to the expansion of digital health data and technological advancements in artificial intelligence (AI). AI has the ability to support many different

procedures, including administration, clinical research, personalised medicine, diagnosis, and drug discovery.<sup>1</sup> Large amounts of data must be accessed in order to employ AI in healthcare, which creates privacy issues. Numerous nations, especially those in the European Union (EU), have made significant investments in AI efforts, allocating budgets and increasing funding for AI-related healthcare projects.<sup>2</sup> While India is following the steps of GDPR through its Digital Personal Data Protection Bill, 2022, it is yet to be enacted. As of now, GDPR is applicable mostly to the EU nations.

In the context of healthcare AI, the intersection of advancing AI and safeguarding data privacy presents a complex challenge that requires careful consideration. On one hand, the expansion of AI in healthcare holds immense potential for improving patient outcomes, accelerating medical research, and revolutionizing healthcare delivery. AI-assisted systems can analyze vast amounts of health data along with recognizing patterns which can subsequently help enhance diagnosis, treatment, and personalized medicine. However, this reliance on data access raises significant concerns regarding privacy, security, and the ethical use of personal information.

The proposed Artificial Intelligence Act and Guidelines for Trustworthy AI<sup>3</sup> are two ethical and legal tools the European Commission has developed to direct the ethical design of AI systems.<sup>4</sup>

But there is a conflict between advancing AI and safeguarding data privacy. Striking a balance between the benefits of AI and the protection of data privacy necessitates both, the consideration of rights of individuals, along with societal benefits of advancing healthcare. It is crucial to establish robust data governance frameworks that enforce stringent privacy measures, consent mechanisms, and data anonymization techniques. Clear guidelines and regulations should be implemented that ensure the collection, storage and processing of data in a transparent way, with strong safeguards against unauthorized access, breaches, or misuse.

The need for diversified and high-quality healthcare data is emphasised in the proposed EU AI Act.<sup>5</sup> It takes careful planning and resource allocation to strike a balance between the privacy

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<sup>1</sup> N.J. Schork, N.J., *Precision medicine in Cancer therapy*, 265-283 (2019); N. Fleming, *How artificial intelligence is changing drug discovery*. NATURE, 55(2018);

<sup>2</sup> KPMG, <https://kpmg.com/xx/en/home/insights/2018/04/venture-pulse-q1-18-global-analysis-of-venture-funding.html> (last visited Jun. 28, 2023).

<sup>3</sup> N.A. Smuha, N.A., *The EU approach to ethics guidelines for trustworthy artificial intelligence*, COMPUTER LAW REVIEW INTERNATIONAL, 97-106 (2019).

<sup>4</sup> B. Custers et al., *EU personal data protection in policy and practice* (2019).

<sup>5</sup> S. McLennan et al., *Practices and attitudes of Bavarian stakeholders regarding the secondary use of health data for research purposes during the COVID-19 pandemic: Qualitative Interview Study* (2022).

threats posed by AI and its beneficial purposes.

### **GDPR Trends in different countries with respect to patient data**

Patient data is necessary for the creation and evaluation of AI models in applications connected to health. The GDPR, which aims to secure personal information and standardise data protection practises, is the primary legal foundation for data protection in Europe.<sup>6</sup> The varying approaches to data governance in European countries highlight the ongoing debate and challenges surrounding the balance between data privacy and advancing AI in healthcare. The GDPR does, however, permit Member States to enact derogations for public interest, academic, historical, or statistical purposes, resulting in a variety of data governance strategies across Europe.<sup>7</sup> Germany's emphasis on patient consent and strict data privacy rules demonstrates a cautious approach to protect individuals' personal information, which can limit the use of data for research. While Germany has a more thorough approach to control, emphasising patient consent for data processing<sup>8</sup>, countries like Finland take a more liberal approach, promoting big data and open data policies to facilitate research and public access to health information.<sup>9</sup> Big data and open data policies have been adopted by Finland, which also prioritises public education and offers online services for citizens to access health information.<sup>10</sup> While Finland's approach may foster development of new technologies and resource sharing, it also raises concerns about potential privacy risks and the need for robust safeguards. Germany, on the other hand, places a higher priority on patient consent and has rigorous data privacy rules, which researchers find to be confusing and limit the use of the research exemption.<sup>11</sup> In Germany, secondary health data research often requires either anonymization or consent. The differences in strategies across Europe highlight the complexity of navigating the ethical and legal landscape surrounding healthcare data and the ongoing need for harmonization and clarity to ensure responsible and beneficial use of AI in healthcare.

The difficulty in achieving a balance between data privacy and the advancement of AI in healthcare is highlighted by the complexity of data governance plans in Europe. To enable responsible data use, facilitate international partnerships, and realise the full potential of AI in

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<sup>6</sup> M. Shabani & P. Borry, *Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation*, EJHG 149-156 (2017).

<sup>7</sup> M.A. Bak et al., *Stakeholders' perspectives on the post-mortem use of genetic and health-related data for research: a systematic review*, EJHG 403-416 (2020).

<sup>8</sup> F. Molnár-Gábor et al., *Harmonization after the GDPR*, 84 SICB 271-283 (2018).

<sup>9</sup> T. Vrijenhoek et al., *Clinical genetics in transition*, JCG 12, 277-290 (2021).

<sup>10</sup> V. Jormanainen et al., *Half of the Finnish population accessed their own data*, FJHW 298-310.

<sup>11</sup> *Supra* at 2.

enhancing healthcare outcomes, the ethical and legal landscape must be harmonised and made clear.

### **Making the most of Artificial Intelligence's potential in healthcare**

There are trade-offs between data access and privacy due to the various methods to data governance in healthcare. These difficulties are a result of varying interpretations of GDPR requirements and different perspectives on juggling principles like solidarity and informational self-determination.<sup>12</sup> Making a decision between data access and privacy poses moral questions and may have repercussions for bias in AI development and privacy rights. Public opposition to liberal methods to data governance arises from worries about privacy, bias, and discrimination. Consent or anonymization are prioritised in restrictive techniques, although they might result in administrative challenges, biases in selection, and a lack of representativeness in the data. Full anonymization is becoming more and more elusive, and it might not even ensure people's privacy or the effectiveness of AI models.<sup>13</sup> There have been questions expressed regarding the impact on data sharing and AI innovation as well as the potential overprotection of personal data.<sup>14</sup> Due to differing interpretations of data legislation, disregarding the significance of data access could lead to lost investments in the development of AI public instruction.

The complex ethical and practical issues involved in healthcare data governance are reflected in the trade-offs between data access and privacy. The differing interpretations of the GDPR standards and the opposing principles at stake make it difficult to strike the correct balance. The decision-making process entails balancing privacy, bias, and discrimination concerns against the requirement for data access to support AI advancement. While consent or anonymization are prioritised by restricted procedures, these methods can also cause administrative difficulties, biases in selection, and restrictions in the representativeness of the data. Furthermore, obtaining complete anonymization is becoming more and more challenging, and it could not provide privacy or the best performance of AI models. Questions concerning the influence on data sharing, AI innovation, and the possible danger of overprotecting personal data are also raised by the discussions surrounding data governance. Ignoring the value of data access could lead to lost chances for public health AI developments.

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<sup>12</sup> A. Podgurski, *Balancing privacy, autonomy, and scientific needs in electronic health records research*, SMUL 85 (2012).

<sup>13</sup> M. Mostert et al., *Challenges to the consent or anonymise approach*, EJHG 956-960 (2016).

<sup>14</sup> M.C. Ploem et al., *Proposed EU data protection regulation is a threat to medical research*, BMJ 346, (2013).

A balanced and sophisticated strategy is needed to address the difficulties and trade-offs between data access and privacy in healthcare data governance. Engaging in open and transparent talks among stakeholders, such as politicians, researchers, healthcare professionals, and the general public, is necessary to strike the correct balance.

Clear rules and procedures should be established in order to preserve people's privacy while simultaneously enabling responsible and secure data exchange for research and AI development. This can be done by putting in place privacy-preserving technology, like secure data exchange platforms, encryption methods, and differential privacy techniques, which permit the analysis of aggregate data while protecting personal data.

It takes a complete approach that takes into account ethical issues, regulatory frameworks, technological advancements, and cultural expectations to correctly balance data access and privacy. We can traverse the complicated environment of data governance in healthcare, stimulate AI innovation, and make sure that the advantages of cutting-edge technology are realised while preserving privacy rights and addressing potential biases by integrating a variety of viewpoints and encouraging interdisciplinary discourse.

### **Is the extravagant spending on data privacy worth it?**

Due to rigorous and conflicting data governance policies in many nations, Europe's potential for healthcare AI is constrained.<sup>15</sup> Because of complicated data protection regulations, a lack of staff, and poor data governance frameworks, national public health institutions only occasionally deploy AI. Researchers want increased access to patient data in a secure setting while yet respecting privacy concerns in order to fully utilise the benefits of AI in healthcare.

To promote health AI innovation while protecting the privacy of patient data, policymakers must find the proper balance. Given the limited nature of public resources, it is unethical to prioritise the development of AI-driven solutions over other healthcare goals or data infrastructure development. Proposed rules, like the EU AI act, may restrict AI applications in healthcare if widespread access to pertinent healthcare data is not available. This would complicate issues even further.

Alongside the creation of AI tools, solid data governance and management frameworks like the European Health Data Space (EHDS) and interoperability standards for medical records should be built to solve these concerns. Prior to making significant investments in AI-driven

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<sup>15</sup> R. Haneef et al., *Innovative use of data sources: A Cross-sectional study of Data Linkage Practices across European Countries*, (2020).

healthcare technology, it is essential to invest in addressing data governance issues to prevent resource wastage.<sup>16</sup>

Additionally, focusing only on health AI could deprioritize approaches that don't use AI but have a track record of success. Aside from investing in AI, authorities should think about bolstering evidence-based approaches and tackling fundamental barriers to care given the unknown usefulness of AI treatments and their limited real-world impact.<sup>17</sup> This strategy recognises the necessity of combining human expertise and AI in healthcare.

Allocating resources fairly for health AI is a difficult undertaking that calls for thorough analysis of the advantages, constraints, and competing agendas. To fully realise the potential of AI developed on the healthcare system in Europe while respecting privacy and guaranteeing the efficiency of the entire healthcare system, it is necessary to balance data governance and resource allocation.<sup>18</sup>

Collaboration and cross-border knowledge sharing are essential for achieving the right balance in data governance and resource allocation for healthcare AI. European countries should cooperate to harmonise data privacy laws, simplify data exchange procedures, and establish uniform guidelines for moral AI development in the healthcare industry. This can be done through sharing best practises between nations, conducting collaborative research projects, and collaborating internationally.

Additionally, it is crucial to involve the general public in talks around healthcare AI. Concerns about data security, privacy, and the possible impact on healthcare results must be addressed. Policymakers may make sure that the creation and application of AI in healthcare are in line with social values and priorities by including patients, healthcare professionals, and advocacy groups.

Additionally, funds should be allocated to building the technical infrastructure required to facilitate the ethical application of AI in healthcare. Strong data management and storage systems, safe data exchange platforms, and continual education and training for healthcare personnel are all part of this.

The creation and application of AI-driven solutions can also be hastened by encouraging

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<sup>16</sup> Supra at 7.

<sup>17</sup> de Inversiones Innovation, B.B.E. and Advisory, *Artificial intelligence, blockchain and the future of Europe*, EIB (2021).

<sup>18</sup> A. D'Amour et al., *Underspecification presents challenges for credibility in modern machine learning*, TJMLR 10237-10297 (2022).

collaboration across academic, industrial, and healthcare institutions. Public-private partnerships can aid in bridging the gap between research and practical implementations, ensuring that AI technologies are approved, scalable, and adapted to the unique requirements of healthcare systems.

Europe can realise the full potential of healthcare AI while preserving privacy rights, providing fair access to healthcare, and improving the efficacy and efficiency of healthcare systems by adopting a comprehensive approach that takes into account ethical, legal, social, and technical issues. Europe will be able to handle the challenges of data governance and resource allocation in the age of healthcare AI through these cooperative efforts and a dedication to responsible innovation.

### **Ethical considerations of data access in Health sector**

The research on AI ethics usually overlooks the trade-offs between resource allocation and resource access as well as privacy in lieu of fairness and bias issues. Existing regulations, like those set forth by the EC, have a tendency to limit the ethical discussion to particular AI uses while ignoring more general moral conundrums.<sup>19</sup> Ethics debates concerning AI should be preceded by a larger conversation on priorities and public investments to assure accountability. Steps that involve identifying health needs and prioritising them, should receive more attention in the creation of health interventions.<sup>20</sup> This strategy is in accordance with the suggestions made by the World Economic Forum, which emphasise the value of examining strengths, weaknesses, opportunities, and dangers when developing national AI plans.<sup>21</sup> In the end, decisions about how to allocate resources and use technology entail political debates and trade-offs between conflicting values.

According to Norman Daniels, the emphasis should be on fair procedures and procedural values in the lack of agreement on substantive principles.<sup>22</sup> A useful approach for debating resource allocation in the context of digital health and ethical AI development is the Accountability for Reasonableness (A4R) concept, which highlights important requirements for justifiable decision-making in public health.<sup>23</sup> To ensure justice, decision-makers in EU nations should discuss the trade-offs between data privacy and the benefits of AI with a diverse set of stakeholders, including researchers, data subjects, clinicians, and others. This broad

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<sup>19</sup> Supra at 4.

<sup>20</sup> M.A. Bak, *Computing fairness: ethics of modeling and simulation in public health*, SIMULATION 98 (2022).

<sup>21</sup> L. Madzou, & P. Shukla, *A framework for developing a national Artificial Intelligence strategy*, WEF(2019).

<sup>22</sup> N. Daniels & J. Sabin, *Limits to health care*, PPA 303 (1997).

<sup>23</sup> P.H. Wong, *Democratizing algorithmic fairness*, P&T, 33, 225-244 (2020).

engagement, or "data democracy," strengthens public confidence and gives affected groups more influence.<sup>24</sup> Ethicists can help by providing insight into difficult moral dilemmas. For educated decision-making, clear understanding of the available funds and conflicting needs is essential. The morality of judgements regarding data privacy and access techniques ultimately depends on how well they adhere to procedurally fair, accountable, and transparent requirements.<sup>25</sup>

Interdisciplinary cooperation is essential to promote a thorough knowledge of the complicated challenges surrounding data protection, access, and resource allocation in AI ethics. Together, ethicists, legal professionals, lawmakers, healthcare workers, technologists, and members of the public should have open and inclusive debates.

It is crucial to take these conversations into account on a global scale as well. Collaboration between nations can help to set worldwide standards for ethical AI development in healthcare, identify shared values, eliminate discrepancies in resource allocation, and identify shared values. By leveraging the collective expertise and diverse perspectives from different regions, we can avoid a fragmented approach to AI ethics and work towards a more harmonized and globally applicable framework.

In addition, continual research and empirical investigations are required to improve ethical standards and influence governmental decisions. This entails analysing the societal gains and hazards connected with AI deployment in the healthcare industry, as well as the influence of AI interventions on various demographic groups, the efficacy of data governance systems, and more.

In the end, it takes a thorough awareness of the available resources and the competing needs within society to make informed decisions about data privacy, data access, and technology use. We cannot ensure that the development and application of AI in healthcare are consistent with the concepts of justice and serve the best interests of all concerned parties without adopting a transparent and accountable strategy that is based on fair procedures and procedural values.

## **Conclusion**

When developing and using AI in healthcare, trade-offs must be made between protecting personal data and optimising the capabilities of the technology. To solve this, nations should

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<sup>24</sup> M. Ienca et al., *Considerations for ethics review of big data health research*, 13 PLoS ONE (2018).

<sup>25</sup> S. McLennan et al., S., *The challenge of local consent requirements for global critical care databases*, 45 INTENSIVE CARE MEDICINE, 246-248 (2019).



develop standardised digital health programmes that embody their core values. In order for countries to convey their priorities and strike a balance between data access and privacy, public discussion is crucial. The chosen balance should manifest in European and national AI resource allocation.

It is critical to address the issue of the digital divide and discrepancies in access to technology in order to ensure the responsible and equitable allocation of resources for healthcare AI in Europe. Although artificial intelligence (AI) has the power to revolutionize healthcare, it is crucial to take accessibility and inclusion into account, especially for vulnerable populations or areas with low resources.

By encouraging digital literacy programmes and investing in infrastructure, especially in marginalised communities, efforts should be made to close the digital divide. Policymakers may ensure that the advantages of healthcare AI are not concentrated in select wealthy areas but are available to all people, regardless of their socioeconomic situation, by ensuring equal access to technology and promoting digital inclusion.

Furthermore, to achieve the ideal balance between AI and human competence in healthcare, an interdisciplinary approach is required. Even though AI has the potential to be innovative and efficient, healthcare personnel should still play a crucial role.

AI should be incorporated as an enhancement to human judgement, speeding up decision-making and increasing patient outcomes. Policymakers can ensure that funds are allocated to assist both AI developments and the development of a trained healthcare staff by recognising the significance of the human element in healthcare.