

The Use of Data in Public Health

Understanding the Potential for Artificial Intelligence in Medicine



Policy Department for Transformation, Innovation and Health
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Abstract

Artificial intelligence (AI) has the ability to transform healthcare for the benefit of both healthcare providers and patients. Implementing a framework that facilitates the (re-)use of data is pivotal to its advancement. However, the development and deployment of AI face various challenges. This study outlines some of the AI technologies applied in the healthcare sector, examines essential EU legal frameworks facilitating the (re-)use of data for the development of medical AI, and discusses some of the key concerns arising in this context. Finally, it presents policy recommendations to address these issues.

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
AI Act	Artificial Intelligence Act
AILD	AI Liability Directive
CJEU	Court of Justice of the European Union
CVD	Cardiovascular disease
DGA	Data Governance Act
EC	European Commission
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EHDS Regulation	European Health Data Space Regulation
EU	European Union
GDPR	General Data Protection Regulation
HDAB	Health Data Access Body
HLEG AI	High-Level Expert Group on AI
i.a.	Inter alia
ICT	Information and Communication infrastructure
IVDR	In Vitro Diagnostic Regulation
LLMs	Large Language Models
MDR	Medical Devices Regulation
MRI	Magnetic Resonance Imaging
NIS II Directive	Network and Information Systems II Directive
OECD	Organisation for Economic Co-operation and Development
PLD	Product Liability Directive

SANT	Committee on Public Health
SPE	Secure Processing Environment
WHO	World Health Organisation

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EXECUTIVE SUMMARY

Background

The increased adoption of artificial intelligence (AI) is changing the healthcare environment. This development leads to a more complex health ecosystem that enhances the quality of personalised care, while also carrying various challenges for the relational dynamics in the doctor-patient relationship.¹

To ensure an ethical and lawful transition towards the use of AI in healthcare, the framework shaping the use of data for public health purposes must be able to meet the new legal challenges created by these technological advancements. It should serve as a facilitator for the successful move towards a data-driven healthcare ecosystem.

Yet, the existing data protection framework has been said to reach its limits in facilitating the successful use of data, as more recent legislations such as the Data Governance Act (DGA) and the European Health Data Space Regulation (EHDS Regulation) appear to move the use of health data that was initially foreseen for exceptional reasons towards a broader use, thereby raising additional questions especially in terms of cross-regulatory coordination.

Aim

The objective of this paper is to provide insight into the current challenges and opportunities related to policies aimed at:

- Enhancing data-driven patient care;
- Strengthening the protection of health data systems; and
- Promoting responsible AI adoption in healthcare.

To start, this paper will explore the AI technologies currently deployed or available in healthcare across the EU.

Considering the need for data (re-)use to leverage the potential of medical AI to enhance personalised care, it will then move to the legal analysis of relevant EU data and data protection laws. The European Health Data Space Regulation (EHDS Regulation) as the new facilitator for the secondary use of health data builds an important cornerstone, together with the General Data Protection Regulation as the fundamental EU data protection framework.

In this context, focus will be given to the illustration of some of its key opportunities and challenges arising with regard to the (re-)use of data for the development of AI. Additionally, the EHDS Regulation's relationship with other EU laws, in particular the Data Governance Act, will be elaborated upon in terms of the recently established data altruism consent, as this mechanism is expected to support data sharing under the EHDS Regulation.

With the objective in mind to promote the responsible adoption of AI, the AI Act and AI liability considerations in healthcare will be elaborated upon. Additionally, ethical considerations will be briefly discussed, given the influence of ethics on EU legislative developments related to AI and as a yardstick for evaluating policy decisions and legal choices.

¹ Mittelstadt, B., 2021, *The impact of artificial intelligence on the doctor-patient relationship*, Report commissioned by the Steering Committee for Human Rights in the field of Biomedicine and Health (CDBIO), Council of Europe. Available at: <https://www.coe.int/en/web/human-rights-and-biomedicine/report-impact-of-ai-on-the-doctor-patient-relationship>.

Based on the impediments identified, reflections and recommendations concerning EU regulations and policy will be formulated with the aim of promoting responsible AI adoption in healthcare.

Key Findings

Significant progress has been made in recent years in the field of medical AI. Whilst this technology has the ability to transform the healthcare sector for the benefit of both healthcare workers and patients, the deployment faces practical challenges. On the one hand, the degree of deployment of medical AI across the EU seems difficult to estimate. The healthcare sector indicates insecurity about the adequate use of AI in clinical practice.

Additionally, legal challenges surround the use of (health) data for the development of medical AI. While the EHDS Regulation has the potential to accelerate the (re-)use of electronic health data for the development of AI, challenges concerning legal uncertainty remain, in particular concerning the interplay with the General Data Protection Regulation (e.g., in terms of the application “scientific research” as a legal basis), the Data Governance Act (i.e., in terms of the data altruism consent mechanism), and the AI Act (e.g., in terms of the act’s research exemption).

Furthermore, currently, the use of AI in healthcare appears to create a burden for healthcare professionals in terms of liability. The allocation of responsibility in healthcare relies on the “standard of care”. In order to constitute a valuable tool for healthcare practitioners, AI systems need to produce reliable results in order to balance out liability risks. This is indispensable to ensuring that patients receive safe and reliable care.

1. INTRODUCTION

The interest in the development and deployment of artificial intelligence (AI) in healthcare has gained increasing interest, particularly as the capabilities of medical AI have been improving over the last decade. At present, medical AI has been implemented in different healthcare scenarios, such as medical imaging analysis for diagnostics or disease prediction.

The development of medical AI depends on the availability of good-quality health data, which is legally protected due to its sensitivity. Different legislative initiatives have been transposed in order to increase data availability. Specifically tailored to one sector, the European Health Data Space Regulation (EHDS Regulation) has been adopted as the first context-specific data space legislation, aiming at enhancing the availability of health data for the development of AI in healthcare.

Several interconnected initiatives have been established under the framework of **AI@EU** (Deployment of AI in Healthcare) to tackle challenges arising from the use and deployment of AI in medical research and healthcare.²

The legal and regulatory progress supporting the deployment of medical AI varies across Member States. Even though they are dedicated to assessing implementation gaps from a legal perspective, basic health-specific AI ethics guidelines have not been developed.³ An OECD report shows that many countries did not have a **dedicated AI for health strategy**.⁴ There is even less information on a health data governance strategy for the context-specific use for data for AI. The WHO calls for the creation of a **centralised catalogue of verified AI solutions** within the EU, which should be kept up to date.⁵ Currently, healthcare professionals may have problems identifying which AI applications are “safe, what is legally acceptable, what is clinically validated, who is responsible, and how these tools should be implemented in real workflows”⁶.

The objective of this in-depth analysis is to provide insights into the **current challenges and opportunities** related to policies that are aimed at enhancing data-driven patient care, strengthening the protection of health data systems, and promoting responsible AI adoption in healthcare. With that in mind, this document will look into the following aspects:

Firstly, this paper will provide an overview of current applications of responsible AI in healthcare. Secondly, it will analyse the EU legislative framework, facilitating or possibly impeding the availability of health data for public interest use. Thirdly, it will give a brief outlook concerning some of the key

² European Commission, *Artificial Intelligence in healthcare*. Available at: https://health.ec.europa.eu/ehealth-digital-health-and-care/artificial-intelligence-healthcare_en; Similarly, the successful transposition of the European Health Data Space has also been the subject of EU projects (see, for instance: TEHDAS/TEHDAS2; <https://tehdas.eu/>).

³ WHO, 2026, *Artificial intelligence is reshaping health systems: state of readiness across the European Union*, Report, 20 April 2026. Available at: <https://www.who.int/europe/publications/i/item/WHO-EURO-2026-12707-52481-81471>; At the EU level, the HLEG Ethics Guidelines for trustworthy AI are one of the most prominent guidelines, as they have shaped the AI Act. Besides, in the context of healthcare, the European Medicines Agency (EMA), together with the US Food and Drug Administration (FDA), developed ten guiding principles of good AI practice in drug development in January 2026. These principles should guide the use of AI through all phases of human and veterinary medicine, i.e., starting from the research phase through the process of manufacturing (see: European Medicines Agency, Artificial Intelligence. Available at: <https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other-sources/artificial-intelligence#principles-for-ai-in-medicine-development-81282>).

⁴ Schwaiger, C., 2026, *Netherlands lacks dedicated health AI strategy, hospitals face legal uncertainty. Dutch doctors are already facing situations where the correct use of AI is not always clear*, 5 June 2026. Available at: <https://www.euractiv.com/news/netherlands-lacks-dedicated-health-ai-strategy-hospitals-face-legal-uncertainty/>; referring to: OECD, 2026, *Scaling Artificial Intelligence in Health*, Report, March 2026. Available at: https://www.oecd.org/content/dam/oecd/en/publications/reports/2026/04/scaling-artificial-intelligence-in-health_77610b12/a436e12d-en.pdf

⁵ WHO, 2026, *ibid.* (footnote 3), p. xiii.

⁶ Schwaiger, C., 2026, *ibid.* (footnote 4).

ethical issues will be provided. Finally, it will propose multiple policy options seeking to enhance data usage to enhance data-driven patient care and the responsible adoption of medical AI in the EU.

2. THE APPLICATION OF AI AND ITS VALUE FOR MEDICINE

KEY FINDINGS

Artificial intelligence (AI) has the potential to optimise resource allocation, workflow and accuracy in medical diagnosis. However, the specific degree of deployment is currently difficult to estimate given the lack of reliable data.

2.1. Artificial Intelligence: Definition and Use Cases

2.1.1. Definition

An **AI system** is defined in **Article 3(1) AI Act**. It applies a broad definition, considering AI to be a

“machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it received, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments”.

The regulation applies a **risk-based approach**, considering four categories based on potential risks to health, safety and fundamental rights, namely unacceptable risks (**Article 5 AI Act**), high risks, limited and low/minimal risks. AI systems in the healthcare sector are typically considered **high-risk systems** since AI-based tools are used in critical sectors, including medical diagnostics in healthcare (**Annex III AI Act**). Providers of healthcare-related AI systems have to comply with multiple requirements under the AI Act (e.g., documentation obligations, effective human oversight, etc.), considering the significant impact that these high-risk systems have on patients. However, responsible and trustworthy AI is more than just compliance with legislation. The **Ethics Guidelines for Trustworthy AI** issued by the High-Level Expert Group on AI (**HLEG AI**) stress that AI-based systems need to be lawful, ethical, and robust to be trustworthy.⁷

2.1.2. AI Use Cases in Healthcare

A **study on the deployment of AI in healthcare** shows that existing AI systems have the potential to optimise resource allocation, workflow and administrative tasks, and accuracy in medical diagnosis.⁸

The evaluation of AI supporting the detection of diseases in medical imaging presented promising results.⁹ For instance, AI-driven medical image analysis can be used for lung cancer screening or CVD classification using biomechanical modelling.¹⁰ Medical image analysis, which identifies patterns in medical data (e.g., X-Rays or Magnetic Resonance Imaging (MRI)), can improve accuracy in

⁷ High-level expert group on artificial intelligence, 2019, *Ethics Guidelines for Trustworthy AI*. Available at: <https://digital-strategy.ec.europa.eu/en/policies/expert-group-ai>.

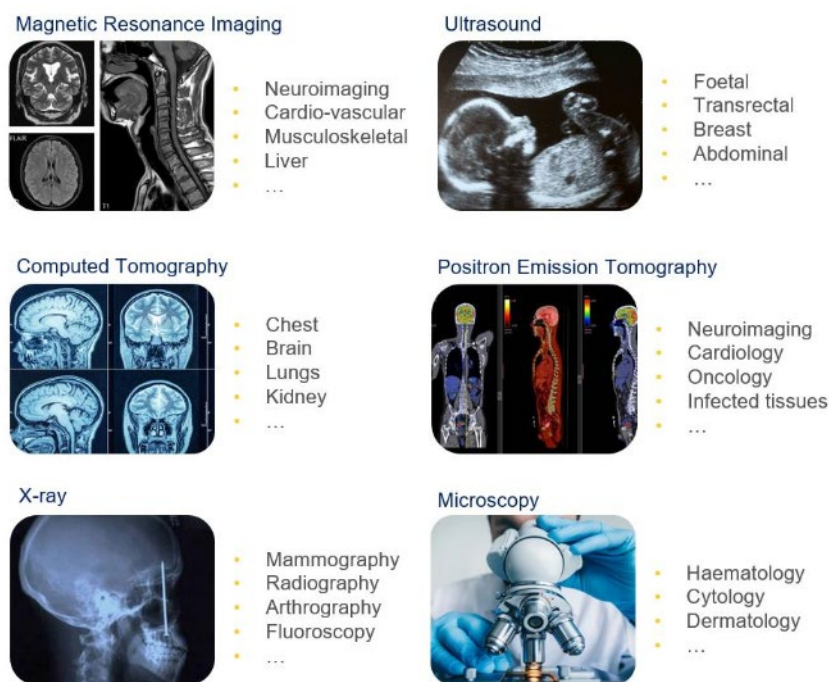
⁸ European Commission: Directorate-General for Health and Food Safety, PwC, EEIG and Open Evidence, [Directorate-General for Health and Food Safety, PwC, EEIG, Open Evidence], 2025, *Study on the deployment of AI in healthcare – Final report*, Publications Office of the European Union. Available at: <https://data.europa.eu/doi/10.2875/2169577>.

⁹ World Health Organisation (WHO), 2021, *Ethics and Governance of Artificial Intelligence for Health*, WHO Guidance, p. 6–7. Available at: <https://www.who.int/publications/i/item/9789240029200>.

¹⁰ Comte, V., Bertolini, L., Hulsman, R., Consoli, S., Leoni, G. et al., 2025, *AI-driven innovation in medical imaging – Focus on lung cancer and cardiovascular diseases*, Publications Office of the European Union, p. 20. Available at: <https://data.europa.eu/doi/10.2760/6281523>.

diagnostics, whilst also reducing the workload for clinical staff, allowing them to make decisions faster.¹¹

Figure 1: Overview of major medical imaging modalities and their primary clinical applications



Source: Comte, V., Bertolini, L., Hulsman, R., Consoli, S., Leoni, G. et al., 2025. *AI-driven innovation in medical imaging – Focus on lung cancer and cardiovascular diseases*, Publications Office of the European Union, p. 21. Available at: <https://data.europa.eu/doi/10.2760/6281523>.

Furthermore, AI facilitating personalised medicine, real-time decision-making, and predictive analysis could also support healthcare in the future.¹² For instance, **predictive AI tools** can assist in evaluating the risk for patients to develop diabetes or cardiovascular disease¹³, or assessing the demand for services by detecting patients who are likely to need immediate medical assistance or intensive care¹⁴. By doing so, predictive AI systems support the allocation of workforces, balance out the workload of pressure and, hence, foster better delivery of healthcare.¹⁵

Additionally, AI can be based on the use of data from electronic health records to develop clinical best practices for medical research and more personalised care.¹⁶ The use of large language models (LLMs) can extract medical information from patients' records, help summarise and structure that information with the aim of supporting diagnostic decision-making and the administration of tasks in

¹¹ Comte, V., Bertolini, L., Hulsman, R., Consoli, S., Leoni, G. et al., *AI-driven innovation in medical imaging – Focus on lung cancer and cardiovascular diseases*, Publications Office of the European Union, 2025, p. 20. Available at: <https://data.europa.eu/doi/10.2760/6281523>.

¹² European Commission: Directorate-General for Health and Food Safety, PwC, EEIG and Open Evidence, [Directorate-General for Health and Food Safety, PwC, EEIG, Open Evidence], 2025, *Study on the deployment of AI in healthcare – Final report*, Publications Office of the European Union, p. 18. Available at: <https://data.europa.eu/doi/10.2875/2169577>; World Health Organisation (WHO), 2021, *Ethics and Governance of Artificial Intelligence for Health*, WHO Guidance, p. 6-7. Available at: <https://www.who.int/publications/i/item/9789240029200>.

¹³ WHO, 2021, *ibid.* (footnote 9), p. 6-7.

¹⁴ European Commission, 2025, *ibid.* (footnote 12), p. 20.

¹⁵ European Commission, 2025, *ibid.* (footnote 12), p. 20.

¹⁶ WHO, 2021, *ibid.* (footnote 9), p.11-12.

medical practice.¹⁷ Finally, AI could also assist in the administration of care, supporting the scheduling of patients or the identification of fraud or public health surveillance and the identification of disease outbreaks.¹⁸

Yet, despite its potential to support better medical and prediction-based diagnosis, it seems that it is not yet regularly used by clinicians in their decision-making routine.¹⁹ The **specific level of deployment** of medical AI in clinical practice is difficult to estimate due to the lack of a comprehensive database concerning both the deployment of AI in general and AI in medical practice.²⁰

An overarching survey performed with healthcare professionals, healthcare professional associations, and hospital representatives showed that the majority of the survey respondents were using AI solutions, though the results seem to incorporate different stages of AI deployments. Some survey respondents actually deployed AI in their clinical practice, while others used AI in the piloting phase, for clinical trials, or the AI system was still under development. Notably, the survey suggests that these AI tools have been predominantly adopted in **urban areas** compared to rural areas.²¹

As of yet, the transformative potential associated with the deployment of AI seems to be stakeholder dependent, according to the study.²² Representatives from the healthcare sector are of the impression that **administrative AI tools** supporting clinical staff and workflow (e.g., AI systems for the management of electronic health records and clinical documentation) and AI diagnostic tools in the field of **radiology and pathology**, appear to promise the biggest potential to transform and improve healthcare. Less faith is put into other AI diagnostic tools and AI-driven surgery or robotics as a transformative solution. On the other hand, AI developers and researchers see transformative potential mostly in diagnostic technologies. Notably, from the patients' perspective, patients expressed their comfort with the use of AI to the extent that it fosters administrative tasks and workflows, whereas they indicated that the majority felt uncomfortable with the interaction of chatbots as tools for patient assistance.²³

Notwithstanding the evolving AI capabilities, the development and application of responsible AI in healthcare and medical research encounter **diverse challenges**. Some of the **key technical issues** leading to a limited deployment of AI in healthcare are rooted in the **lack of interoperability** with IT systems, including electronic health records, medical devices and other IT systems. Also, **limited computational resources** hinder the effective adoption in real-world scenarios. Others criticise the **reliability** of AI tools, which do not provide accurate results to be deployable in clinical practice. Some also fear being replaced by AI, leading to **job loss** and subsequently a decrease in the quality of care.²⁴

¹⁷ European Commission, 2025, *ibid.* (footnote 12), p. 19.) Deployment of AI in healthcare – Final Report, p. 19.

¹⁸ WHO, 2021, *ibid.* (footnote 9), p.11.

¹⁹ WHO, 2021, *ibid.* (footnote 9), p. 6–7.

²⁰ European Commission, 2025, *ibid.* (footnote 12), p. 40.

²¹ European Commission, 2025, *ibid.* (footnote 12), p. 42.

²² European Commission, 2025, *ibid.* (footnote 12), Section 10.4.3.

²³ European Commission, 2025, *ibid.* (footnote 12), Section 10.4.3.

²⁴ European Commission, 2025, *ibid.* (footnote 12), Section 0.2 – Annex 2 – Survey questionnaires.

3. REVIEW OF THE EU FRAMEWORK FACILITATING THE USE OF DATA FOR THE DEVELOPMENT OF AI IN HEALTH: CURRENT CHALLENGES AND OPPORTUNITIES

KEY FINDINGS

The European Health Data Space Regulation (EHDS Regulation) has the potential to accelerate the use of electronic health data for the development of AI. However, challenges concerning legal uncertainty remain, in particular:

- The interplay between the EHDS Regulation and the General Data Protection Regulation, especially the application of legal bases requires clarification;
- The mechanism of data altruism consent established under the Data Governance Act and its interaction with the EHDS Regulation lack guidance concerning its practical execution;
- To achieve the incentive of the EHDS Regulation, supporting guidance on data anonymisation and the AI Act's research exemption is needed;
- Finally, questions concerning the allocation of responsibility for the use of AI in healthcare depend on the professional standards in healthcare.

3.1. The European Strategy for Data and the European Data Union Strategy

From a macroeconomic point of view, the availability and accessibility of data are essential for the economic growth of the European economy as well as for the further development of new digital technologies. In 2020, the European Commission announced the **European Strategy for Data**²⁵ dedicated to the formation of a data-agile economy through **Common European Data Spaces** that improve data availability while protecting the rights and interests of citizens. An important key action outlined in the European Strategy for Data is the establishment of multiple legislative initiatives aimed at fostering the availability of both personal and non-personal data.²⁶ Important frameworks include, *i.a.*, the Data Governance Act, the Data Act, and the European Health Data Space Regulation:

- **Data Act**²⁷: The Data Act entered into force in 2024 and came into application in September 2025.²⁸ It seeks to empower consumers and businesses by **harmonising rules on fair access to and use of data** generated through connected devices (Internet of Things devices, such as smartphones, smartwatches, or smart home appliances). Additionally, the act enables public

²⁵ European Commission, 2020, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A European strategy for data* (hereinafter: A European strategy for data), COM(2020) 66 final, 19.02.2020.

²⁶ European Commission, 2024, *A European Strategy for Data*. Available at: <https://digital-strategy.ec.europa.eu/en/policies/strategy-data>.

²⁷ Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act), PE/49/2023/REV/1, OJ L, 2023/2854.

²⁸ European Commission, 2025, *Data Act*. Available at: <https://digital-strategy.ec.europa.eu/en/policies/data-act>.

sector bodies to access and use data held by the private sector for purposes in the public interest, in particular to respond to a public emergency or other exceptional cases.

- **Open Data Directive**²⁹: The Open Data Directive regulates the reuse of non-personal, **publicly available** data held by the public sector. Considering that the public sector holds valuable personal data as well, this framework was complemented by the Data Governance Act, which extends the reuse of data to personal data via (i.a.) secure processing environments.
- **Data Governance Act (DGA)**³⁰: The objective of the DGA, which has been in force since 2022, is to support the creation of data spaces and to boost voluntary data sharing, including both personal and non-personal data. The framework aims to increase trust by adopting **cross-sectoral governance rules** for **data intermediaries** and to implement the so-called "data altruism consent," which supports the use of personal (health) data for the common good.³¹
- **European Health Data Space (EHDS) Regulation**³²: The mission of the EHDS Regulation is to extend and **strengthen the (re-)use of health data**, including individual patient data, which is critical for healthcare innovation. The regulation governs the processing of electronic health data for primary use (healthcare) and secondary use (other purposes for which it was originally collected, such as scientific research, public health).

These frameworks developed under the **European Strategy for Data** are part of a European vision that takes an open, yet assertive approach to transnational data exchange based on European values, therefore promoting the development of artificial intelligence throughout the European Union.³³

However, some frameworks were criticised for creating an administrative and financial burden to businesses, public administrations and citizens. Also, regulatory complexity and fragmented approaches among EU countries, next to access to top computing infrastructure, impede innovation and data accessibility.³⁴

As a consequence, the EU recently developed the **European Data Union Strategy**³⁵. The objective of the European Data Union Strategy is twofold, i.e., to foster **trusted data environments**, such as data labs, and to **scale up access to high-quality data for AI development** by **simplifying and streamlining** the EU's data acquis.

Data labs could provide specialised services for data pooling and anonymisation/pseudonymisation techniques.³⁶ Data Labs will, thus, be a practical enabler to foster AI development by linking the EU AI ecosystem with data holders, the common European data spaces and data ecosystems.³⁷

²⁹ Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information (recast) (Open Data Directive), PE/28/2019/REV/1, OJ L 172, 26.6.2019, pp. 56–83.

³⁰ Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act), PE/85/2021/REV/1, OJ L 152, 3.6.2022, pp. 1–44.

³¹ European Commission, 2024, *European Data Governance Act*. Available at: <https://digital-strategy.ec.europa.eu/en/policies/data-governance-act>.

³² Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, PE/76/2024/REV/1, OJ L, 2025/327 (hereinafter: EHDS Regulation).

³³ European Commission, 2020, *A European strategy for data*, *ibid.* (footnote 26), p. 23.

³⁴ European Commission, 2025, *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL. DATA UNION STRATEGY. UNLOCKING DATA FOR AI*. COM(2025) 835 final (hereinafter: European Data Union Strategy), p.2–3. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025DC0835>.

³⁵ European Commission, 2025, *European Data Union Strategy*, *ibid.* (footnote 34).

³⁶ European Commission, 2025, *European Data Union Strategy*, *ibid.* (footnote 34), p. 6.

³⁷ European Commission, 2025, *European Data Union Strategy*, *ibid.* (footnote 34), p. 6 and 8.

As the European Data Union Strategy suggests optimising EU data laws, the European Commission released the so-called **Digital Omnibus Regulation proposal**³⁸ in November 2025, with the objective of optimising existing digital and data legislation, and enhancing competitiveness for businesses. The Digital Omnibus Regulation proposal includes a **set of amendments** to a large amount of the digital legislation, including the DGA and the AI Act. The European Data Union Strategy highlights the European Health Data Space Regulation as a “key bridge between health data ecosystems and AI development”³⁹, and changes to the EHDS Regulation are not explicitly envisioned.

3.2. The European Health Data Space Regulation

3.2.1. Background

The **European Health Data Space Regulation (EHDS Regulation)** constitutes the first sector-specific data space regulation in the EU. The aim of the regulation is, on the one hand, to establish a data space to improve individual access and control over personal electronic health data in the healthcare context, and, on the other hand, to foster, among others, healthcare-related research, policymaking, health threats preparedness and personalised medicine.⁴⁰ With these objectives in mind, the EHDS has become the leading framework driving the **secondary use of data**, including the use of data for the development and adoption of AI in healthcare.

To this end, the EHDS becomes relevant in two different ways, namely for the collection and use of electronic health data for the development of AI as well as the collection of electronic health data through AI (or, in other words, AI-based data curation). Both scenarios require high-quality health data in order to foster responsible application of AI in healthcare and public health. As a basis, Member States will have to digitalise patient files to facilitate access to patient data. This is an important prerequisite as the development of proper functioning AI tools requires vast amounts of input data.⁴¹

The following section will explore key opportunities and challenges as to how the EHDS enables the use of health data for AI, whilst focusing on its secondary use to improve patient care and public health.

3.2.2. Secondary Use of Electronic Health Data

According to **Article 2(2)(e) EHDS**, “secondary use” is defined as “the processing of electronic health data for the purposes set out in Chapter IV of this Regulation, other than the initial purposes for which they were collected or produced”. Even though the term “secondary use” has been criticised for creating inconsistency with the terminology used in pre-existing legislation, specifically

³⁸ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as regards the simplification of the digital legislative framework, and repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868, and Directive (EU) 2019/1024 (Digital Omnibus; hereinafter referred to as: Digital Omnibus Proposal) COM/2025/837 final. Available at: <https://digital-strategy.ec.europa.eu/en/library/digital-omnibus-regulation-proposal>.

³⁹ European Commission, 2025, *European Data Union Strategy*, ibid. (footnote 34), p. 6.

⁴⁰ See Recital 1 EHDS Regulation.

⁴¹ Giovanni, S., Lagioia, F., 2020, *The impact of the General Data Protection Regulation (GDPR) on artificial intelligence*, Study performed at the request of the Panel for the Future of Science and Technology (STOA) and managed by the Scientific Foresight Unit, within the Directorate-General for Parliamentary Research Services (EPRS) of the Secretariat of the European Parliament PE 641.530. Available at: [https://www.europarl.europa.eu/RegData/etudes/STUD/2020/641530/EPRS_STU\(2020\)641530_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2020/641530/EPRS_STU(2020)641530_EN.pdf).

the **General Data Protection Regulation (GDPR)**,⁴² it needs to be differentiated from the primary use⁴³ covering the processing of electronic health data for the provision of healthcare.

“Electronic health data” encompasses both personal and non-personal electronic health data, whereby **“personal electronic health data”** means data concerning health and genetic data (as defined under the General Data Protection Regulation), processed in an electronic form.⁴⁴ Conversely, **“non-personal electronic health data”** should encompass electronic health data other than personal electronic health data. This includes anonymised data which no longer relates to an identified or identifiable natural person, as well as anonymous data which never related to a natural person.⁴⁵

Even though the definition for “personal electronic health data” refers to the concepts that have been established under the General Data Protection Regulation, a closer look at the EHDS Regulation illustrates how personal electronic health data is specified. **Article 51 EHDS Regulation** enumerates the categories of electronic health data that must be made available by health data holders for secondary use. In addition to electronic health data from electronic health records, the provision also includes data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health.⁴⁶

In consideration of the **data minimisation and purpose limitation principle**, which requires processing data only to the extent necessary for the designated purpose, **health data access bodies (HDABs)** should provide access to electronic health data in an anonymised format.⁴⁷ Contrary to **pseudonymous data**, where individuals can be reidentified through the use of additional information,⁴⁸ truly **anonymous data** does not enable re-identification. Thus, only in the instances where the health data user can demonstrate that the purpose cannot be achieved with anonymised data in accordance with **Article 68(1) EHDS Regulation**, it is allowed under the EHDS Regulation for HDABs to provide access to pseudonymised data. Access to electronic health data pursuant to a data permit shall only be provided through a secure processing environment that is subject to technical and organisational measures and security and interoperability requirements.⁴⁹

3.2.3. Purpose

Article 53 EHDS Regulation enlists multiple purposes for which electronic health data can be processed for secondary use. Amongst the enlisted purposes is a specific provision dedicated to the collection and processing of data for medical AI. Specifically, **Article 53(1)(e)(ii) EHDS Regulation** allows the processing of data by a health data user for AI, namely for the purpose of:

“scientific research related to health or care sectors that contributes to public health or health technology assessments, or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators, including:

(...)

⁴² See, for instance: De Zegher, I., et al., 2024, *Artificial intelligence based data curation: enabling a patient-centric European health data space*, Front. Med. 11:1365501. Doi: 10.3389/fmed.2024.1365501. Available at: <https://doi.org/10.3389/fmed.2024.1365501>.

⁴³ Article 2(2)(d) EHDS Regulation.

⁴⁴ Article 2(2)(a, c) EHDS Regulation.

⁴⁵ See Article 2(2)(b) EHDS Regulation.

⁴⁶ Article 51(1)(a, b) EHDS Regulation.

⁴⁷ Article 66(2) EHDS Regulation.

⁴⁸ See definition of “pseudonymisation” according to Article 4(5) GDPR.

⁴⁹ Article 73 EHDS Regulation.

(ii) training, testing and evaluation of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications”.

This provision, therefore, focuses explicitly on the **development of AI in healthcare** and allows access to data for scientific research purposes. The concept of scientific research mentioned in the provision has been subject to debate under the GDPR and is therefore carried into the EHDS. The term **scientific research** is meant to serve society in general, whilst private interests may not automatically be excluded.⁵⁰ The **question raised by some is whether the public interest serving a societal cause has to be prevalent over any private interest**.⁵¹ Contrary to the GDPR, the EHDS Regulation narrows down the scope by determining the cause that the research must serve (e.g., scientific research that contributes to public health, etc.).

Additionally, other provisions are dedicated to the use of data for more general, meaning not explicitly AI dedicated, purposes, such as for the following data processing activities concerning:

- “the public interest in the areas of public or occupational health, such as activities to protect against serious cross-border threats to health, public health surveillance or activities ensuring high levels of quality and safety for healthcare, including patient safety, and of medicinal products or medical devices;” (**Article 53(1)(a) EHDS Regulation**);
- Policymaking (...) (**Article 53(1)(b) EHDS Regulation**);
- The improvement of the delivery of care (**Article 53(1)(f) EHDS Regulation**).

Member States must transpose the **right to opt out** from the secondary use of their personal electronic health data (**Article 71 EHDS Regulation**). This means that individuals have the right to opt out at any time, requiring that data related to them cannot be made available or processed after they have exercised their rights. However, Member States can introduce exceptions to this right in national law if the requirements of Article 71(4) EHDS Regulation are met. To this end, access to data may still be granted, for instance, if the access is necessary to a public sector body or a Union institution with a mandate to perform tasks in the area of public health for the purpose of “public interest in the areas of public or occupational health”, “policymaking”, or “statics” (as per Article 53(1)(a-c) EHDS Regulation), or for scientific research for important reasons of public interest (Article 71(4)(1)(ii) EHDS Regulation).

Designated **national health data access bodies (HDABs)** will decide whether the purpose requirement for which data access is requested has been fulfilled, and subsequently, whether the data will be shared for the requested purpose.

It is not allowed to seek access and process data for any secondary use that is prohibited **under Article 54 EHDS Regulation**. This provision outlines multiple prohibited usages, such as possibly making decisions detrimental to a natural person, or developing products or services that may harm individuals, public health or possibly cause a risk to human health. However, currently, there are still open questions about the practical operability of HDABs, such as what type of in-house expertise is

⁵⁰ See Recital 61 EHDS Regulation, which clarifies that scientific research should be understood in a broad manner, including the “technological development and demonstration, fundamental research, applied research and privately funded research.” It further outlines that activities related to scientific research include, for instance, training of AI algorithms for healthcare, and the evaluation and further development of existing algorithms and products.

⁵¹ Raposo, V.L., 2025, *Can personal data be recycled? The reuse and repurposing of data under the EHDS*, International Journal of Law and Information Technology, Volume 33, 2025, eaae016. Available at: <https://doi.org/10.1093/ijlit/eaee016>, p. 10; referring to European Data Protection Supervisor (EDPS), 2020, *A Preliminary Opinion on data protection and scientific research*, 6 January 2020. Available at: https://www.edps.europa.eu/sites/default/files/publication/20-01-06_opinion_research_en.pdf.

needed for determining if the requested dataset is fit for the intended purpose. Beyond in-house expertise, it could also be beneficial to obtain the opinions of data holders themselves.

3.2.4. Data altruism in the EHDS

One of the aims described by the European strategy for data is the enhancement of sharing personal and non-personal data for **altruistic purposes**. The legislation laying the groundwork for the endorsement of accessing altruistic data is the **Data Governance Act (DGA)**, which applies as a horizontal framework to multiple sectors, including the healthcare sector. Altruistic data sharing should be facilitated through a specific mechanism, namely the so-called “**data altruism consent form**”. As the name suggests, individuals are encouraged to consent to the voluntary sharing of their (health) data. Specifically, data altruism is defined as:

“the voluntary sharing of data on the basis of the consent of data subjects to process personal data pertaining to them, or permissions of data holders to allow the use of their non-personal data without seeking or receiving a reward that goes beyond compensation related to the costs that they incur where they make their data available for objectives of general interest as provided for in national law, where applicable, such as healthcare, combating climate change, improving mobility, facilitating the development, production and dissemination of official statistics, improving the provision of public services, public policy making or scientific research purposes in the general interest;”⁵²

Data altruism consent thus covers any objective of general interest that is provided for in national law, including healthcare and scientific research purposes that are in the public interest. Even though the notion of scientific research has to be interpreted broadly, encompassing both publicly and privately funded research as per **Article 159 GDPR**, its notion has been subject to debate⁵³ and has subsequently created legal uncertainty for scientific research as a legal basis.

In the **DGA**, it seems that the term “scientific research purposes in the general interest” is narrowing down the wording of the law from the GDPR (“scientific research”). However, it does not define it. The definition of this term falls to be determined by the EU Member State level on a national level. Notably, the recently published Digital Omnibus Proposal maintains the notion “scientific research purposes in the general interest” but does not clarify it.⁵⁴

This may lead to **differences in interpretation** and a **fragmentation of national legislation** that ultimately can hamper the sharing of health data among EU countries.⁵⁵ Coordination between Member States could potentially mitigate national divergences, ensuring legal interoperability of data altruism consent.

Data altruism consent will be managed by so-called “**data altruism organisations**” (**DAO**). These organisations operate as data intermediaries and have to be registered and recognised as a DAO to facilitate altruistic data sharing. Data intermediaries will operate as third parties, constituting a neutral “middleman” to connect individuals and companies with data users. Despite the opportunity to increase trust in data sharing, these intermediaries could have the potential to help individuals

⁵² Article 2(16) DGA.

⁵³ EDPS, 2020, *ibid.* (footnote 51).

⁵⁴ See: Digital Omnibus Proposal, (*ibid.*, footnote 38) Article 1 Amendments to Regulation (EU) 2023/2854, Paragraph 2(d).

⁵⁵ Spajić, D., 2025, *Data Altruism Consent: A Move Forward Towards the Creation of a European Health Data Space?*, in: Casarosa, F., Gennari, F., Rossi, A. (eds) *Enabling and Safeguarding Personalized Medicine*. Data Science, Machine Intelligence, and Law, vol 7. Springer, Available at: https://doi.org/10.1007/978-3-031-99709-9_3#DOI.

exercise their rights and to support less experienced data users in curating data to enhance the usability of the data.⁵⁶

When looking at the relationship between the Data Governance Act and the EHDS, **the Data Governance Act** constitutes the **main legislation for data altruism**, whereas the **EHDS** focuses on the **realisation of a sector-specific data space**. Yet, the role of data altruism organisations and how they should facilitate health data sharing remains vague.⁵⁷ The EHDS does not formulate how to precisely enable and coordinate altruistic activities beyond a high level. For instance, **Recital 78 EHDS** confirms that health data access bodies should cooperate with the competent authorities designated under the Data Governance Act to supervise the activity of data altruism organisations in the health and care sector, and that the general rules for the management of data altruism are laid down in the Data Governance Act.⁵⁸

However, the EHDS also underlines the sensitivity of health data and therefore justifies the establishment of a rulebook with additional criteria for data altruism in the context of the EHDS. On the one hand, this rulebook has the potential to mitigate the risk for national variances established under the DGA, on the other hand, it is still unclear how such a rulebook will ultimately be enforced. According to the Digital Omnibus Proposal, the obligation to develop a rulebook and a European data altruism consent form should be repealed altogether.⁵⁹

3.2.5. Data quality

To prevent liability concerns and, in the worst case, severe impacts on the health and safety of people, the development of AI requires quality data. To this end, standardisation efforts can support the creation of trustworthy and usable datasets. The EHDS foresees the creation of a data quality and utility label dedicated to the secondary use of electronic health data.

A **data quality and utility label** must cover multiple elements as per **Article 78(III) EHDS**, which help to standardise and ensure the reliability of datasets made available by health data access bodies. These inform health data users about the quality and utility characteristics of a dataset, and, thereby, enable them to select the dataset that **fits their needs** the best. To create AI beneficial for patients, the adopted data quality and utility label must represent the population that the technology targets effectively and avoid bias.⁶⁰

By creating more transparency on individual datasets, this approach helps data users improve the value of outcomes benefitting healthcare, research, and evidence-based regulatory and policy decision-making in return.⁶¹

Electronic health data collected and processed with the support of Union or national public funding must incorporate the following elements according to **Article 78(2-3) EHDS**:

- For data documentation
- For assessment of technical quality

⁵⁶ De Zegher, I., et al., 2024, *ibid.* (footnote 42), p. 6.

⁵⁷ Spajić, D., 2025, *ibid.* (footnote 55).

⁵⁸ Recital 78, Article 57(2)(c) EHDS Regulation.

⁵⁹ See: Digital Omnibus Proposal, *ibid.* (footnote 38), Recital 7.

⁶⁰ Kalra, D., et al., 2025, *AI Needs High-Quality Health Data at Scale - Will the EHDS Deliver?*, Journal of Applied Interdisciplinary Research, Special Issue, 116–118. Available at: <https://doi.org/10.25929/d5p2-np32>.

⁶¹ Recital 85 EHDS Regulation.

- For data quality management processes
- For assessment of coverage
- For information on access and provision
- For information on data modification

Overall, the adoption of the data quality and utility label should be promoted to achieve the incentive that the EHDS Regulation seeks to achieve. Additionally, it should stimulate **data quality at the source**, for instance, through complementary measures for health systems that feed into the EHDS ecosystem, including electronic health records as well as commercial devices (e.g., wellness apps).⁶²

3.2.6. IP and trade secrets protection

The balancing between the economic value of personal data on one side, and an individual's interest in privacy on the other side, constitutes the basis of the data sharing ecosystem. The **General Data Protection Regulation (GDPR)** created a foundation for a governance framework and unites private and public interest-driven benefits. While the GDPR has been said to impede data sharing⁶³, practice has shown that economic interests raised in this context have had the potential to hamper data sharing in the past. The EHDS addresses this issue by establishing a different balance, attempting to harmonise the commercial interest in securing data protected by intellectual property rights and trade secrets with the public interest in (re)using such data to foster innovation benefiting patients.⁶⁴

Specifically, **Article 52 EHDS** regulates the **data holders' interests in intellectual property rights and trade secrets protection**. Even though health data holders are expected to identify and report which parts of a dataset are protected, they are not automatically exempt from sharing that data. The provision states that electronic health data protected by intellectual property rights, trade secrets or covered by the regulatory data protection right should be made available for secondary use to health data access bodies. They are required to justify the need for the protection, based upon which health data access bodies must determine the necessity for and transpose appropriate and proportionate measures of a legal, organisational and technical nature.⁶⁵ Only where the use of such data entails a serious risk to infringe such rights, despite the envisaged safeguards, health data access bodies can refuse access to such data.⁶⁶

The approach to securing IP and trade secret protection under the EHDS has created friction as different private stakeholders, such as pharmaceutical companies and the MedTech industry, fear exposure of their expertise.⁶⁷ For instance, it has been argued that clinical trial data (e.g., generated or collected for the development of new pharmaceutical compounds) should not be made available before its finalisation, as otherwise innovation may be hindered in the EU.⁶⁸ Since national health data

⁶² Kalra, D., et al., 2025, *ibid.* (footnote 60).

⁶³ For instance regarding cross-border data sharing for rare diseases by healthcare professionals: Calomme, A., et al., 2025, *In-depth analysis of the public consultation of the European Parliament on rare diseases*, publication for the Committee on Public Health, Policy Department for Transformation, Innovation and Health, European Parliament, Luxembourg, PE 778.583, p. 43. Available at: [https://www.europarl.europa.eu/thinktank/en/document/ECTI_STU\(2025\)778583](https://www.europarl.europa.eu/thinktank/en/document/ECTI_STU(2025)778583).

⁶⁴ See, for instance, Recital 60 EHDS Regulation.

⁶⁵ See Article 52, and in particular Article 52(1-3) EHDS Regulation.

⁶⁶ Article 52(5) EHDS Regulation.

⁶⁷ Digital Europe, 2026, *Safeguarding intellectual property and trade secrets in the European Health Data Space*, 15 January 2026. Available at: <https://www.digitaleurope.org/resources/safeguarding-intellectual-property-and-trade-secrets-in-the-european-health-data-space/>

⁶⁸ European Federation of Pharmaceutical Industries and Associations (EFPIA), *EFPIA response to the consultation on a legislative proposal for a European Health Data Space (EHDS)*, p. 4. Available at: <https://www.efpia.eu/media/676468/efpia-response-to-the-consultation-on-legislative-proposal-for-a-european-health-data-space.pdf>.

access bodies will play a key role in maintaining the confidentiality of IP and trade secret-protected data, ensuring the necessary in-house expertise will be crucial.

Access to certain IP and trade-secret-protected electronic health data may be made conditional on the basis of legal, organisational and technical measures (e.g., contractual arrangements between health data holders and health data users). This, in return, requires establishing best practices for legal, organisational and technical safeguards. While the European Commission is expected to develop and recommend models of contractual terms for such arrangements, these will be non-binding.⁶⁹

3.2.7. Duties of health data users: Publication of results

According to **Article 61 EHDS Regulation**, health data users who have been granted access to electronic health data for secondary use must restrain their processing activities to the purpose defined in and accepted by the data permit (**Article 68 EHDS Regulation**) or approved through the health data request (**Article 69 EHDS Regulation**).

To this end, health data users are required to make public the results or output of secondary use, which also includes such information that is relevant for the provision of healthcare (**Article 61(4) EHDS Regulation**). The results or output stemming from the data processing activity has to be made available **within 18 months** after the completion of the processing of the electronic health data or after having received the response to their health data request. The 18-month period can be extended by health data access bodies, particularly if the results are to be published in a scientific publication, such as a scientific journal. It is up to the health data access bodies to assist health data users in making the information public on health data access bodies' websites.

When health data users use electronic health data for secondary use, they need to acknowledge the source of the data obtained and the fact that it has been obtained under the EHDS framework. It remains, however, unexplained by the EHDS framework how this may affect IP protection.

3.3. General Data Protection Regulation

The **General Data Protection Regulation (GDPR)** is the leading data protection framework at the EU level, as it lays down the provisions for the processing of personal data, meaning any data that relates to an identified or identifiable natural person. The **GDPR** constitutes an overarching framework for the **processing of personal data** and special categories of personal data, such as data concerning health. It also regulates AI systems by protecting individuals against solely automated decision-making. The **GDPR**, therefore, remains applicable for the processing of personal data and special categories of personal data (including data sharing), while the **EHDS** regulates **access to electronic health data**.

To facilitate access to data concerning health, setting up a **data-sharing agreement** is pivotal. The GDPR requires a so-called **data processing agreement**, which is a **legally binding contract** between the data controller and the data processor, that lays out the rights and obligations of each party involved in the data sharing activity.⁷⁰ Supplementary contractual arrangements, for instance, concerning IP protection, may be required under the EHDS as indicated above.

⁶⁹ Article 52(4) EHDS Regulation.

⁷⁰ See Article 28(3) GDPR.

3.3.1. Legal basis for the processing of personal data and special categories of personal data

In order to share or access data, the GDPR mandates that data controllers and processors must identify a legal basis for the processing of **personal data (Article 6 GDPR)** and introduces an exemption from the prohibition to process **special categories of personal data (Article 6 and 9 GDPR)**, respectively.

A study investigating the impact of the GDPR on AI has shown that the data protection regulation has issues addressing the challenges posed by AI on the processing of personal data, as the regulation creates “vague and open-ended” commands.⁷¹

In particular, when intending to facilitate the use of personal data for public health, issues can occur with regard to the applicability of the research exemption, as Member States can diverge in their requirements.⁷² This requires that the research is recognised as a societal good contributing to overall wellbeing. The envisaged research has to be genuinely scientific, which can be implied by **six key-indicative factors** according to recent draft guidelines published by the **European Data Protection Board (EDPB)**, namely a methodical and systematic approach, adherence to ethical standards, verifiability and transparency, autonomy and independence, research objectives and potential to contribute to existing scientific knowledge or contribute to its novelty.⁷³

Also, scientific research has been considered to be in the public interest (**Article 6(1)(e) GDPR**).⁷⁴ In particular, the **EDPB draft guidelines** indicate that the legal basis for tasks carried out in the public interest is not restricted to public entities conducting scientific research. This means that private entities intending to process personal data can also rely on the “public interest” as a legal basis, provided that the legal act encompasses their activities.⁷⁵

With adequate safeguards as per **Article 89 GDPR** in place, the processing of data concerning health can be admissible for **scientific research purposes**, such as the development of (medical) AI.⁷⁶ However, relying on “scientific research” as an adequate legal basis has been difficult where commercial and public interests intertwine. The GDPR integrates a broad definition, encompassing both commercial and private interests. The lack of a clear definition has created legal uncertainty as to who can rely on that legal ground.⁷⁷ However, the EDPB and European Data Protection Supervisor (EDPS) reiterate in a joint opinion the legitimate use of “legitimate interest” (**Article 6(1)(f) GDPR**) as a possible legal basis for the development and deployment of AI.⁷⁸

In this vein, processing sensitive patient data for commercial interests bears a significant risk for the commercialisation of patient data. In principle, **commercial interests** may stand in opposition to what healthcare embodies, which is in the interest of many. Furthermore, it also challenges the protection of **sensitive patient data**, which was **originally protected by medical secrecy** under the patient-

⁷¹ Giovanni, S., Lagioia, F., 2020, *ibid.* (footnote 41).

⁷² Kiseleva, A., De Hert, P., 2021, *Creating a European Health Data Space: Obstacles in Four Key Legal Area*, European Pharmaceutical Law Review, Volume 5, Issue 1, Pages 21 – 36. Available at: <https://doi.org/10.21552/eplr/2021/1/5>.

⁷³ EDPB, 2026, *Guidelines 1/2026 on processing of personal data for scientific research purposes*, Adopted on 15 April 2026. Draft. Available at: https://www.edpb.europa.eu/public-consultations/guidelines-12026-on-processing-of-personal-data-for-scientific-research_en.

⁷⁴ EDPB, 2026, *ibid.* (footnote 73), p. 50 (paragraph 126).

⁷⁵ EDPB, 2026, *ibid.* (footnote 73).

⁷⁶ EDPB, 2026, *ibid.* (footnote 73).

⁷⁷ EDPS, 2020, *ibid.* (footnote 51), p. 9-12.

⁷⁸ EDPB-EDPS, 2026, *EDPB-EDPS Joint Opinion 2/2026. On the Proposal for a Regulation as regards the simplification of the digital legislative framework (Digital Omnibus)*. Adopted on 10 February 2026, p. 16. Available at: https://www.edpb.europa.eu/documents/legislative-opinion/edpb-edps-joint-opinion-22026-on-the-proposal-for-a-regulation-as_en.

doctor relationship. This protection is undermined when patient data is brought out of its original healthcare context and transferred to stakeholders outside of it. While the EHDS has the objective to support personalised medicine in the public interest, its mechanism, facilitating the secondary use of health data through a wide array of stakeholders, is challenged by the dynamics of the stakeholders accessing such data.

When it comes to the processing of special categories of personal data (**Article 9(1) GDPR**), such as data concerning health, the GDPR generally prohibits their use. However, it provides multiple exemptions from this prohibition, including, for instance, the provision of **healthcare or medical diagnosis (Article 9(2)(h) GDPR)**, or for reasons of **public interest in the area of public health (Article 9(2)(i) GDPR)**, such as cross-border threats to health as experienced during the COVID-19 pandemic. Moreover, health data can be processed if it is in the **substantial public interest (Article 9(2)(g) GDPR)**, though relying on this provision as a legal basis has been shown to be difficult.⁷⁹

When processing special categories of personal data, including data concerning health, for scientific research, data controllers need to take into account potential derogations (further conditions or limitations) in national legislation.⁸⁰ This is explicitly set out in **Article 9(4) GDPR**. However, the **EHDS Regulation** retracts the applicability of this provision, excluding the possibility for EU Member States to transpose derogations in the context of their health data space.⁸¹

3.3.2. Data protection principles

Additionally, practice has shown that the GDPR has difficulties acknowledging technologies or techniques that process vast amounts of data. The use of data for the development and use of AI belongs to one of them. The drawbacks highlighted in this context concern, in particular, the **data minimisation and purpose limitation principle**. The principle of data minimisation requires that only such data ought to be processed as far as they are necessary for the development of the technology at stake. In the context of AI, research has shown that it may not always be straightforward to determine in advance which data types are necessary for the development of AI (e.g., for the development of synthetic data generation techniques).⁸²

3.3.3. Data anonymisation

The use of **anonymous or anonymised data** could be an alternative while protecting patients' privacy. The EHDS Regulation anticipates the sharing of anonymous data as a default, unless the purpose cannot be achieved with anonymous data.⁸³ In that case, access to electronic health data in a pseudonymised format can be granted. The use of anonymous data falls outside of the scope of the GDPR considering that it is more privacy friendly and thus does not require a legal basis to be processed. However, data anonymisation is not a static concept, and practical issues remain with regard to its use.

A key concern relates to the anonymisation of personal data, as the line between where anonymisation ends, and pseudonymisation starts constitutes a challenge in practice.⁸⁴ Whether data

⁷⁹ EDPS, 2020, *ibid.* (footnote 51), p. 23.

⁸⁰ See Article 9(IV) GDPR.

⁸¹ Recital 9(4) EHDS Regulation.

⁸² Big Data Value Association (BDVA), 2025, *Synthetic data in healthcare. Benefits and opportunities. Technological, clinical, regulatory gaps & challenges. Ways ahead for impact maximisation*, September 2025, p. 29. Available at: <https://bdva.eu/downloads/#71-92-wpfd-publications>.

⁸³ Article 66(2 and 3) EHDS Regulation.

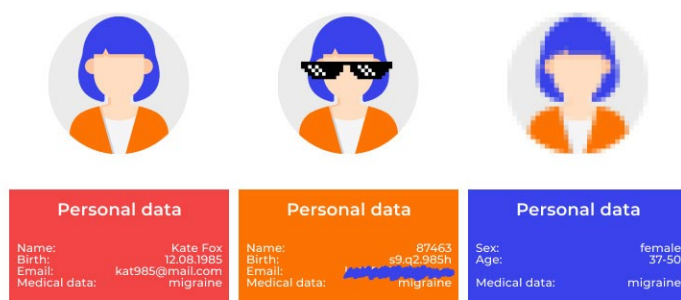
⁸⁴ European Commission, 2025, *European Data Union Strategy* (*ibid.*, footnote 34), p. 14.

is related to an identified or identifiable natural person using means reasonably likely to be used is the key factor in the assessment.⁸⁵

Figure 2: Pseudonymisation vs Anonymisation of data



Pseudonymization vs Anonymization: Key Differences



Source: Lee, I., Pseudonymization, Wallarm, <https://www.wallarm.com/what/pseudonymization>, accessed 2 July 2026.

Understanding the difference between anonymous and pseudonymous data is essential in light of the case law issued by the Court of Justice of the European Union (CJEU). Thus far, the court highlighted the **context-specific nature** of personal data.⁸⁶ This means that the nature of the data depends on the specific context in which it is used. While the data could be anonymous to one party, it may be considered pseudonymous to someone else if it is possible for them to re-identify one or more individuals based on the combination of information.

With that in mind, it needs to be taken into account that the anonymity of AI models trained with personal data cannot be assumed, as the European Data Protection Board highlighted. The sharing of AI models that run on sensitive data can pose a privacy challenge, and, therefore, AI models need to be assessed on a case-by-case basis to ensure that personal data is not revealed.⁸⁷

Data anonymity is related to a central principle in healthcare, i.e., the patients' right to medical secrecy. The data collected and used under the EHDS is **patient data**. Patient data is subject to high protection in the doctor-patient relationship. Under the EHDS, these sensitive data will be transferred outside the patient-doctor relationship, eroding the traditional protection created for patient safety if the data is not properly anonymised.⁸⁸ Ensuring a proper level of data anonymisation is thus essential, whilst **Article 61(3) EHDS** forbids health data users from re-identifying or attempting to re-identify the people to whom the data originally relates.

⁸⁵ To determine whether a personal is identifiable, and thus constitutes personal data as per Article 4(1) GDPR, see Recital 26 GDPR; The European Data Protection Board (EDPB) recently adopted guidelines on anonymisation open for consultation, see: EDPB, *Guidelines 02/2026 on Anonymisation*, Version 1.0, Adopted on 07 July 2026. Available at: https://www.edpb.europa.eu/public-consultations/guidelines-022026-on-anonymisation_en#no-back.

⁸⁶ See, for instance: Case T-557/20, Court of Justice of the European Union, Judgment of the General Court of 26 April 2023, Single Resolution Board v European Data Protection Supervisor; Case C-319/22, Court of Justice of the European Union, Judgment of the Court of 9 November 2023, Gesamtverband Autoteile-Handel eV. v Scania CV AB.

⁸⁷ European Data Protection Board (EDPB), 2024, *Opinion on certain data protection aspects related to the processing of personal data in the context of AI models*, Adopted on 17 December 2024. Available at: https://www.edpb.europa.eu/system/files/2024-12/edpb_opinion_202428_ai-models_en.pdf

⁸⁸ Spajić, D., 2025, *Transforming the secondary use of patient data in the European Health Data Space. A challenge for the patient's right to medical confidentiality?*, in: Slokenberga S, O Cathaoir K, Shabani M (eds.) *The European Health Data Space. Examining A New Era in Data Protection*. Routledge. Available at: <http://dx.doi.org/10.4324/9781003544111-7>.

3.3.4. Automated individual decision-making, including profiling

It should be noted that the **General Data Protection Regulation (GDPR)** forbids solely automated decision-making resulting in decisions as per **Article 22 GDPR** that were based on special categories of personal data, such as data concerning health, unless the decision is grounded on explicit consent or is in the substantial public interest.⁸⁹ These rules can become relevant, especially when providing healthcare services where only certain individuals are affected, whereas medical research might have a less direct impact on individuals.⁹⁰

The use of AI for the purpose of providing healthcare services, hence, has to comply with strict data protection rules (e.g., when using AI for medical diagnosis), yet it does not provide a comprehensive framework for AI. Instead, the **AI Act** constitutes the main framework for the cross-sectoral use and application of AI.

3.4. Artificial Intelligence Act

On 1 August 2024, the **European Artificial Intelligence Act (AI Act)**⁹¹ entered into force and will be fully applicable starting this year, i.e. as of 2 August 2026. The objective of the AI Act is to support the responsible development and implementation of artificial intelligence-driven systems in the EU. The AI Act takes a **risk-based approach** in categorising the systems that ought to be placed on the EU market.

AI-driven tools applied in the healthcare sector may regularly be classified as **high-risk** given their potential impact on people's health and safety. AI systems that are categorised as high-risk systems, such as AI systems foreseen for medical purposes, have to fulfil several requirements under the regulation, such as **high-quality data sets** and **human oversight**.⁹² In that vein, the AI Act complements the Medical Devices (MDR)⁹³ and In Vitro Diagnostics Medical Devices Regulations (IVDR)⁹⁴, and constitutes an important protection through its safeguards for AI-embedded medical devices.⁹⁵

In terms of the use and sharing of health data, **Article 10 AI Act** lays out a set of quality criteria for data sets used for the training of high-risk AI systems, including data governance and management practices concerning, i.e. data collection and data-preparation processes, formulation of assumptions and examination of biases that can affect the health and safety of individuals.

It should therefore be possible to exceptionally process special categories of personal data, such as data concerning health, to detect and correct bias with appropriate safeguards in place if privacy-

⁸⁹ Article 22(4) GDPR.

⁹⁰ Meszaros, J., Minari, J., and Huys, I., 2022, *The future regulation of artificial intelligence systems in healthcare services and medical research in the European Union*. Front. Genet. 13:927721. Doi: [10.3389/fgene.2022.927721](https://doi.org/10.3389/fgene.2022.927721).

⁹¹ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act; hereinafter: AI Act), PE/24/2024/REV/1, OJ L, 2024/1689, 12.7.2024,

⁹² See, for instance: Articles 13–17 AI Act.

⁹³ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117 (Medical Device Regulation (MDR)), 5.5.2017, pp. 1–175.

⁹⁴ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017 (In Vitro Diagnostic Regulation (IVDR)), pp. 176–332.

⁹⁵ European Consumer Organisation (BEUC), 2026, *Joint Open Letter: The AI Act must keep regulating AI-embedded medical devices*, 15 July 2026. Available at: https://www.beuc.eu/sites/default/files/publications/BEUC-X-2026_068_Open_Joint_Letter_The_AI_Act_must%20keep_regulating_AI-embedded_medical_devices.pdf.

preserving data (meaning, for instance, the use of anonymous or synthetic data) is insufficient to mitigate bias.⁹⁶

Recital 70 AI Act highlights in that regard that AI providers should be able to process data concerning health to mitigate bias in AI systems and prevent discrimination as a matter of substantial public interest as per **Article 9(2) GDPR**. Besides, training, validation and testing data sets must be sufficiently representative, and, as much as possible, error-free. They also need to be complete with a view to the intended purpose, and have the appropriate statistical properties concerning the (groups of) people in relation to whom the AI system will be used.⁹⁷

The AI Act takes into consideration anonymous or synthetic data as potential privacy safeguards. Thus, AI has also been used to support anonymisation techniques, such as **synthetic data**, which has received increased attention as a possible solution to fill data gaps, especially for underrepresented populations, whilst mitigating privacy concerns. Yet, some voices have voiced their concern against AI-generated synthetic data as a possible solution, as the opacity inherent to the AI's operating "black box" may aggravate existing biases.⁹⁸

Since responsible AI in medicine requires access to high-quality data sets, the **European Health Data Space Regulation (EHDS Regulation)** plays a significant role in enabling the secondary use of electronic health data and access to high-quality datasets for the development and deployment of medical AI.

Notably, the AI Act also acknowledges the need for innovation and thus includes a **research exemption** to accelerate the development of AI. According to **Article 2(6)** and **Recital 25 AI Act**, the regulation should not apply to AI systems and models, including their output, specifically developed and put into service for the sole purpose of scientific research and development. However, any other AI system that *may* be used for research and development activity remains subject to the regulation according to **Recital 25 AI Act**. For instance, if a healthcare provider buys a commercial AI tool that is anticipated to be used only for research purposes, the AI Act remains applicable.⁹⁹

Yet, similarly to the discussion under the General Data Protection Regulation, the **concept of scientific research is not clearly defined**, thereby creating ambiguity, especially where commercial and scientific interests interlink. Subsequently, the creation of **best practices** to navigate the research exemption, whilst defining and continuously refining its application in a discourse between policymakers, private and public stakeholders, to identify the needs and challenges in practice, has been suggested as a solution to foster AI development.¹⁰⁰ Stakeholder exchange revealed that clarification is needed on how this exemption applies in a specific sectoral context, including pre-clinical research and for the development of medicinal products and medical devices.¹⁰¹

⁹⁶ Article 10(5)(a) AI Act.

⁹⁷ Article 10(1-3) AI Act.

⁹⁸ Baggio, S., 2026, *Artificial Intelligence-generated Synthetic Data in Healthcare: A False Promise for Underserved Populations?*, *Bioethics* (2026): 1-6. Available at: <https://doi.org/10.1111/bioe.70121>.

⁹⁹ Meszaros, J., Huys, I. & Ioannidis, J.P.A., 2026, *Challenges in applying the EU AI act research exemptions to contemporary AI research*. *npj Digit. Med.* 9, 288. Available at: <https://doi.org/10.1038/s41746-025-02263-0>.

¹⁰⁰ Meszaros, J., Huys, I. & Ioannidis, J.P.A., 2026, *ibid.* (footnote 102).

¹⁰¹ See: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) {SWD(2025) 836 final}, 2025/0359 (COD), explanatory memorandum, p. 4. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025PC0836>.

3.5. Cybersecurity

AI systems form part of **an Information and Communication (ICT) infrastructure** that is vulnerable to potential cybersecurity threats from both internal and external actors. Particularly in the healthcare sector, malicious attacks on IT and AI systems pose significant risks to patients' lives and their well-being.¹⁰²

Adhering to pertinent cybersecurity regulations is therefore essential to the transposition of responsible AI systems in healthcare to ensure that AI, in fact, improves the quality of care and does not jeopardise it. Meeting cybersecurity requirements warrants resilience to possible threats and security-by-design, making AI more robust.

Relevant cybersecurity requirements are implemented across multiple frameworks, to which efforts have been increasingly dedicated over the past years.

In essence, the **NIS II Directive**¹⁰³ imposes enhanced cybersecurity requirements for 18 critical sectors across the EU, including for the health sector. The **Cybersecurity Act (CSA)**¹⁰⁴ grants a permanent mandate to the **EU Agency for Cybersecurity ENISA**, which obtained a key role for overseeing voluntary European cybersecurity certification schemes for ICT products, services and processes in the EU that validate best practices in cybersecurity, especially for high-risk AI tools.¹⁰⁵ Additionally, the performance of cybersecurity risk assessments during the design, development and operation stage ensure adherence to common requirements for products with digital elements, including connected devices and AI components, under the **Cyber Resilience Act (CRA)**^{106, 107}

The **EHDS Regulation** builds upon these requirements and lays out dedicated provisions specifying cybersecurity requirements and creating an infrastructure for the secure use of health data in the European health data space. For instance, the EHDS Regulation mandates in **Article 73** the deployment of a **secure processing environment (SPE)** for the secondary use or processing of health data, which was laid down under the **Data Governance Act (DGA)** and will be further specified under the EHDS Regulation. An SPE is a controlled environment where permitted users can process electronic health data, in principle, without downloading the data. To safeguard the rights and freedoms of natural persons (e.g., re-identification of individuals), only non-personal electronic data may be downloaded from an SPE (Article 73(2) EHDS Regulation). In this context, the European Commission is expected to adopt an implementing act, stating the technical, organisational, information security, confidentiality, data protection and interoperability requirements for secure processing environments.¹⁰⁸

¹⁰² According to the European Commission, 309 incidents with cybersecurity risks in healthcare were reported in 2023 (see: European Commission, *Cybersecurity of hospitals and healthcare providers: A healthcare sector resilient to cyber threats*, last reviewed on 26 June 2026. Available at: https://commission.europa.eu/topics/digital-economy-and-society/cybersecurity-healthcare_en).

¹⁰³ Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive), PE/32/2022/REV/2, OJ L 333, 27.12.2022, pp. 80–152.

¹⁰⁴ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act), PE/86/2018/REV/1, OJ L 151, 7.6.2019, pp. 15–69.

¹⁰⁵ See, for instance, Articles 48–56 Cybersecurity Act.

¹⁰⁶ Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act), PE/100/2023/REV/1, OJ L, 2024/2847, 20.11.2024.

¹⁰⁷ See Articles 5–10 Cyber Resilience Act.

¹⁰⁸ See Article 73 EHDS Regulation, and in particular Article 73(5) EHDS Regulation.

3.6. The Digital Omnibus Proposal

In November 2025, the European Commission put forward a package for the amendment of the EU's digital and data legislations. The package consists of **two Digital Omnibus Proposals**, namely **the Digital Omnibus**¹⁰⁹ and **the Digital Omnibus on AI**¹¹⁰. The draft packages aim to simplify the EU's data acquis to accelerate the creation of AI.

The **Digital Omnibus** suggests, *i.a.*, **accelerating the availability of data for the development of AI** by **repealing multiple EU data legislations** (i.e., the Free Flow of Non-Personal Data Regulation, the Data Governance Act, and the Open Data Directive) and **migrating essential provisions into the Data Act**, whilst refinements of its rules for practical implementation are anticipated. Additionally, certain provisions under the General Data Protection Regulation (GDPR) should be amended to enhance legal clarity.¹¹¹

For instance, the proposal seeks to clarify the notion of scientific research in the context of the GDPR, which is going in the right direction. The European Data Protection Board and the European Data Protection Supervisor (EDPS), in their joint opinion on the Digital Omnibus Proposal¹¹², welcome the attempt for clarification and recommend further developing that term.¹¹³ However, the suggested amendments to the definition of personal data and pseudonymisation through an implementing act can have detrimental effects on the fundamental rights of data protection of individuals.¹¹⁴

The **Digital Omnibus on AI** is, as the name suggests, specifically about the AI Act. The proposal suggests targeted changes clarifying the interplay between the AI Act and other EU laws, and simplification measures to ensure adequate implementation of some of the AI Act's provisions. These amendments followed a series of exchanges and consultations with stakeholders sharing experiences and needs concerning the transposition of the AI Act.¹¹⁵

At the time of writing, the discussions among EU legislators have advanced in terms of the Digital Omnibus on AI.¹¹⁶

¹⁰⁹ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as regards the simplification of the digital legislative framework, and repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868, and Directive (EU) 2019/1024 (Digital Omnibus) COM/2025/837 final. Available at: <https://digital-strategy.ec.europa.eu/en/library/digital-omnibus-regulation-proposal>.

¹¹⁰ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) {SWD(2025) 836 final}, 2025/0359 (COD) explanatory memorandum. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025PC0836>

¹¹¹ Digital Omnibus, *ibid.* (footnote 109).

¹¹² EDPB-EDPS, 2026, *ibid.* (footnote 78).

¹¹³ EDPB-EDPS, 2026, *ibid.* (footnote 78), p. 12-13.

¹¹⁴ EDPB-EDPS, 2026, *ibid.* (footnote 78), p. 8-11.

¹¹⁵ See: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) {SWD(2025) 836 final}, 2025/0359 (COD) explanatory memorandum, p. 1-2. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025PC0836>

¹¹⁶ The co-legislators reached a trilogue agreement on 7 May 2026. The provisional agreement needs to be adopted by both Parliament and Council before the proposal can enter into law. The Parliament approved the agreement on 16 June 2026, and the Council on 29 June 2026. See here: European Parliament, 2024–2029, PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS, Subject: Proposal for a regulation Amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) (COM(2025)0836 – C10-0304/2025 – 2025/0359(COD)) (hereinafter: Provisional agreement). Available at: [https://www.europarl.europa.eu/RegData/commissions/imco/inag/2026/05-13/CJ40_AG\(2026\)789081_EN.pdf](https://www.europarl.europa.eu/RegData/commissions/imco/inag/2026/05-13/CJ40_AG(2026)789081_EN.pdf); European Parliament 2026, *Digital Omnibus on AI*, Briefing, 16 June 2026. Available at: [https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI\(2026\)782651](https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI(2026)782651); European Parliament, 2026, *AI Act: deal on simplification measures, ban on “nudifier” apps*, press release, 7 May 2026. Available at: <https://www.europarl.europa.eu/news/en/press-room/20260427IPR42011/ai-act-deal-on-simplification-measures-ban-on-nudifier-apps>; Council of the EU, 2026, *Artificial Intelligence: Council and Parliament agree to simplify and streamline rules*, press release, 7

The AI Act is going to be simplified following the approval by both the Council presidency and the European Parliament in June 2026.¹¹⁷ Amongst other things, the proposed changes foresee adjusting the **timeline for the applicability of rules concerning high-risk AI systems**, i.e., 2 December 2027 for stand-alone high-risk AI systems and 2 August 2028 for high-risk AI systems embedded in products.¹¹⁸

The new regulation also introduces the possibility of **processing sensitive personal data** for bias detection and correction, though it reinstates the strict necessity for the processing of special categories of personal data for the purpose of ensuring bias detection and correction. For this, a new provision (i.e., **Article 4a AI Act**) should be introduced as a legal basis for providers and deployers of AI systems and models to **exceptionally** process special categories of personal data for bias detection and correction, which shall constitute a substantial public interest to protect individuals from adverse effects such as discrimination.¹¹⁹

Furthermore, whereas **Article 4 AI Act** originally obliges providers and deployers to take measures to the best extent possible to ensure **AI literacy** of their staff and other people operating and using AI systems, that stringent obligation has been removed. To reduce compliance burden, providers and deployers should take measures to support AI literacy. The Commission and the Member States shall now support AI providers and deployers in this effort. To achieve that goal, the Commission should publish **practical examples** for compliance.¹²⁰

An amendment to Article 60 AI Act will expand the scope of **real-world testing** outside AI regulatory sandboxes to **high-risk AI systems** under sufficient safeguards¹²¹, which may benefit the testing AI systems in clinical settings.

3.7. AI Liability

Allocating responsibilities proves to be difficult in the context of AI. The AI ecosystems are complex, including **multiple actors** with diverse backgrounds, such as developers, data suppliers, and end users (e.g., hospitals and healthcare professionals).

The **complexity** manifests itself in foundational questions surrounding the development of AI. For instance, to ensure a safe AI application with adequate outcomes, the use of qualitative data is essential for the development of AI. Yet, who determines which data is actually needed and important to feed AI when developing it? Is it the developer or also the data supplier, or – in the specific context of the European Health Data Space – the health data access body?

May 2026 and last updated on 18 May 2026. Available at: <https://www.consilium.europa.eu/en/press/press-releases/2026/05/07/artificial-intelligence-council-and-parliament-agree-to-simplify-and-streamline-rules/>; and here: Council of the European Union, 2026, *Artificial Intelligence: Council gives final green light to simplify and streamline rules*, press release, 29 June 2026. Available at: <https://www.consilium.europa.eu/en/press/press-releases/2026/06/29/artificial-intelligence-council-gives-final-green-light-to-simplify-and-streamline-rules/>.

¹¹⁷ Council of the EU, 2026, *Artificial Intelligence: Council gives final green light to simplify and streamline rules*, *ibid.* (footnote 116).

¹¹⁸ European Parliament, 2026, REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI), 2025/0359(COD), PE-CONS 30/26, Brussels 18 June 2026. Available at: <https://www.consilium.europa.eu/en/press/press-releases/2026/06/29/artificial-intelligence-council-gives-final-green-light-to-simplify-and-streamline-rules/>.

¹¹⁹ Digital Omnibus on AI, (*ibid.*, footnote 118), Recital 9, Article 1(6).

¹²⁰ Digital Omnibus on AI, (*ibid.*, footnote 118), Recital 8, Article 1(5).

¹²¹ Digital Omnibus on AI, (*ibid.*, footnote 118), Recital 23, 26, Article 1(24).

Basic questions like these can shape the allocation of responsibility during both stages, namely in terms of its development and use. This section will thus provide a high level and brief overview of the liability regime.

3.7.1. EU level

At the EU level, AI is currently governed by **multiple horizontal legislations**, encompassing particularly AI-specific (AI Act), sector-specific (EHDS Regulation), data protection (GDPR), product liability (revised product liability directive) and cybersecurity legislation.

The Artificial Intelligence Act (AI Act) constitutes the main legislation shaping the obligations and requirements for providers and professional deployers of AI. Presently, an AI-specific EU liability regime does not exist.

In 2022, the European Commission proposed a draft on adapting non-contractual civil liability rules to artificial intelligence, i.e., **the EU's AI Liability Directive (AILD)**¹²², aimed at complementing the AI Act. The AILD formed part of a broad set of initiatives, including the (back then) proposal for an AI Act, and the revision of the General Product Safety Directive and the Machinery Directive. The AILD framework was designed to facilitate minimum harmonisation across EU Member States by establishing guidelines for adapting civil liability laws to address damages caused by AI systems.

A **key objective** of the proposal was the transposition of a rule covering the **presumption of causality**, which lifted the burden of proof for victims to provide evidence that the claimed damage was caused by an AI system. Furthermore, the AILD granted **national courts the right to order the disclosure of evidence** about high-risk AI systems that were in question to have caused the harm.

However, multiple stakeholders raised their concerns about the effectiveness of the AILD, also vis-à-vis national legislations, and its negative impact on innovation.¹²³ Hacker, for instance, suggests **transitioning from directives to regulations** to prevent market fragmentation and notes that a **strict liability regime** for essential services such as healthcare may harm AI deployment.¹²⁴ In 2025, the European Commission officially decided to **withdraw** the proposal for the AILD.¹²⁵

Consequently, the main frameworks influencing AI liability questions are national legislations and, from an EU perspective, the recently revised **Product Liability Directive (PLD)**¹²⁶.

The PLD sets out updated rules in terms of **liability for new technologies**, warranting that victims suffering damage through defective products can claim compensation from **economic operators**. By extending its scope to software, the PLD now applies to AI systems in healthcare. Victims are granted a period of **3 years** to bring the claim before the national court. Yet, the directive may place an

¹²² Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM/2022/496 final. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0496>.

¹²³ An overview of the stakeholder views is enlisted here: European Parliament, 2023, *Artificial intelligence liability directive*. Briefing, EU Legislation in Progress. Available at: [https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739342/EPRS_BRI\(2023\)739342_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739342/EPRS_BRI(2023)739342_EN.pdf).

¹²⁴ Hacker, P., 2024, *Proposal for a directive on adapting non-contractual civil liability rules to artificial intelligence. Complementary impact assessment*, Study written at the request of the Ex-ante Impact Assessment Unit of the Directorate for Impact Assessment and Foresight, within the Directorate-General for Parliamentary Research Services (EPRS) of the Secretariat of the European Parliament, p. 31-32. Available at: [https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU\(2024\)762861](https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU(2024)762861).

¹²⁵ European Parliament, *Legislative Train Schedule. AI liability directive*. In "A Europe Fit for the Digital Age". Available at: <https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-ai-liability-directive>.

¹²⁶ Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC, PE/7/2024/REV/1, OJ L, 2024/2853, 18.11.2024.

evidentiary burden on victims harmed by AI systems.¹²⁷ This is because it can be difficult for victims to prove the product defect, the damage and the causal link between those two requirements due to the information imbalance on how the AI system works between the manufacturer and the victim.¹²⁸

3.7.2. A national perspective

At the **national level**, national law remains important to allocate liability when damage is related to AI, both with regard to contractual and extra-contractual or tort law.

For instance, Ireland is currently working on a national law governing the regulation of artificial intelligence, i.e., the draft General Scheme of the Regulation of Artificial Intelligence Bill 2026.¹²⁹ The national law aims at implementing rules for the supervision and enforcement of the obligations laid down in the EU AI Act. It will supplement the rules of the AI Act and should therefore be read in conjunction with the EU framework. The national law will, however, not integrate liability-related rules.

Similarly, in Austria, the EU AI Act constitutes the main legislative framework, and no plans or drafts are currently being prepared for the implementation of AI-specific legislation in Austria, including liability-related ones. Nonetheless, they did adopt national guidelines to guide the responsible use of AI within Austrian administrative bodies¹³⁰ and outlining national priorities for the deployment of AI in Austria.¹³¹

In the healthcare sector, healthcare professionals are increasingly using and relying on AI.¹³² Physicians may be held liable in particular where treatments may not meet the requirements for **professional medical standards**.¹³³

While the interest in medical AI is increasing, it is, as of yet, a technology in development. Its concrete application and outcome are currently still being defined, and AI results can differ from one context to another. It thus may be difficult to consider the outcome of applied AI as reliable at this stage, as long as steady and reliable outcomes of a specific AI system are not attainable and are thus not

¹²⁷ Wachter, S., 2024, *Limitations and Loopholes in the EU AI Act and AI Liability Directives: What This Means for the European Union, the United States, and Beyond*, Yale Journal of Law & Technology, Volume 26, Issue 3, Available at: <http://dx.doi.org/10.2139/ssrn.4924553>.

¹²⁸ De Bruyne, J., et al., 2025, *Research Briefs on Artificial Intelligence and Liability – Some Points of Attention and Future Perspectives*, CiTiP Working Paper, p. 25–26. Available at: <https://www.law.kuleuven.be/citip/en/docs/books/citip-working-paper-ai-liability.pdf>.

¹²⁹ Department of Enterprise, Tourism and Employment, *General Scheme of the Regulation of Artificial Intelligence Bill 2026*. Available at: <https://enterprise.gov.ie/en/legislation/general-scheme-of-the-regulation-of-artificial-intelligence-bill-2026.html>.

¹³⁰ Bundesministerium Kunst, Kultur, öffentlicher Dienst und Sport, 2024, *Leitfaden Digitale Verwaltung: KI, Ethik und Recht. Praxisleitfaden für die Verwaltung*, Version 2.0. Available at: <https://www.bundeskanzleramt.gv.at/dam/jcr:ad3e12e4-a7d4-409b-b673-12a1b0726fea/Leitfaden-Digitale-Verwaltung-v-2-0-2025-nB.pdf>.

¹³¹ Bundesministerium Innovation, Mobilität und Infrastruktur, 2024, *Strategie der Bundesregierung für Künstliche Intelligenz Umsetzungsplan 2024*. Available at: <https://www.bmimi.gv.at/themen/innovation/publikationen/ikt/ai/Umsetzungsplan-2024.html>.

¹³² Though it is not strictly related to healthcare, it is worth noting that the deployment of AI at the government level are planned. In particular, the Federal State of Bavaria, Germany, has initiated an amending law aimed at the modernisation of the public administration. One of its objectives is to implement artificial intelligence (AI) to replace human-led discretionary decisions. The draft foresees that decisions made by public servants will be replaced by algorithmic decisions, where humans previously decided on administrative acts at their own discretion. The concrete context or environment in which AI should be applied has yet to be decided. Automated decisions may be issued for administrative acts regarding the registration of motor vehicles, or the payment of broadcasting fees or garbage collection charges. The legislative proposal has been criticised, in particular for not determining the limitations of AI sufficiently due to its incapability to provide value judgements (see: Sehl, M., 2026, *Ermessen? Pah, das soll die KI machen*. LTO Legal Tribue Online, 18.06.2026. Available at: <https://www.lto.de/recht/hintergruende/h/ki-verwaltung-ermessen-bayern-aendert-verwaltungsrecht-bund-kontrolle-kritik>; see also: Knopp, D., Kveton, P., 2026, *Bürokratieabbau: Behördengang soll vereinfacht werden*. Available at: <https://www.br.de/nachrichten/bayern/buerokratieabbau-behoerdengang-soll-vereinfacht-werden,VK4eNUK>).

¹³³ van Staaldunin, J.H., 2024, *European Product Liability for AI-based Clinical Decision Support Systems*. In: Prifti, K., Demir, E., Krämer, J., Heine, K., Stamhuis, E. (eds) Digital Governance. Information Technology and Law Series, vol 39. T.M.C. Asser Press, The Hague. Available at: https://doi.org/10.1007/978-94-6265-639-0_2.

comparable with the professional medical standard. This also leads to the problem that, as long as the use of AI by healthcare professionals does not meet professional medical standards, it is considered to be a “new method” and does not constitute a routine device that is applied in the healthcare sector.¹³⁴

Notably, in a recent court case in Germany, the higher regional court Hamm (*Oberlandesgericht Hamm*) ruled that **companies offering AI chatbots as a service**, which enable the booking of medical appointments and replying to questions, are **responsible for the chatbot’s replies**.¹³⁵ The court ruled that the (false) replies generated by the chatbot have to be attributed to the company at issue. The allocation of **responsibility remains with the company** deploying the chatbot, interestingly, even if the algorithm was fed with **accurate data** as the court ruling stipulates. In the case at stake, the AI-chatbot generated fictional, non-existing medical specialist titles, even though it was trained on a correct dataset. Thus, the company remains responsible even if the content and communication are automatically generated by the AI tool.¹³⁶

¹³⁴ Price, W.N. 2nd, Gerke, S., Cohen I.G., 2019, *Potential Liability for Physicians Using Artificial Intelligence*, JAMA, 322(18):1765–1766. Available at: <https://doi.org/10.1001/jama.2019.15064>; Frielitz, F.S., Meinel, J., Schröder, D., 2025, *Künstliche Intelligenz: Was die EU-KI-Verordnung für die ärztliche Haftung bedeutet*, 01/2025, Deutsches Ärzteblatt. Available at: <https://www.aerzteblatt.de/archiv/kuenstliche-intelligenz-was-die-eu-ki-verordnung-fuer-die-aerztliche-haftung-bedeutet-2b1f34b8-9f76-4c44-86af-919de73bf028>; referring to: Schulz-Große S, Genske A, 2023, *Auswirkungen der neuen KI-Verordnung auf den Behandlungsalltag – Datenschutzrechtliche Anforderungen und Sorgfaltspflichten der Behandelnden beim Einsatz von künstlicher Intelligenz zu Behandlungszwecken*, *Gesundh Pflege Rechtszeitschrift Für Gesamte Gesundheitswesen*, 81–94.

¹³⁵ Oberlandesgericht Hamm, Case 4 UKI 3/25, ECLI:DE:OLGHAM:2026:0512.4UKL3.25.00. Available at: https://nrwe.justiz.nrw.de/olgs/hamm/j2026/4_UKI_3_25_Urteil_20260512.html;

¹³⁶ Oberlandesgericht Hamm, Case 4 UKI 3/25, *ibid.*; press release from 12.05.2026. Available at: <https://www.justiz.nrw.de/presse/2026-05-12>.

4. ETHICAL CONSIDERATIONS

Ethics has been an important yardstick to evaluate and address risks with regard to the use and development of new technologies, especially where legal gaps exist. When applied methodologically, ethics can help inform policy decisions and legal choices. Given its place in the creation of AI-dedicated legislation, this section will briefly outline the ethical impact on the evolution of AI laws at the EU level, and highlight some of the ethical key concerns in relation to medical AI, with the attempt to create awareness.

The increasing interest in the development and application of medical AI has triggered a fast-paced growth of diagnostic tools and other medical products. Despite their promising prospects for better personalised medicine and improved medical analysis, AI bears various ethical concerns for individuals and society as a whole.

To mitigate these risks, in 2019, the **High-Level Expert Group on AI (HLEG AI)** created ethics guidelines for trustworthy AI, highlighting a **human-centric approach** to AI, and respecting the three key components (i.e., lawfulness, ethical principles, and technical robustness) as important pillars for an AI's trustworthiness. With that in mind, the HLEG AI established a foundational framework with seven key requirements that can be verified through a specific assessment (**ALTAI**).¹³⁷

Yet, completing an assessment tool is not always a straightforward solution to address ethical problems effectively, especially not as a "one-stop shop" or "checklist".¹³⁸ Ethical problems are **complex**, particularly when technical solutions are **continuously evolving**, leading to new issues.

Some general issues concern the **potential misuse** of sensitive patient data. Access to data may be inadvertently provided through the sharing of AI models. Furthermore, access to patient data may be misused for public health surveillance, which impacts individual or community **privacy and autonomy**.¹³⁹

Key ethical issues in terms of AI in healthcare encompass algorithmic **bias** that can perpetuate stigmatisation and inequality in healthcare through the algorithmic opacity created by the "**black box**".¹⁴⁰ Because of the opaque way that AI operates, Clinicians as well as patients may not always fully understand the recommendations put forward by AI. This issue can be reinforced where algorithms are trained on a limited number of people, hampering the needed variety of data from different groups of the human population, and possibly resulting in misdiagnoses.¹⁴¹

Some first evaluations seem to suggest that the use of AI by doctors could lead to the destruction of competence; though more research still needs to be performed in this area.¹⁴² If clinicians do not question the AI's output, they may become too reliant on the AI's suggestions without critical reflection. This can lead to a **loss of professional skills**, imminently also diminish the value of human oversight and subsequently the trust in healthcare services in general. It thus remains important that

¹³⁷ High-level expert group on artificial intelligence, 2020, *Assessment List for Trustworthy AI (ALTAI)*. Available at: <https://digital-strategy.ec.europa.eu/en/policies/expert-group-ai>.

¹³⁸ Hofmann, B., 2025, *Biases in AI: acknowledging and addressing the inevitable ethical issues*. Front. Digit. Health 7:1614105. Available at: [10.3389/fdgth.2025.1614105](https://doi.org/10.3389/fdgth.2025.1614105).

¹³⁹ WHO, 2021, *ibid.* (footnote 9), p. 12.

¹⁴⁰ Schönberger, D., 2019, *Artificial intelligence in healthcare: a critical analysis of the legal and ethical implications*, International Journal of Law and Information Technology, Volume 27, Issue 2, Pages 171–203. Available at: <https://doi.org/10.1093/ijlit/eaz004>.

¹⁴¹ Natalia, N., et al, 2021, *Addressing bias in big data and AI for health care: A call for open science*, Patterns, Volume 2, Issue 10, 100347, ISSN 2666-3899. Available at: <https://doi.org/10.1016/j.patter.2021.100347>.

¹⁴² Lenharo, M., 2026, *Is AI ruining our skills? Early results are in — and they're not good*, 18 June 2026, Correction 22 June 2026, Nature 655, 15–16. Available at: <https://www.nature.com/articles/d41586-026-01947-1#correction-0>

physicians remain up to responsibilities to maintain a high standard of healthcare and a critical stance towards AI, in particular, where the reliability of AI's output needs to be improved. Otherwise, the patients' health may be jeopardised, questioning the value for patients for making their data available under the EHDS.

Equitably benefit sharing, especially where commercial stakeholders are involved, is one of the components that can contribute to **fairness** in the secondary use of their health data.¹⁴³ For instance, profits obtained from research by commercial stakeholders may be returned through corporate taxation, while other possibilities to ensure fairness could be affordable access to research results or the redistribution of economic benefits to individuals and communities.¹⁴⁴

Furthermore, the introduction of AI can impose a **shift in the healthcare provider-patient relationship**, where healthcare moves away from formal clinical settings to more self-management and home-based care.¹⁴⁵ Ethical problems might accelerate where healthcare-based AI systems are considered **wellness applications** that do not have to abide by the stringent requirements as medical applications have to.¹⁴⁶ These types of applications may create privacy concerns (e.g., if the data is shared with third (possibly non-EU) parties) and endorse false reassurance with patients who attempt to manage certain medical conditions with wellness applications based on inaccurate data.

The overview shows that ethical challenges associated with medical AI are manifold and go beyond questions of legal compliance and technical capabilities. They also encompass **broader questions** of which types of AI applications society considers **desirable**. Medical AI has the potential to shape public and healthcare services, which impact patients' health and clinical routines. The development and use of AI should, thus, orient itself after the collective, societal will and public value.¹⁴⁷

¹⁴³ Cervera de la Cruz, P., Shabani, M., 2025, *Conceptualizing fairness in the secondary use of health data for research: A scoping review*, Accountability in Research, 32(3), 233–262. Available at: <https://doi.org/10.1080/08989621.2023.2271394>.

¹⁴⁴ Cervera de la Cruz, P., Shabani, M., 2025, *ibid.* (footnote 143), p. 243–254.

¹⁴⁵ Mittelstadt, B., 2021, *The impact of artificial intelligence on the doctor-patient relationship*, Report commissioned by the Steering Committee for Human Rights in the field of Biomedicine and Health (CDBIO), Council of Europe. Available at: <https://www.coe.int/en/web/human-rights-and-biomedicine/report-impact-of-ai-on-the-doctor-patient-relationship>.

¹⁴⁶ WHO, 2021, *ibid.* (footnote 9), p. 8.

¹⁴⁷ Lopez Solano, J., et al., 2022, *Governing data and artificial intelligence for all: Models for sustainable and just data governance*, Study written at the request of the Panel for the Future of Science and Technology (STOA) and managed by the Scientific Foresight Unit, within the Directorate-General for Parliamentary Research Services (EPRS) of the Secretariat of the European Parliament, 11 July 2022, PE 729.533, p. IV. Available at: [https://www.europarl.europa.eu/stoa/en/document/EPRS_STU\(2022\)729533](https://www.europarl.europa.eu/stoa/en/document/EPRS_STU(2022)729533).

5. CONCLUDING REMARKS AND POLICY CONSIDERATIONS

In order to further maximise the full potential of AI in healthcare, the existing legislative gaps that were identified need to be closed, while respecting patient privacy and safety. Addressing these gaps with regard to the use of data for the development of AI in medicine necessitates an evidence-based approach that incorporates the perspective of patients, healthcare providers, and researchers. Patients are not merely passive beneficiaries of healthcare, but provide essential contributions to the European health system. EU policies must be inclusive and incorporate participants' perspectives to address regulatory challenges. Based on the foregoing elaboration, the following recommendations can be summarised as follows:

Table 1: Reflections and policy recommendations

Reflections and policy recommendations concerning the facilitation of data usage for the development of AI in medicine	
European Health Data Space (EHDS)	• The European Health Data Space Regulation, the General Data Protection Regulation and the AI Act generally provide meaningful possibilities for the use of personal health data in public health and the development of AI in medicine. However, legal uncertainty (e.g., regarding the concept of scientific research) requires clarification, including the regulations' practical execution. • Administrative burden for health data holders, such as healthcare professionals, needs to be reduced to enhance data sharing (e.g., data sharing agreements). • Guidance encompassing potential legal, organisational and technical safeguards needs to be developed to secure patient privacy and safety. • Fostering a common understanding of the scope of application of legal bases, such as scientific research and public interest, through EU-wide coordination may alleviate a possible imbalance in data access among EU countries. • Medical AI has the potential to unravel significant findings concerning patients' health. Patients have the right to be informed about significant findings under the EHDS, which researchers are required to communicate to health data access bodies. While this right needs to be ensured through communication to physicians and their patients, a uniform approach across countries should be supported, also considering the workforce's experience, i.e., the physicians' knowledge and their relationship with the patient.
Innovation	• Whilst the EHDS acknowledges IP-related rights, it does not specify how the commercial interest in IP rights should be carefully balanced against the public interest in innovation. It leaves the balancing of public interests (e.g., in medical advancements) and private interests (e.g., a commercial interest in IP-related protection and commercially profitable innovation) unclear and unanswered.

Reflections and policy recommendations concerning the facilitation of data usage for the development of AI in medicine	
	The problem manifests itself particularly if national health data access bodies apply different standards in their balancing exercise.
Patient data as a collective resource for the public interest	• The development of AI requires qualitative patient data. In the same vein, access to non-anonymised patient data should be carefully balanced against the interest for which it is requested. Patient data as a common and sensitive resource should resist the risk of commodification. • Considering AI's dependence on large amounts of data, the EHDS facilitates its access, which challenges the traditional view on patient data being subject to medical secrecy within the patient-doctor relationship. Regulatory agencies such as the EDPB and EDPS should guide the (re-)use of the (anonymised) patients' health data for the training and development of medical AI. Clear guidelines for healthcare providers are required to enable the secure reuse of patient data without violating their duty of medical secrecy. • To support the reuse of data collected for altruistic purposes, creating legislative alignment between the Data Governance Act's data altruism mechanism and the EHDS Regulation's objective is pivotal. Additionally, with a view to reducing administrative burden, legislators should maintain their support for the development of a uniform data altruism consent mechanism. • The development and use of AI should orient itself after the societal will and public value. This applies to AI in general and in healthcare more specifically. Attention should be given to such AI applications that create the biggest value (to be balanced against risks) for the workforce and patients.
Trustworthiness and reliability	• For AI to be trustworthy, a reliable and lawful system alone is not enough. The end users deploying and using them contribute to its trustworthiness. Training healthcare workers in AI is thus an essential step for the safe use of AI. Ensuring the ability to interpret AI output secures the needed human oversight whilst easing the administrative workload and improving personalised care. • The creation of a centralised catalogue of verified AI solutions within the EU, can help address practical questions related to the deployment of AI. This approach can support the deployment of AI as a reliable technology that meets medical standards as the technology evolves, thereby also helping healthcare workers as users of these technologies to balance liability risks.

Source: Author's own elaboration.

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Artificial intelligence (AI) has the ability to transform healthcare for the benefit of both healthcare providers and patients. Implementing a framework that facilitates the (re-)use of data is pivotal to its advancement. However, the development and deployment of AI face various challenges. This study outlines some of the AI technologies applied in the healthcare sector, examines essential EU legal frameworks facilitating the (re-)use of data for the development of medical AI, and discusses some of the key concerns arising in this context. Finally, it presents policy recommendations to address these issues.

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