ARE DATA IN CLINICAL GENETICS SUFFICIENTLY PROTECTED? PROTECTING GENETIC DATA IN THE LIGHT OF ARTIFICIAL INTELLIGENCE TOOLS

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Abstract: Artificial intelligence (AI) and its tools are found at every turn nowadays. AI is appearing in all spheres of social life, including healthcare. In clinical practice, its use is becoming more and more widespread. But is its use in healthcare safe enough to protect the health and personality of the patient? What about genomic and genetic data, which is among the most sensitive?

We will look at this issue in more detail, including in comparison with the international environment, in particular the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: The Convention on Human Rights and Biomedicine[2] (hereinafter the "Convention on Human Rights and Biomedicine") and 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 certain EU legislative acts (hereinafter the "Artificial Intelligence Act") or Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation). The article will also focus on the consequences within the framework of national legal regulation, in particular within the limits of Act No. 372/2011 Coll., on Health Services and Conditions of Their Provision (Act on Health Services), and Act No. 373/2011 Coll., on Specific Health Services.

The current legislation seems to be sufficiently protective of the processing of genomic or genetic data and does not change the processing of such data in its essence. If there are to be changes to regulation or changes to legal regulation, they should be sensible, focusing in particular on liability for the use of systems or tools using artificial intelligence.

Resumé: Umělou inteligenci (dále jen „AI") a její nástroje nalézáme v současné době na každém kroku. AI se objevuje ve všech sférách společenského života, včetně zdravotnictví. V klinické praxi se její užití stává stále rozšířenějším. Je však její využití ve zdravotnictví dostatečně bezpečné pro ochranu zdraví a osobnosti pacienta? Jak je tomu v oblasti genomických a genetických dat, která patří mezi nejcitlivější?

Na tuto problematiku se podíváme podrobněji, a to i v komparaci s mezinárodním prostředím, zejména s Úmluvou o ochraně lidských práv a důstojnosti lidské bytosti v sou-

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[2] Communication No. 96/2001 Coll. of the Ministry of Foreign Affairs concerning the adoption of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine, available [on line], accessed 11 February 2025 https://www.e-sbirka.cz/sm/2001/96/0000-00-00?vs=%C3%9Amluva%20o%20ochran%C4%9B%20lidsk%C3%BDch%20pr%C3%A1v%20a%20d%C5%AFstojnosti%20lidsk%C3%A9%20bytosti&zalozka=text.

vislosti s aplikací biologie a medicíny: Úmluva o lidských právech a biomedicíně[3](dále jen „Úmluva o lidských právech a biomedicíně“) a Nařízením Evropského parlamentu a Rady 2024/1689, kterým se stanoví harmonizovaná pravidla pro umělou inteligenci a mění určité legislativní akty Unie (dále také jen „Akt o umělé inteligenci“) či Nařízením Evropského parlamentu a Rady (EU) 2016/679 ze dne 27. dubna 2016 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů a o volném pohybu těchto údajů a o zrušení směrnice 95/46/ES (Obecné nařízení o ochraně osobních údajů). Článek se zaměří i na důsledky v rámci vnitrostátní právní regulace, zejména v mantinelech zákona č. 372/2011 Sb., o zdravotních službách a podmínkách jejich poskytování (zákon o zdravotních službách), a zákona č. 373/2011 Sb., o specifických zdravotních službách.

Platná právní úprava se jeví jako dostatečně chránící zpracování genomických, resp. genetických údajů a ve své podstatě jejich zpracování nemění. Pokud by se mělo jednat o změny úpravy či změny právní regulace, měly by býti účelnými se zaměřením zejména na odpovědnost za užití systémů či nástrojů využívající umělou inteligenci.

Key words: data protection, genetic data, AI in medicine, AI in research, medical law, health law, Czech law

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Introduction

The use of artificial intelligence is undoubtedly related to data and data processing. Therefore, we must clarify at the outset which data we will be discussing in the following lines. **Genomic data and genetic data.** Not everyone is familiar with their meaning, and for some, the two terms are even considered synonymous. Let us therefore look at their definitions as found in the literature or in legal regulations.

The human genome is defined by the Act No. 373/2011 Coll., on Specific Health Services, as amended (hereinafter also referred to as the “Act on Specific Health Services”) in Section 28(1): *“The human genome means the sum of hereditary information that has been inherited from ancestors or newly created in the person under examination and may be transmitted to future generations.”* As can be seen from the above definition, the scope of genomic data is very broad and its significance enormous. It includes both hereditary information that has been obtained from ancestors or, on the other hand, information that may affect future generations. In other words, genomic data includes not only the past and present, but also the future of one generation.

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[3] Sdělení Ministerstva zahraničních věcí č. 96/2001 Sb. m. s., o přijetí Úmluvy na ochranu lidských práv a důstojnosti lidské bytosti v souvislosti s aplikací biologie a medicíny: Úmluva o lidských právech a biomedicíně [Communication of the Ministry of Foreign Affairs No. 96/2001 Coll. of International Treaties, on the adoption of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine], available [on line], accessed 11 February 2025 https://www.e-sbirka.cz/sm/2001/96/0000-00-00?vs=%C3%9Amluva%20o%20ochran%C4%9B%20lidsk%C3%BDch%20pr%C3%A1v%20a%20d%C5%AFstojnosti%20lidsk%C3%A9%20bytosti&zalozka=text.

As mentioned in the previous paragraph, the human genome is defined within the framework of national legislation. On the other hand, in the international arena, it is not explicitly defined in the Convention on Human Rights and Biomedicine, although Chapter IV is entitled The Human Genome. However, in this chapter we find the basic principles that apply to any work with it, as will be further elaborated in the following text.

Another internationally valid standard where we find the definition of the human genome is the UNESCO "Universal Declaration on the Human Genome and Human Rights" from 1997. This declaration states that the human genome is a fundamental element of human identity and its manipulation must be carried out with the utmost care and respect for human rights.[4] Although this declaration is not legally binding, it has significant moral and ethical influence and serves as an important reference document for national and regional legislation on medicine, privacy and genetic research.

Genetic data includes information about specific genes or DNA (deoxyribonucleic acid) sequences that are associated with certain traits or diseases. The definition of genetic data can be found in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (hereinafter also referred to as "GDPR"), which defines it in Article 4(1)(a)(i) of the GDPR. (1)(13) as *'… personal data relating to inherited or acquired genetic characteristics of a natural person which provide unique information about the physiology or health of that natural person and which result, in particular, from the analysis of a biological sample of the natural person concerned;'* with recital 34 further specifying it as *'… personal data relating to the inherited or acquired genetic characteristics of a natural person, which result from the analysis of a biological sample of the natural person concerned, in particular chromosomes or deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), or from the analysis of another element which makes it possible to obtain equivalent information.'* A gene refers to a specifically located unit of hereditary information and, in terms of molecular genetics, is a section of the DNA molecule.[5] DNA was first isolated in 1869 by Friedrich Miescher, a Swiss scientist who decided to study white blood cells, which are abundant in pus and which he had in abundance in bandages from a hospital near his university. Miescher isolated a phosphorus-rich material from these cells and called it nuclein. He also found nuclein in other types of cells. There are a number of definitions of DNA and its structure, for example, "*Its molecule is made up of two polynucleotide strands of DNA… The two polynucleotide strands (the primary structure of DNA) form (most commonly) a right-handed helix referred to as a double helix (the secondary structure of DNA).*"[6] DNA sequencing then "…describes a *general laboratory technique for determining the exact sequence of nucleotides or bases in a DNA molecule. The sequence of bases (often referred to by the first letters of their chemical names: A, T, C and G) encodes the biological information that cells use to develop and function*."[7] There are also

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[4] UNESCO, Universal Declaration on the Human Genome and Human Rights, 1997, available [on line], accessed 11 February 2025 https://unesdoc.unesco.org/ark:/48223/pf0000253908.

[5] MUDr. Antonín Šípek, Genetics-Biology, Gen, available [on line], accessed 11 February 2025: http://www.genetika-biologie.cz/gen.

[6] Antonín Šípek, M.D., Genetics – Biology. deoxyribonucleic acid, available [on line], accessed 11 February 2025: http://www.genetika-biologie.cz/deoxyribonukleova-kyselina.

[7] NIH. National Human Genome Research Institute, 2025, available [on line], accessed 11 February 2025: https://www.genome.gov/genetics-glossary/DNA-Sequencing.

other nucleic acids that can carry information (e.g. RNA). Genetic data is often used to identify genetic predispositions to disease, to diagnose genetic disorders and in personalised medicine, where it helps to tailor treatment to patients' individual genetic profiles.

Both types of data – genomic and genetic – are crucial for modern biomedical research and clinical practice, including personalised medicine. However, they require careful protection and ethical handling due to their sensitive nature.

And now let's turn our attention to AI tools, or the definition of AI itself. We owe the term artificial intelligence to American scientist Marvin Minsky, who defines AI as "… *the science that makes machines do things that would require intelligence if done by humans*."[8] However, its actual name was not coined until 1956 at the Summer Research Project on Artificial Intelligence at Dartmouth, organized by John McCarthy and Marvin Minsky.[9] The legislative anchor for AI can be found in the Artificial Intelligence Act, which defines an AI system as *"… a machine system designed to operate with varying levels of autonomy and which, when implemented, can exhibit adaptability and which, for explicit or implicit purposes, infers from the inputs received how to generate outputs such as predictions, content, recommendations, or decisions that can affect physical or virtual environments."*[10]

AI tools are widely used in social life, and we can say that their use has become more and more widespread in recent years. This is also true for the healthcare sector. For this reason, the World Health Organization (WHO) and the EU have addressed both the definition and, in particular, the need for its legal regulation. The WHO has defined artificial intelligence as *"…a field of computer science that emphasises the simulation of human intelligence processes by machines that work and react as humans do."*[11] The EU then set the world's first legal framework for this field and adopted the "Artificial Intelligence Act".

Having defined the basic concepts, we now turn to their protection under the law, whether at national or international level. In the following text, we will deal with the following legal norms, which, in the author's opinion, are relevant in the search for an answer to the question posed by the very title of the article. These are:

- **Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine),**
- **Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation),**

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[8] Michael Aaron Dennis, fact-checked Encyclopaedia Britannica, accessed 14 February 2025, [online] available from: https://www.britannica.com/biography/Marvin-Lee-Minsky.

[9] TĚŠITELOVÁ, Vladimíra, Telemedicine and its legislative anchorage in the Czech Republic, UK Faculty of Law, final thesis of the internationally recognized LL.M. course, 30 January 2024.

[10] 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), Article 3(1), accessed 17 February 2025, [online] available from: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=celex%3A32024R1689.

[11] Who.int. 2021. Global strategy on digital health 2020-2025. Geneva: World Health Organization; 2021. ISBN 978-92-4-002092-4, p. 39 accessed 14 February 2025 [online] available from: https://iris.who.int/bitstream/handle/10665/344249/9789240020924-eng.pdf.

- **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 certain EU legislative acts (Artificial Intelligence Act),**
- **Act No. 372/2011 Coll., on Health Services and Conditions of Their Provision (Act on Health Services),**
- **Act No. 373/2011 Coll., on Specific Health Services.**

1. Protection of genetic data in international law

As mentioned above, the fundamental legal regulation at the international level is the Convention on Human Rights and Biomedicine, an international treaty adopted by the member states of the Council of Europe in 1997. The Czech Republic ratified it in 2001. The Convention grants specific rights to patients and imposes specific obligations on health service providers. It is an international treaty which is superior to all national legislation. Article 10 of the Constitution of the Czech Republic states *"…Declared international treaties to the ratification of which Parliament has given its consent and by which the Czech Republic is bound shall form part of the legal order; if an international treaty provides for something different from the law, the international treaty shall apply."*

The Convention on Human Rights and Biomedicine is a key document that sets ethical and legal standards for the application of biology and medicine, and ensures that human rights and dignity are always paramount. Its main areas that can be related to the protection of genomic or genetic data are as follows:

- **Protection of human dignity**: the Convention emphasises the protection of human rights and dignity in the context of the application of biology and medicine. The interests and welfare of the human being are paramount to the interests of society or science.
- **Privacy**: the Convention ensures the protection of privacy and the right to information. Patients have the right to protection of their personal data and to access information about their health.
- **Human genome**: the Convention prohibits any form of discrimination on the basis of genetic heritage and stipulates that interference with the human genome may only be carried out for preventive, diagnostic or therapeutic purposes.

As stated above, the protection is particularly strong in relation to the protection of human dignity and human rights; at the same time, the protection of personal data is ensured, there is a very clear purpose definition in relation to interference with the human genome, and last but not least, the prohibition of any discrimination on the basis of genetic heritage is declared. The Convention on Human Rights and Biomedicine is a binding legal instrument which each of the contracting parties, not excluding the Czech Republic, has undertaken to respect. At the same time, the above-mentioned Convention states the obligation of the Contracting Parties to introduce measures to ensure the fulfilment of the obligations arising from the Convention into national legislation: *"Each Contracting Party shall adopt in its legal order the measures necessary to ensure the effectiveness of the provisions of this Convention."*[12]

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[12] Communication No. 96/2001 Coll. of International Treaties of the Ministry of Foreign Affairs concerning the adoption of the Convention for the Protection of Human Rights and Dignity of the Human Being with

Another provision of the Convention on Human Rights and Biomedicine that needs to be addressed is the issue of professional standards, where, according to Article 4 of the Convention, any intervention in the field of health care, including scientific research, can only be carried out in accordance with relevant professional duties and standards.[13] In this context, it can be noted that if the relevant professional standards also introduce standards for working with AI tools, this will be done in full compliance with the Convention on Human Rights and Biomedicine.

To conclude on the Convention on Human Rights and Biomedicine, although it does not contain an explicit provision on AI tools, the protection of human rights and personal data is explicitly enshrined here at a general level. We can therefore conclude that the use of AI tools must also respect the principles set out in the Convention.

2. Genetic data in European law

Another international law that explicitly deals with the issue of genetic data is Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) ("GDPR"). The legislative treatment of genetic data under the GDPR is very specific. Recital 34 defines it as *"…personal data relating to the inherited or acquired genetic characteristics of a natural person resulting from the analysis of a biological sample of the natural person concerned, in particular chromosomes or deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), or from the analysis of another element which makes it possible to obtain equivalent information…"*[14] and then in Article 4(13) as *"… personal data relating to the inherited or acquired genetic characteristics of a natural person which provide unique information about his or her physiology or health and which result in particular from the analysis of a biological sample of the natural person concerned;"*[15] Primarily, the processing of genetic data is directly prohibited within the meaning of Article 9(1) of the GDPR, on the other hand, its processing is only permitted in the explicit cases set out in Article 9(2) of the GDPR.

However, the GDPR makes no mention of artificial intelligence or tools using artificial intelligence in its provisions. What we do find in the GDPR, however, is a demarcation against emerging technologies, which certainly include artificial intelligence tools. Data

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regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine, available [on line], Article 1, accessed 14 February 2025: https://www.e-sbirka.cz/sm/2001/96/0000-00-00?vs=%C3%9Amluva%20o%20ochran%C4%9B%20lidsk%C3%BDch%20pr%C3%A1v%20a%20d%C5%AFstojnosti%20lidsk%C3%A9%20bytosti&zalozka=text.

[13] Communication No. 96/2001 Coll. of International Treaties of the Ministry of Foreign Affairs concerning the adoption of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine, available [on line], Article 4, accessed 17 February 2025: https://www.e-sbirka.cz/sm/2001/96/0000-00-00?vs=%C3%9Amluva%20o%20ochran%C4%9B%20lidsk%C3%BDch%20pr%C3%A1v%20a%20d%C5%AFstojnosti%20lidsk%C3%A9%20bytosti&zalozka=text.

[14] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Recital 34 available [on line], accessed 17 February 2025: https://eur-lex.europa.eu/legal-content/cs/TXT/?uri=CELEX%3A32016R0679.

[15] Ibid, Article 4(14).

protection should be independent of the technologies used and should be technology neutral[16] . The GDPR also sets out what technical and organisational measures must be put in place when processing large volumes of data or when introducing new technologies; an example is the obligation to carry out a data protection impact assessment.[17]

The GDPR does not explicitly mention AI tools, but it provides special protection for genetic data due to its sensitivity, gives data subjects rights of access, rectification, erasure and restriction of processing, and sets strict conditions for processing and international transfer. These measures aim to protect privacy and prevent the misuse of genetic information. At the same time, the GDPR allows national legislation to introduce or maintain additional conditions for the processing of genetic data (as well as biometric data and, where applicable, health data).[18]

Of the above three international laws, the "Artificial Intelligence Act" is the most recent. This unique piece of legislation is a harmonising legislation within the EU, it is a directly applicable piece of legislation with a phased-in effect until 2027. The "Artificial Intelligence Act" comes into force on the twentieth day after its publication in the Official Journal of the EU; specifically, the "Artificial Intelligence Act" came into force on 1 August 2024.

In its press release of 9 December 2023, the Council of the EU summarised the importance of this harmonising legislation also in relation to data protection *"The proposed Regulation aims to ensure that AI systems to be marketed and used in the EU are safe and respect fundamental EU rights and values."*[19]

In addition to basic definitions of AI and other terms, the Artificial Intelligence Act establishes a basic regulatory framework for AI and its use. One of the already effective areas of this regulation (as of 2 February 2025) is, among others, for prohibited AI practices (Chapter II). A glance at this chapter reveals that the prohibited AI practices are:

- **Manipulative techniques**: the use of AI systems that use subliminal or manipulative techniques to disrupt the behaviour of individuals is prohibited.
- **Exploitation of vulnerabilities**: the use of AI systems that exploit the vulnerabilities of individuals due to age, disability or social situation is prohibited.
- **Social credit**: The evaluation or classification of persons based on their social behaviour that results in adverse treatment is prohibited.
- **Crime prediction**: the use of AI systems to predict crime based on personal profiling is prohibited.
- **Facial recognition**: The creation or expansion of facial recognition databases without targeted image retrieval is prohibited.
- **Emotion inference:** The use of AI systems to infer emotions in the workplace and schools is prohibited unless for medical or safety reasons.
- **Biometric categorisation**: it is prohibited to categorise persons on the basis of biometric data in order to infer their race, political opinions, religious beliefs, etc.

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[16] Ibid, recital 15.

[17] Ibid, Article 35(1).

[18] Ibid, recital 53 and Article 9(4)

[19] Council of the EU, Artificial Intelligence Act: Council and Parliament reach agreement on the world's first rules for artificial intelligence, 9 December 2023, available [online], accessed 25 February 2025: https://www.consilium.europa.eu/cs/press/press-releases/2023/12/09/artificial-intelligence-act-council-and-parliament-strike-a-deal-on-the-first-worldwide-rules-for-ai/pdf.

- **Biometric identification**: the use of real-time remote biometric identification systems in public areas for law enforcement purposes is prohibited unless strictly necessary.

The Artificial Intelligence Act focuses on the protection of individual rights through several key measures. AI systems must not unlawfully collect, process or share personal data. Article 10(5) addresses a specific category of personal data, which allows for the processing of such personal data in the case of high-risk systems, but subject to full compliance with the technical and organisational measures under the GDPR, and goes beyond them to provide explicit conditions under which such data may be processed in such systems. These conditions must all be met. Specifically, the following conditions apply:

a) *detection and correction of bias cannot be effectively performed by processing other data, including synthetic or anonymised data;*
b) *special categories of personal data are subject to technical restrictions on the re-use of personal data as well as state-of-the-art security and privacy measures, including pseudonymisation;*
c) *special categories of personal data are subject to measures to ensure that the personal data processed are secured and protected and are subject to appropriate safeguards, including strict controls and documentation of access, to prevent misuse and to ensure that only authorised persons with appropriate confidentiality obligations have access to such personal data;*
d) *Special categories of personal data are not transferred, transmitted or otherwise made available to other parties;*
e) *specific categories of personal data shall be deleted as soon as the distortion is corrected or the retention period for those data expires, whichever is the earlier;*
f) *the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 contain the reasons leading to the conclusion that the processing of specific categories of personal data was strictly necessary to detect and correct the distortion and that this purpose could not be achieved by processing other data.*[20]

Finally, on data protection, it is necessary to mention the interrelationship between the GDPR and the Artificial Intelligence Act. As already mentioned above, the GDPR is aimed at protecting personal data and lays down rules for the processing of personal data, which the Artificial Intelligence Act fully respects and declares in Article 2(7). On the contrary, the Artificial Intelligence Act goes beyond the regulation provided for by the GDPR, in the case of the conditions for the processing of special categories of personal data (see above), but also in the case of further processing of personal data for the purposes of developing certain AI systems in the public interest within the regulatory sandbox for AI under Article 59. Specifically, these conditions are as follows:

a) *AI systems are developed by a public authority or other natural or legal person to protect a substantial public interest in one or more of the following areas:*
    i) *public safety and public health, including the detection, diagnosis prevention, control and treatment of disease and the improvement of health care systems;*
    ii) *High level of protection and improvement of environmental quality, protection of biodiversity, protection against pollution, green transformation measures, climate change mitigation and adaptation measures;*
    iii) *energy sustainability;*

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[20] Ibid., Article 10(5)(a).

   - *iv) Security and resilience of transport systems and mobility, critical infrastructure and networks;*
   - *v) the efficiency and quality of public administration and public services;*
- *b) the data processed are necessary for compliance with one or more of the requirements set out in Chapter III, Section 2, insofar as those requirements cannot be effectively met by processing anonymised, synthetic or other non-personal data;*
- *c) there are effective monitoring mechanisms in place to identify whether any high risks to the rights and freedoms of data subjects referred to in Article 35 of Regulation (EU) 2016/679 and Article 39 of Regulation (EU) 2018/1725 may arise during the sandbox experimentation, and there are response mechanisms in place to mitigate those risks immediately and, where necessary, to stop the processing;*
- *d) all personal data to be processed within the sandbox is located in a functionally separate, isolated and secure data processing environment under the control of the potential provider and is accessible only by authorised persons;*
- *e) Providers may only further share the data originally collected in accordance with Union data protection law; any personal data created within the sandbox cannot be shared outside the sandbox;*
- *f) any processing of personal data within the sandbox does not lead to measures or decisions affecting data subjects or affect the exercise of their rights under Union law in the field of personal data;*
- *g) all personal data processed within the sandbox is protected by appropriate technical and organisational measures and deleted once participation in the sandbox or the retention period of the personal data has ended;*
- *h) logs of the processing of personal data within the sandbox shall be kept for the duration of the participation in the sandbox, unless otherwise provided for by Union or national law;*
- *i) a full and detailed description of the procedure and rationale for training, testing and validation of the AI system shall be kept with the test results as part of the technical documentation listed in Annex IV;*
- *j) a brief summary of the AI project developed in the sandbox, its objectives and expected results is published on the website of the competent authorities; this obligation does not apply to sensitive operational data relating to the activities of law enforcement, border protection, immigration or asylum authorities.*[21]

Another key measure introduced by the Artificial Intelligence Act is transparency. Users must be informed that they are interacting with AI systems and have access to information about how their data is being used. The Artificial Intelligence Act prohibits discriminatory practices that could lead to unfair treatment of individuals based on their personal characteristics. All AI systems must be designed to be safe and reliable, minimise risks and protect users from potential harm. They also set out the rights of individuals, which include both the right to access and the right to correct or delete their data.

To conclude on the Artificial Intelligence Act, all the measures introduced or being introduced in this Regulation aim to ensure that the use of AI systems is in line with the values of the Union and protects the fundamental rights of individuals.

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[21] Ibid Article 59(1).

Last but not least, in the case of European legal regulations, we must not forget 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 (hereinafter referred to as the "EHDS Regulation"), which is the youngest piece of legislation.

The "EHDS Regulation" is the essential legislative framework for the digitalisation of healthcare in the EU. Its main objective is to create a single and interoperable system for the primary and secondary use of electronic health data across Member States. The "EHDS Regulation" strengthens the rights of individuals to access and control their health data, while setting the legal and technical conditions for the secure sharing of these data for research, innovation, policy-making and public health purposes. The "EHDS Regulation" promotes the harmonisation of electronic health record (EHR) systems, thus contributing to the development of a single digital market for health services and products. The "EHDS Regulation" responds to the experience of the COVID-19 pandemic and emphasises preparedness for health threats, the protection of personal data and the strengthening of the European Health Union.

From the point of view of genetic data, we can find specific mention both in the introductory recitals, which summarize their importance and the need to share them for the purpose of their secondary use, and then in the specific provisions of the "EHDS Regulation" itself. In particular, their inclusion in the list of minimum categories of electronic health data for secondary use.[22] Article 51(1)(f) mentions, inter alia, both genetic data and genomic data *"… (f) genetic, epigenomic and genomic data relating to human beings."*[23]

The "EHDS Regulation" also takes into account the link with the "Act on Artificial Intelligence". Both at the level of cooperation with the European Council on Artificial Intelligence established by this Act[24], and in the requirements for AI systems[25], which must be met. In this respect, the introductory Article 1(5) already establishes a clear link to the Artificial Intelligence Act: *"5. This Regulation is without prejudice to Regulations (EU) 2017/745, (EU) 2017/746 and (EU) 2024/1689 as regards the safety of medical devices, in vitro diagnostic medical devices and artificial intelligence (AI) systems that interact with EHR systems."*

Regulation (EU) 2025/327 on the European Health Data Space (EHDS) protects health data through several key mechanisms. It introduces harmonised rules for the processing of electronic health data across the EU, ensuring legal certainty and protecting the rights of individuals. Individuals have the full right to access their data, to make it portable and to decide who has access to it and for what purpose. The Regulation requires systems for sharing and processing health data to meet strict security standards, including encryption, authentication and audit trails. Data for secondary use can only be used for research, innovation or policy-making in anonymised or pseudonymised form and under the supervision of the competent authorities.

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[22] Article 51(1)(f).

[23] Ibid.

[24] Recital 30 REGULATION (EU) 2025/327 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 February 2025 on the European Health Data Area and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.

[25] Recital 42 ibid.

To conclude on the EHDS Regulation, it can be stated that this Regulation provides for a comprehensive legal framework for the primary and secondary processing of health data, including genetic and genomic data. It sets out quite precisely the scope of health data for primary and secondary processing, sets out precisely the rights of patients to access these data and sets out clearly the rights of the patient to allow or not to allow access to these data, all within the European Health Data Area.

3. Protection of genetic data in Czech law

And now to national legislation. To do so, let us start again with the Convention on Human Rights and Biomedicine, specifically right in its Article 1, which provides, inter alia, that *"… each Party shall adopt in its legal order the measures necessary to ensure the effectiveness of the provisions of this Convention."*[26] The two key laws that introduce these measures in relation to the protection of genomic data are Act No. 372/2011 Coll., on Health Services and Conditions of Their Provision (Act on Health Services) and Act No. 373/2011 Coll., on Specific Health Services.

3.1 Act on Health Services

If we look at the Act on Health Services, we can find protection of genetic data in several ways. Firstly, there are the obligations of health service providers and secondly, there are the rights of patients. First of all, there are the provisions governing confidentiality.[27] Healthcare professionals are obliged to maintain confidentiality of all facts relating to the health status of patients, including genetic information. However, the obligation of confidentiality applies not only to healthcare professionals according to the above-mentioned Section 51 of the Act on Health Services; according to paragraph 5 of the same section, it is extended to other persons as well:

(5) The obligation of confidentiality under subsection (1) shall also apply to
  - *(a) health professionals and other professionals, in connection with the exercise of their profession,*
  - *(b) health professionals or other professionals who are no longer practising their profession and who acquired the information in connection with their former occupation as a health professional or other professional or employment in the provision of health services,*
  - *(c) persons acquiring competence to practise as a health professional or other professional,*
  - *(d) persons referred to in § 65(2) who, without the patient's consent, consult the medical records kept on the patient,*
  - *(e) members of expert committees under the Specific Act on Health Services,*
  - *(f) the persons referred to in Article 46(1)(g),*

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[26] Communication No. 96/2001 Coll. of International Treaties of the Ministry of Foreign Affairs concerning the adoption of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: The Convention on Human Rights and Biomedicine, available [online], accessed 25 February 2025 https://www.e-sbirka.cz/sm/2001/96?zalozka=text.

[27] § 51 of Act No. 372/2011 Coll., on Health Services and Conditions of their Provision (Act on Health Services), as amended.

(g) *other persons who, in the context of their activities carried out on the basis of other legislation, become aware of information about the patient's health or information relating thereto.*[28]

Other obligations given to health service providers are the maintenance of medical records. This must be kept in accordance with the law and protected from unauthorised access; the data contained therein shall be processed only to the extent provided for by law and necessary for the provision of healthcare. Specific provisions can be found in Section 53 et seq. of the Act on Health Services.

As another provision within the Act on Health Services, we can mention the maintenance of the National Health Information System, which in some parts can be (and is) a carrier of records of, for example, genetically determined diseases (e.g. within the National Register of Reproductive Health *"….data on detected congenital and developmental defects and genetically determined diseases in fetuses and persons,…"*[29]. The National Health Information System is a public information system and its maintenance is subject to strict and explicit legal regulation set out in sections 70 to 78 of the Act on Health Services. The purpose of keeping personal data, their scope and the range of persons authorised to access this personal data, including genomic data, are set. The administrator of the NHSI, which is by law the Institute of Health Information and Statistics of the Czech Republic[30], is responsible for ensuring the protection of personal data by adopting the appropriate technical and organisational measures according to the applicable legislation both at national and European level (especially GDPR).

From the perspective of patients' rights, we can mention the right to protection of patients' personal data or the quality and safety of health services provided to them, and the corresponding obligations of health service providers to ensure that the following points are respected:

- Any processing of personal data, including genetic data, must comply with data protection legislation such as the GDPR. This includes ensuring data security and minimising the risks associated with processing.
- Patients must be informed about the use of any tools, including AI, in the provision of health services. This includes information on the purpose, scope and potential risks of using these technologies,
- Healthcare providers are required to ensure that all tools and technologies used, including AI, meet the quality and safety requirements of healthcare services.

The use of AI in healthcare should comply with ethical principles that include respect for patients' rights, transparency and accountability in the use of these technologies.

Interim conclusion: from the point of view of the use of AI tools, we can conclude that the Act on Health Services does not explicitly address the issue of the use of AI tools, but it does contain some provisions that can be applied to the use of AI tools.

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[28] Ibid, para. 5.

[29] Annex to Act No 372/2011 Coll., on health services and conditions of their provision (Act on Health Services), as amended.

[30] § 70(3) of Act No 372/2011 Coll., on Health Services and Conditions of their Provision (Act on Health Services), as amended.

3.2 Act on Specific Health Services

Within the framework of the Act on Specific Health Services, we find the legal regulation of genetic data and their protection within the framework of assisted reproduction[31], as well as specific definitions and specifications of genetic examinations[32]. These provisions, among other things, set not only definitional terms, but also the obligations of health service providers within the framework of providing these specific health services. The circle of health service providers providing these health services, and the purpose of their implementation are set here.

The Act on Specific Health Services stipulates a written form of consent[33] as a mandatory form in the case of genetic examinations and stipulates the obligation for health service providers to provide information to the patient about the purpose, nature of this examination and the impact on health. In this context, in the author's opinion, the patient should also be informed about the use of artificial intelligence tools.

At this point, however, we must mention the connection between the Act on Specific Health Services (lex specialis) and the Act on Health Services (lex generalis), where, according to Section 2, paragraph 2 of the Act on Specific Health Services, the following applies*: (2) The provisions of the Act on Health Services shall apply in connection with the provision of specific health services, unless otherwise provided by this Act.* This means that in the case of the provision of the above-mentioned specific health services, the general elements of genetic data protection set out in the previous chapter shall also apply.

Interim conclusion: If we assess the Act on Specific Health Services in its entirety with the general rules set by the Act on Health Services, it is obvious that although artificial intelligence tools are not specifically mentioned, we can conclude that the Act on Specific Health Services contains legal regulations ensuring the protection of genetic data and work with it.

3.3 Selected other relevant legislation

In the case of the protection of genomic data, we will not only encounter the two national laws mentioned above; we will also find protection of genomic data when using AI tools in other legal texts. Act No. 375/2022 Coll., on Medical Devices and In Vitro Diagnostic Medical Devices, can undoubtedly be considered as such legislation; it includes several provisions that may apply to the use of artificial intelligence (AI) tools.

In the case of this legal provision, it is in particular the definition of a medical device. A medical device is, inter alia, software, which may include AI tools if they are intended for medical use. Medical devices, including those using AI, must undergo a certification and functional capability assessment process to ensure that they meet safety and efficacy requirements The law sets out obligations regarding the monitoring and reporting of adverse events associated with the use of medical devices, including those using AI. Last but not least, the law addresses the issue of liability for damage caused by medical devices, including those using AI, is addressed under the general liability legislation.

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[31] § 3 et seq. of Act No 373/2011 Coll., on Specific Health Services.

[32] Ibid, para. 28 et seq.

[33] Ibid, para 28 (10).

Conclusion

If we are to answer the question posed in the title of this article (i.e. whether data in clinical genetics are sufficiently protected), the answer is – in the author's opinion – yes, from a general legislative point of view. Czech legislation corresponds in principle to the standard of protection enshrined in the relevant international treaties and in European law. However, if we ask another question, i.e. whether specific legislation for the use of AI tools in healthcare would be appropriate, in the author's opinion it would be advisable to anchor it, at least in the areas related to informed consent to the provision of health services or liability for the use of AI tools.