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*HealthTech and AI in Hungary**

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ABSTRACT Consumers are keen on the use of technology. People trust in technology more and more. What is happening in the Health Sector? What solutions can be used and for what purposes? What is happening in the care service and on the patient's side? The study will evaluate the cooperation of healthcare and technology (HealthTech) from legal and technology point of view in the Hungarian Healthcare. The cooperation among legal and tech people is key when a medical malpractice occurr
Firstly, the law appoints the rules applicable in a certain case. Secondly, the product lifecycle of a medical device would tell who was liable for the malpractice. Besides introducing studies in medical sociology referring to the changes of the social impacts like the doctor – patient relationship in the online domain, this paper describes the laws to be used to find the liability clauses and demonstrates technology matters in the Hungarian jurisdiction.

1. *Introduction*

The lockdown during COVID19 amplified the online presence. Like people work online rather than in the office (home office). Instead of the weekly shopping, they order food from online platforms, also select technical goods in digital stores, *and even they buy clothes and shoes online. Consumers use technology and people trust in technology more and more. What is happening in the Health Sector? What technology can be used for what purposes? What is happening in the Health Society in the care service and on the patient's side? The study will evaluate the cooperation of healthcare and technology ('HealthTech') from legal and technology point of view in healthcare. The cooperation among legal and tech people is always key when a medical malpractice occurred. Firstly, the law appoints the rules applicable in a certain case. Secondly, the evaluation of the product lifecycle of a medical device would tell who was liable for the malpractice. Results of studies in medical sociology referring to the changes of the social impacts will show changes of the doctor – patient relationship. Besides these results, this paper describes the laws to be used to find the liability clauses and demonstrates technology matters in the mirror of the Hungarian Healthcare System.

2. *Emergency Legislation*

The patient – doctor touch facilitated the spread of the COVID. Besides the threatened people with chronic diseases, the medical staff was also in risk. On the other hand, patients still needed the diagnosis, therapy, advice, and prescriptions. The Government Decree on Telemedicine Applications[1] introduced a widespread engagement of this technology, and which regulation was later integrated into the higher legal hierarchy.[2]

When the "Health Emergency Situation" passed by, the Act on Healthcare[3] secured permanently the general rules of providing healthcare services by telemedicine applications. Further detailed rules were laid down by a Ministry Decree on Basic Requirements of Healthcare Service Providers.[4] Pursuant to Section 3 of the aforementioned Decree, the healthcare service must provide proper info - communication equipment, medical devices, telemedicine care procedures and notice to the patient with the information necessary for the health service provided by telemedicine. According to Subsection 1 of Section 9 of the Decree, it is the competence of medical staff to decide whether the characteristics of care and the medical professional judgement allow the performance of activities based on personal meetings through info-communication tools. In this way the doctor can make a diagnosis, provide therapeutic recommendations, counselling, arrange consultations, patient management, give referrals, prescribe medications.

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[1] Government Decree no. 157/2020 (IV. 29.) and Decree of Health Ministry no. 33/2020 (IX. 16.) 'EMMI'.
[2] Act on Health Emergency (2020. évi LVIII.), Art. 85, § Section 2.
[3] Act on Healthcare (1997. évi CLIV.), Sections 106/A, 247.
[4] Decree of Health Ministry no. 60/2003 (X. 20.) 'ESzCsM', Section 3, Subsection 1, Point g.

Doctors are obliged to document the events of care realized in the form of telemedicine in of medical records. They need to keep records in the medical (praxis) software, in addition to symptomatology, the diagnosis, patient journey, time of control, referral, values measured at the patient's home, and in order to make contact bilateral, current contact details and current location must be kept.[5] Services provided via telemedicine tools are accepted by the National Health Insurance Fund as a type of care.[6]

Some groups of patients suffer from inequality like people who don't have internet access or the knowledge how to use it. They can easily be excluded from a digital service, especially people with disabilities. One study found that COVID19 has amplified digital inequalities because they are less able to adapt technology.[7] According to another research, digital health offers new opportunities for screening, prevention, and monitoring of homeless people.[8] In family and child protection issues the telecommunication tools are also usable.[9] Family and Child Protection Officers providing mediation services for conflict management are allowed to inquire about health status of the person concerned by phone contacting.[10]

Patients confirmed the popularity of telemedicine when 71% of the population requested a prescription online or by phone, so the use of technology transforms the doctor – patient relationship, the health management.[11] Based on the same survey, patients believe that technology makes healthcare more convenient, saves time, improves communication, and helps them get care faster though they think the malfunction of technology could jeopardize their healing.

Patients accepted the new technology in general, there are still some concerns for certain groups of people living with disabilities or in poor living standards.

3. *The Concept of AI in Healthcare*

In healthcare, artificial intelligence ('AI') refers to machine learning systems that help the physicians and the medical staff. Such systems could be Big Data analysis tools, image recognition and evaluation systems, language technology solutions. Healthcare professionals in Hungary use such tools in imaging diagnostics,[12] personalized precision medicine,[13] or drug developments that accelerate virtual clinical research.[14]

They can do it as AI is a kind of software that mimic human capabilities. In terms of technology, it is not just a software. It is a trained and tested machine working on a specific database. There are different types of AI technology based on models, applications, industries, functionalities. In the context of healthcare, let us now narrow down the scope to machine learning methods that support the healthcare system.

The Hungarian Law refers to the Medical Devices Regulation[15] (MDR) which defines the term as follows: 'a medical device is any instrument, appliance, apparatus, software, ... other article intended by the manufacturer for use in humans, alone or in combination, for one or more specific medical purposes.' An AI powered solution is embedded into a software code, and it has an interface to run the engine, and a database to learn from and to process.

The medical purpose could be diagnosis, prevention, monitoring, prognosis, treatment, mitigation of disease, or the diagnosis of injury or disability. Additional such medical purposes include the testing, replacement, or

[5] Zs. Győrffy (ed.), *Telemedicine During COVID-19 in International and Hungarian experiences and guidelines,* in *Medical Journal (Orvosi Hetilap)*, 2020, vol. 24, no. 161, 983-999.

[6] Decree on Health Ministry no. 9/2012 (II. 28.) 'NEFMI'.

[7] J. Boros, E. Girasek, B. Döbrössy and Zs. Győrffy, *Use of digital healthcare among people living with disabilities*, in *Hungarian Journal of Disability Studies & Special Education*, no. 2/2022, 77-78.

[8] Zs. Győrffy, S. Békási, B. Döbrössy, V. K. Bognár, N. Radó, E. Morva, Sz. Zsigri, P. Tari and E. Girasek *Exploratory attitude survey of homeless persons regarding telecare services in shelters providing mid- and long-term accommodation: The importance of trust*, Sungwoo Lim, New York City Department of Health and Mental Hygiene, United States, 2021.

[9] Decree on Health Ministry no. 35/2020 (X.5.) 'EMMI'.

[10] E. Gyulai, *The mediation in person and online in case of family contacts during pandemic,* in *Family Law*, no. 1/2021.

[11] E. Girasek, J. Boros, B. Döbrössy, A. Susánszky and Zs. Győrffy, *E-patients in Hungary: Digital skills in healthcare, traditions in the mirror of a national survey,* Semmelweis University, Medical Sciences, Behaviour Department, Budapest, 2022.

[12] www.kheironmed.com/mammography.

[13] https://oncompass.hu.

[14] https://turbine.ai.

[15] Article 2(1) of Medical Devices Regulation (MDR) no. 2017/745 of the European Parliament and of the Council.

modification of an anatomical, physiological and/or pathological process or condition. The provision of information by testing samples (organs, tissues and blood) from the human body - in vitro (i.e. outside the body, e.g. in a test tube or cup) is also included. The definition of a medical device accessory also complements the concept, as although not serving a medical purpose, when used in conjunction with a medical device, the accessory enables or facilitates the use of the medical device. An active device is one that satisfies its power requirement from outside the human body, such as software.

Previously, the Act on Healthcare[16] provided essentially the same, although slightly narrower definition of medical devices, which was incorporated into the text of the legislation with identical content. At the regulatory level, additional definitions can also be found depending on what the device is made of, how or for what purpose it is used, what purpose it serves.

Within the medical device category, a distinction should be made between medical devices and medical assistive devices,[17] which are medical devices or technical nursing equipment for the personal use of the patient, but which do not require the constant presence of a qualified medical professional and are typically used for diagnostic, therapeutic, rehabilitation or nursing purposes. All the devices must be listed in public registers.[18]

Legislation clearly defines the use of AI or any other technology used in medical devices, people and clinical staff can trust of the used systems since the technology must be validated and admitted by Government Authorities at the end of a successful clinical trial process. Changes in the EU Legislation like the proposed AI Act[19] will require further risk assessments of medical systems.

4. *Clinical Trial of Medical Devices*

There is a huge risk that people's health might be adversely affected by an inadequately tested and controlled product. The legislator has therefore developed a detailed set of procedures that guide applicant manufacturers through a series of stages. According to MDR,[20] a clinical trial is a documented series of events that produces a meaningful and measurable clinical outcome through the evaluation of evidence, under the personal responsibility of the investigator. The trial subject (i.e. participating patient) gives his/her prior informed consent in writing to any information that is relevant to his/her decision. The information should be given to the person concerned (data subject). This confirms his/her consent that it was voluntary and freely expressed to participate in the trial.

A clinical trial is initiated at the request of the manufacturer or developer by submitting the documentation to the competent Member State and entering it into the electronic system set up by the European Commission.[21] As regards the Member State level, in Hungary, the Medical Research Council (ETT) is an opinion and decision-making body of the Minister of Health. The Council is an independent body of experts that gives its opinion on the application. After having the opinion of the Council, the National Institute of Pharmacy and Food Safety[22] issues the official authorisation. If the specified procedural steps and deadlines are met, the device can be used on the basis of the authorisation to start a clinical trial. This requires the prior consent of the trial subject (patient). Whether or not a device is safe and fit for the intended purpose can be established after its clinical evaluation, which also ascertains that there is no more effective procedure, and that the risks to the trial subject are proportionate to the expected benefit and the research objective to be achieved.

The developer or manufacturer monitors the conduct of the research based on the approved trial plan and, if there is a change to the plan, it must be reported to the authority for re-authorisation. Adverse events and device failures occurring during the studies must be reported to the authority.

[16] Section 3 of Act on Healthcare.
[17] Act on the Safe and Economical Supply of Medicines and Medical Assistive Devices and on the Marketing of Medicines (2006. évi XCVIII.), Section 3, Subsection 6.
[18] PUPHAG – Public Medical Assisted Devices Register; SEJK – Online Device Database.
[19] Proposal for a Regulation Of The European Parliament And Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts, 2021/206 (COM).
[20] Article 2.44-59 of the MDR.
[21] Articles 61-82 of the MDR.
[22] Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYÉI). Please note, the authority was merged with National Health Centre (NNK) in 2023 and the new name of the authority is: National Health and Pharmacy Centre (NNGYK).

In clinical research, it is the responsibility of the investigator, principal investigator or investigating physician to obtain the prior consent of the participant. The data controller, typically the healthcare provider, is responsible for managing and processing the relevant health data. Prior notice and explicit consent of the data subject (Patient) needed. Data may be accessed for the purposes of scientific research[23] but no copies may be made of personal data.

In clinical trial, very considerable internal resources need to be devoted to so-called "serious adverse events" (SAE), which include the detection and reporting to the authorities of unforeseen events, injuries, symptoms and device failures during a clinical trial.

The above shows how more efforts are required for the proven applicability of an AI system in clinical research than for another AI system used outside of healthcare.

Within certain limits, social science research may also be performed, and it is not subject to such strict authorisation. In this respect, however, great care must be taken to distinguish what may constitute such a case, because if the device used turns out to be a medical device and the research constitutes medical research, then it is considered as clinical research carried out without authorisation, which is punishable under Article 171 of the Criminal Code as a violation of the rules governing research on human subjects, by imprisonment of 1 to 5 years.

Similarly, deviation from the authorisation is actionable under the same provision, and therefore special attention should be paid if the activity is not included in the study plan or documentation or if research is not performed precisely in accordance with it.

In clinical research, medical responsibility remains unaltered, whether it is for research into an artificial narrow intelligence (ANI) or another device. If the AI device controls the dosage of a product during some interventional trial, or even if it is implanted in the body and used in an invasive way in conjunction with or as part of a medical device, it is still the responsibility of the treating physician to monitor, and override if necessary, or stop the operation performed by such a system. This must be enabled by the developer. Otherwise, there will be no investigator who could responsibly perform the trial.

In the case of predictive AI systems, which give forecasts and calculate probability, and make recommendations that are difficult for the physician to control and follow, the following question arises. How liability should be handled in the clinical study? Firstly, the data subject should be provided with disclosing and understandable information about the risks arising from the operation of the system and consent should be sought. Failure to do so should clearly be the responsibility of the physician. Secondly, all the possible avenues of redress between the developer and the healthcare provider should be regulated in detailed contracts, and separate supplementary liability insurance should be taken out in such cases.

Ultimately, if an injury occurs despite the strict authorisation and monitoring of clinical research, the Government will compensate the patients or their relatives if the research had been carried out in accordance with professional rules and the research protocol. However, the ability to pay damages and compensation must be covered by compulsory liability insurance by the healthcare provider conducting the research.[24]

Clinical research carries the highest risk for healthcare – even without the use of an AI system, since the basic aim of research is to improve diagnostics, treatment, prevention and rehabilitation by intervention or observation, and by deviating from the usual healthcare practice.[25] According to Article 164 of the Act on Healthcare, "the interests of the subject always prevail over the interests of science and society in research", the law endeavours to settle an ethical problem. The conflict of interests is an ethical issue among the patients, society and science.

It is in the patient's interest to get cured and stay healthy. It is in the interest of society to have as many healthy people as possible within the limit of a social insurance budget. It is in the interest of science to make scientific progress and to present it. The legislator is of the opinion that the interests of the patient

[23] Health Data Protection Act (1997. évi XLVII.), Section 21.

[24] Based on the obligation imposed on the Member States under Article 69 MDR, and regulated by Articles 163-164 of the Act on Healthcare.

[25] Article 157 of the Act on Healthcare.

concerned, i.e. the trial subject, are the most important, and everything else must be subordinated to this. In practical terms, therefore, a healthcare AI system must be developed in a way that it should put the patient's interests first in decision-making situations.

Clinical trials controlled by government authorities enable that new technology remains safe and allow people to trust in new technology improvements. Clinical staff and service providers need to trust in the medical devices which therefore must be transparent.

5. *Transparency and trust*

It seems that people have trust in certain online medical systems, especially if systems are controlled by the government. They believe that controlled medical systems must be accountable. Transparency is the hallmark of accountability. Transparency in terms of technical context means that an expert can translate (interpret) from the input and output data of the code what operations the machine performs in the computational process between the two endpoints and why it comes to this conclusion.[26] Transparency encourages people to trust in technology.

Like independently from the epidemics, in the age of information society people first look for information available on the Internet when they have a problem to be solved. Confirmed by research, more than 70% of the Hungarian population uses the Internet in connection with their health issues.[27] According to the survey, sources of information were websites, social media, patient groups (on Facebook), blogs, podcasts. Apart from that the professional literature was not easy to access, participants in the survey also could get information from the medical journals. This is why the initiative to rate patient websites regarding transparency and professionalism was commendable.[28] Why medical journals are closed in front of the wider audience? Professionals say it is because giving information for individuals should depend on the current type of personality, the diagnosis, the health status of the patient, and therefore must be given by a physician.

The e-patient phenomenon involves cultural and social transformation. According to research,[29] a large majority of the healthcare community is aware of and would like to use the technology, which can be found at medical conferences, literature and trainings.

However, according to the survey, there is a significant segment (18%) who do not use telemedicine solutions at all. Projecting doctor-patient survey data onto each other, it could be seen that one-fifth of the patients feel that their doctor was not in favor of searching for information on the Internet. They felt this well, while one-sixth of the doctors indicated that they were opposed to finding information about patients on the Internet. Nevertheless, there were examples of well-managed medical groups on Facebook, like the practical information on non-medical, yet care-related practical information, office hours, holidays, prescription order.[30]

The vast majority of doctors were happy to use remote consultation regardless of the pandemic.[31] In Hungary, the Single Health Database Processor (EESZT) was introduced in 2017 by the Hungarian Government.[32] The spectacular results of the EESZT systems were to spread and generate 800.000 recorded e-prescriptions on a daily basis, yearly 75 million medical reports, and documented 180 million doctor – patient meet.[33]

The e-recipe has almost completely substituted the traditional method of writing recipes. Even in case of a personal visit, the doctor does not print the prescription, or the patient receives a reminder sheet summarizing the medicines, which he can present at the pharmacy and put away for him or herself.

[26] G. Magyar and A. Nemeslaki, *Technical Questions of Digital Transformation,* Budapest, Gondolat, 2021, 175.
[27] E. Girasek, J. Boros, B. Döbrössy, A. Susánszky and Zs. Győrffy, *E-patients in Hungary.*
[28] J. Ködmön, *Healthcare information on the Internet,* in *Medical Journal (Orvosi Hetilap)*, 2018, vol. 159, no. 22, 855–862.
[29] E. Girasek, J. Boros, B. Döbrössy and Zs. Győrffy, *E-healthcare Service in Hungary: Digital Healthcare Experiences and opinions of local doctors,* Semmelweis University, Medical Sciences, Behaviour Department, Budapest, in *Medical Journal (Orvosi Hetilap)*, 2023.
[30] S. Balogh and E. Diós, *Hómofisz. Case Study of Two Weeks in a GP*, Medicus Universalis, LIII. ÉVFOLYAM 2. SZÁM, 2020.
[31] R. Kránicz, A. Hambuch, R. Halász, L. Makszin and A. Sárkányné Lőrinc, *Study of the telecommunication and consultancy in GP and Specialits Service Providers*. Pécs University, Medical Sciences, Public Health and Communication Institute, Bioanalytics Department, Porta Lingua, 2022, 2.
[32] https://hu.wikipedia.org/wiki/EESZT
[33] E. Girasek, J. Boros, B. Döbrössy, A. Susánszky and Zs. Győrffy, *E-patients in Hungary.*

Is there any legislation that demonstrates what makes a code interpretable? Would the algorithm become transparent if the code was published? Is ethical design simply the economic interest of the developers to build trust in their product?

A recent study could be the answer of trust building, how a system could be 'trustworthy'. The first step in such a "human-centered design" is to define the clinical task that the machine had been intended to support and to examine the existence of the personal and material conditions required by health regulations.[34]

It is necessary to determine the characteristics, features, accuracy, explainability, interpretability of the algorithms to be used. It is equally important to understand the capabilities and responsibilities of future device users. According to the study, the second step is to develop an acceptable level of assurance and transparent devices for the user (medical staff).

Without such a design the device will not be used or will not be allowed to use. If developers do not go along that lines, they can't sell their product. In the next steps, it must be ensured that what was laid down at the beginning of the rules will be followed by the model throughout. This should be demonstrated to the user, appropriate measures (metrics) should be linked to the evaluation of the performance, and finally, whether the built-in transparency tool is effective (validation). The latter rule also increases acceptance, it has a direct impact on the economic result of development.

Another study based on the AI-HLEG[35] guidance also emphasizes the importance of co-design for the reliability of a skin lesion testing system.[36] It is recommended to involve not only the physician, but also the patient. It is recommended to perform a distortion of the training data by ensuring the diversity of the database elements. The results should then be presented according to standardized requirements for the transparency of the study (TRIPOD, CONSORT-AI, MINIMAR[37]).

There is also a legal basis for accountability. According to the MDR, the developer must have up-to-date technical documentation, prepare an EU declaration of conformity, ensure compliance with the standards through a quality management system during serial production. The quality management system must guarantee the requirements of safety and performance. Managerial responsibilities include the requirement of supply chain supervision, follow-up and surveillance system, serious incident reporting (SAE) in the context of vigilance.[38]

Building trust in technology is in the interest of both the developer and the healthcare service providers, and patients are who enjoy the benefits. Though patients must be protected against unlawful and malicious practices.

6. *Data Privacy*

Data Protection Authority discovered breaches of data subjects' rights. Like the National Authority for Data Protection and Freedom of Information found unlawful the practice of an AI backed solution and fined a bank for 250m HUF, which used AI solution to evaluate call centre conversations but had not given any notice to the client in advance.[39] In other cases the Authority ordered to provide patients records for free as it is their right to access to data.[40] These shows how important is for the data controller to comply with law when using AI or processing health data. There has not been published any cases yet when controller breached the law related the use of AI on health data.

Due to the nature of the AI, the largest possible dataset is required to get trained on an AI medical device. As the issues related to AI and data protection constitute an important and wide-ranging topic, due to their

[34] H. Chen, C. Gomez and C.M. Huang (eds.), *Explainable medical imaging AI needs human – centered design: guidelines and evidence from a systematic review*, in *Digital Medicine*, 2022.

[35] European Commission High Level Expert Group on AI, 2019.

[36] R.V. Zicari *et al*., *Co-Design of a Trustworthy AI System in Healthcare: Deep Learning Based Skin Lesion Classifier,* in *Frontiers in Human Dynamics*, vol. 3, 2021.

[37] TRIPOD-AI: *Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis*, 2015; CONSORT-AI: *Consolidated Standards of Reporting Trials,* 2010; MINIMAR: *Minimum Information for Medical AI Reporting.*

[38] MDR, Article 10.

[39] National Data Protection Office (NAIH), case no. NAIH-85-3/2022.

[40] NAIH, case no. NAIH-3849-16/2022; NAIH-4137-8/2022.

voluminous nature. There are many phases of the development like collecting data, building model, developing the application, and therefore they arise many questions, especially regarding the data. Like where to obtain a large number of data? Is the database structured? Does it comply with data protection principles and the requirement of equal treatment?[41]

Having the Single Health Database Processor on board (EESZT) it should have a huge advantage over other Member States of the EU or even large States on other Continents where they have units divided into more social insurance funds and service providers. The only instrument is missing from the process is a 'regulatory sandbox' for start up companies to get health data and build their models and applications. Without start up ecosystem in healthcare, the government should develop technology on its own, and start up companies will move to other countries where they can have health data sets. Without having medical start up companies, only tech giants will in a position to offer services and products using AI powered technology.

So, if there is data, machine learning systems will be developed in healthcare. Data in paperwork are not digitized and not structured, and developers need digital datasets. In many cases still the nurses administer manually the temperature chart. Technology[42] could replace the fever plate with sensor technology placed on the patient's wrist. During COVID, vital measurements could have been recorded contactless, which could be automatically uploaded to the hospital information system (HIS), freeing nursing staff from administrative burdens. However, it must also be seen that institutional infrastructure needs to evolve for this, for example in the areas of data transfer capability and speed, storage capacity, information security.

The quality and quantity of data is essential for the AI, without which the AI cannot work. In technical terms, it is important that the data is as easy as possible to process, i.e. structured and organised. For machine learning purposes it needs to be effective, it is important for the AI to have a large amount of correctly recorded, complete data. From a legal and ethical point of view, it is also important to comply with data protection requirements and to ensure that the database is fairly composed and compiled without discrimination (fair database).

A database that is anonymised, i.e. made available in a way that does not identify the person concerned, is less valuable. Data that can be continuously monitored and linked to the subject, reflecting the current health status of the person concerned (subject), is much more valuable in healthcare AI system. The information of the case history, the medical history, the lifestyle shows the lifecycle of the Patient, so the research into diagnosis, the prevention and the therapy for the present and future can be monitored.

It is often not possible to foresee at the time of admission what still needs to be examined in the process of treatment, from the detection of the disease to recovery, so the data hardly can be shared in many cases.[43]

The GDPR defines a data subject only in terms of personal data,[44] while the national law[45] defines a data subject as "any natural person identified or identifiable on the basis of any information".[46] By invoking the concept of a data subject in the Health Data Protection Act, one comes to the concept of a healthy or ill natural person, specifically created or arising in relation to the use of healthcare services.[47] The concept of health data is also regulated by the GDPR,[48] and it is supplemented by Article 3/A of the Health Data Protection Act, which states that EU rules also apply to the health data of deceased persons. In the course of healthcare provision, the personal data that are not considered as sensitive data and that serve to identify the data subject, such as name, address, birth data, identification numbers, social security number, may be processed as part of the

[41] As defined in Article 7(1) of the Act on Healthcare.
[42] www.entremo.com.

[43] C. Watson, *Many researcher say, they will share data, but don't*, in *Nature*, vol. 606, 2022, 853.
[44] Article 4(1) of Regulation (EU) 2016/679 of the European Parliament and of the Council on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data (hereinafter "GDPR").
[45] Act on the Right to Informational Self-Determination and Freedom of Information (CXII of 2011).
[46] Article 3.1 of Act CXII of 2011 on the Right to Informational Self-Determination and Freedom of Information.
[47] Article 2.b of Act XLVII of 1997 on the Management and Protection of Health Data and Related Personal Data ("Health Data Protection Act").
[48] Article 4(15) of the GDPR.

medical records pursuant to Article 3/B of the Health Data Protection Act. From the perspective of AI, the essence is that personal data and special health-related sensitive data are any information, information detail, data fragment, indirect data stream or derived data, which can be linked to the data subject, no matter how distant the correlation is.

The developer, the operator of an AI system must comply with the statutory requirements for the exercise of rights by the data subject. The relevant literature classifies data subjects' rights along the lines of transparency and accuracy as the basic principles of information self-determination.[49] The right to prior information, the right of access and the right to data portability serve to enforce the principle of transparency. The data subject's rights to rectification, erasure (right to be forgotten) and restriction of processing are rights that help to enforce the principle of accuracy. The third group is made up of the other rights set out in the GDPR, such as the right to object, and the prohibition of automated decision-making.

The responsibility of data controllers starts with respect for the data protection principles of lawfulness, fairness and transparency; purpose limitation, data minimisation, accuracy, limited storage, integrity and confidentiality, and finally, accountability.[50] Already at the development stage the manufacturer of the AI application should consider how the institution or healthcare provider that will use the system will be able to comply with the data protection requirements. The requirement of data protection by design is the responsibility of the data controller. So there are legal requirements on data privacy, on medical devices and developers also need data to train, to test and to validate an AI system.

Imagine the burden put on healthcare start-ups comparing to other industries! Developers than need to comply with EU, US, Middle East, Far East, Australian and other data protection regime as well if they want to roll out their activity out of the national market. For a "Tech Giant" this is obviously just another compliance task, but for a start-up it is a barrier to market entry, which is not even realised by developers at the time of launching the business. A global harmonisation of rights and obligations in relation to health data could have a huge cost-reducing effect on the spread of AI in healthcare, and it could start with epidemics, as the control of epidemics is in the global and individual interest of all existing states at the same time.

A prior (in this context: data protection) impact assessment by the data controller is certainly required when an AI application is introduced for specific data processing handled by an institution or service provider in healthcare, which inherently constitute high-risk data processing.[51]

It is also a fundamental obligation for the controller to take appropriate technical and organisational measures under Article 24 of the GDPR. It is the data controller's responsibility to maintain up-to-date records of the processing, and to remedy and report any data breach. Such obligations may lead to unresolved liability situations and disputes in the case of insufficiently thorough arrangements between joint data controllers or a data controller and a data processor. For this reason, in the course of selling the AI application, the developer or manufacturer of the AI system should take particular care to ensure that the roles and responsibilities of either the joint controllers or the data processor are as clearly defined as possible. In any case, the procedural protocol to be followed in the event of an incident should be specified and a time limit should be set. It is worth for the AI developer/manufacturer to strive for processor status (as opposed to the quality of joint data controllers), arguing that the healthcare provider is the data controller, and this determines the purpose and method (tool) of data processing, while the AI only facilitates the technical assessment of the data, and the decision is made by the data controller. The data controller is also responsible for the adequacy of the choice of the data processor under Article 28(1) of the GDPR, and thus if the developer or manufacturer of the AI can present its GDPR compliance to the future data controller in advance, it may facilitate the marketability of the AI application in the EU.

The right referred to in Article 22 of the GDPR is in fact a prohibition, since according to the original wording, the data subject "shall

[49] A. Péterfalvi (ed.), *Explanation of the GDPR,* Wolters Kluwer Hungary, 2018, 149.
[50] Article 5 (1) and (2) of the GDPR.
[51] A. Péterfalvi (ed.), *Explanation of the GDPR*, 231.

have the right not to be subject to" a decision based solely on automated processing, including profiling, if it produces legal effects concerning him or her or similarly significantly affects him or her.

An exception to this rule is where the decision is taken for the performance of a contract between the data subject and the data controller, or on the basis of a legal provision, with appropriate safeguards, or on the basis of the data subject's explicit consent, and the data subject is given the opportunity to request human intervention in the decision, to express his or her views or to object. A further prohibition on special data is contained in paragraph 4 of the same Article, and it is also mentioned in preamble (71) that data concerning health status can only be based on explicit consent and on general public interest.

According to the national law[52] the medical staff can create a profile in the National e-Health Infrastructure Database (EESZT) for the patient including the identification numbers, status of patient, diagnosis, treatments, other records. In case of death the profile will be automatically deleted after 10 years retention period. The patient can request not to upload any information to the database. So it is still recommended to maintain the possibility for the data subject to object, and the possibility to facilitate the right to access, the right to be forgotten regarding data processing.

Data is essential for AI developments, and data protection is essential to keep patients fundamental rights. Healthcare decision makers though need to think about how to keep start up developers in the Country, in the EU and make health datasets available for them to collect data, build models, develop applications in a controlled environment.

7. *Machine Learning and Data*

Important concepts are the training of data, the test and the validation of them. The latter considered as data used to evaluate the AI system and to set the unteachable parameters and learning process. This issue is closely related to the regulation of special data management in the healthcare domain.

Imagine that a trainable AI application is developed in the field of diagnostic, which is supposed to demonstrate its ability to provide accurate, reliable, safe assessment of CT scans in the context of clinical research. Thus, the developer first needs a large amount of historical data to be able to form a data set from the image resolution, to develop appropriate screening conditions from the data set, to correctly evaluate the classification based on the screenings, and then to visualise the correctly classified data set in a way that can be evaluated and processed by the radiologist.

On the other hand, a healthcare provider, may acquire and store imaging recordings and manage them for data protection purposes. Thus, either retrospectively or during an ongoing clinical research, the developer should be involved in the institution's activities, either as a data processor or as a joint data controller, to access already evaluated findings and images.

Moreover, in clinical research, the actual and follow-up data is supposed to be the most important for science and development. Take for example the fact that the accuracy and image resolution capabilities of an AI application allow it to detect changes in a cancer patient's condition (tumour size) after the first or first few chemotherapy treatments. How could this be developed in clinical research without up-to-date data and without a real data subject, not anonymised but actively involved in the therapeutic treatment?

From a therapeutic point of view, this is important if a patient is treated with a pharmaceutical product for months and only then it is found not to be sufficiently effective or ineffective. This time is too long in view of the fact that after just one or two treatments it would be possible to decide whether the active substance is effective, or it needs to be changed. Think about the fact that with certain AI applications, we may be able to get the results in a way that is even more predictable after the test. In practical terms, it is psychologically stressful for the patient to be called back for a follow-up test after a screening test, and it is especially physically stressful for the patient to be subjected to a chemotherapy treatment that is ineffective for him or her but that has been going on for long months.

From a data protection perspective, it is a strategic issue to be able to train and test algorithms on data recorded in each health data space. Such as the Single Health Data

[52] Article 35/J of Act XLVII of 1997 on the Management and Protection of Health Data and Related Personal Data "Health Data Protection Act".

Processor (EESZT). The application developed in this way can then be extracted from the database and the now commercially viable AI tool can be used on live systems. To do this, the developer will otherwise have to overcome additional problems, for example, compatibility with certain imaging equipment, and to ensure that the trained tool works with the same accuracy in a standard environment.

Another strategic question concerns compliance with the provisions of the forthcoming AI code:[53] To what extent will this increase the costs of development, slow down progress or even be a barrier to the EU's health industry?

After all, from the investor's point of view, medical technology and pharmaceutical developments are the projects that carry the highest risks and the longest payback periods due to the specificities of clinical research and authorisation. If this area fails in the market, then an intervention will be required at the level of the EU as well as the Member States to offset the increased costs that Europe will incur. Such may include, for example, the setting up of funds specifically earmarked for supporting R&D, tax incentives, EU or national guarantees, or even measures such as allowing access to a single, controlled but freely searchable and structured data set.

There is a risk of selling one's health data[54] because poorer people would be forced to sell their data, making them less able to protect their data other than the rich. However, who wouldn't give away everything, including the health data, to be cured, or to find the right cure for a family member? In the public interest, the concept of 'data solidarity' already exists in the EU.[55] On a non-profit basis, companies may collect personal data without the consent of the data subject. This may even lead to a grey zone, because the range of data controllers can easily change, and related products are already expected to enrich the business sphere during data management.

The example to follow could be the "Next Generation Medical Infrastructure Law"[56] in Japan, which allows hospitals to transmit health data to accredited companies with patient consent, which anonymizes it and makes it searchable. The EU would also like to set up such data hubs.[57] Patient Society has already started such a recruitment to build databases. For example, when people suffering from the same disease or group of diseases, they share their data for the sake of science and research.[58]

Data processing is ethical and lawful if the patient has freely consented to its processing on the basis of prior information and the data has been used for what he or she has consented to. The question is, should health data be protected as part of the private sector and therefore should not be allowed to benefit from it? Or is the individual's health data the value of the human community, through which many other people can be healed, so it should be used and utilized for the benefit of the community? Or should we leave the decision of the question to the individual freely, so that the data can be traded at the discretion of everyone, and whoever puts it up for sale should bear the consequences of their risk and benefit from it?

The strategy has therefore not yet been decided in the area of data sharing. We emphasize that this is not about data in general, but about health data, the knowledge base of which can help the patient, his relatives, fellow human beings. Technology could also provide an answer to this, for example, blockchain could allow all three trends to prevail at the same time. It could be used anonymously, yet even at the same time, allowing trading (utilization), it would work in the interest of the community. Blockchain technology can solve the privacy issue of the data controller having to share health data with other data controllers. Yet learning through data can take advantage of technology and only the results of testing are shared between the institutions in the network.[59]

[53] 2021/0106 (COD) Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts.

[54] WHO Guidance, *Ethics and Governance of Artificial Intelligence for Health*. Geneve, World Health Organization 2021, CC-BY-NC-SA 3.0. IGO, 76-82; Annex, 141, 84.

[55] 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).

[56] WHO Guidance, *Ethics and Governance of Artificial Intelligence for Health,* 83.

[57] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space.

[58] https://datasaveslives.eu; www.datafair.org; www.registratieaandebron.nl.

[59] S. Warnat-Herresthal *et al*., *Swarm Learning for decentralized and confidential clinical machine learning*,

The need for the health data is growing. It is very difficult for a startup developer to get it. When planning an AI development, it is advisable to make sure in advance from which institution, what patient data, under what conditions can be collected and processed.

8. *Liability for AI systems*

The health legislation itself is very diverse, a recurring legislative reference to the application of directives, professional and ethical rules when determining the appropriate level of care. Thus, in addition to the various levels of legal provisions, the right decision must also be made in the maze of ethics rules, national and local level, different institutional guidelines, and protocols. [60] Doctors often complain that while they must make the right decision within minutes, there are years for high level professionals, legal and forensic staff to establish the responsibility or exempt.

These professional rules, guidelines and protocols can be converted into programmable decision trees and can be queried quickly and easily with the help of an AI system. This still does not mean that a doctor is exempt from responsibility if a machine were to tell what professional rules apply. If this system is trained with continuous feedback, like a conversational assist, a telemedicine application for doctors can be developed by using a machine learning method. Benefits would be to know how others decided in similar cases, what the outcome was, what questions others asked and what else they were curious about.

The final decision, the responsibility for the decision, is always on the doctor. So, the AI system does not replace medical intelligence, but rather an extended intelligence, the intelligence of common medical knowledge and experience. Doctors must understand the logic of the system and its limitations. The institution must implement the system properly, constantly monitoring it in accordance with the documentation.

8.1. *Liability of the developer*

As a result of successful clinical research, the developer gets an assessment of the AI device. The healthcare institution then can buy it and put it into circulation. This creates a contractual relationship and a related contractual liability regime in relation to the product sold.

The developer is liable for defective performance in accordance with the rules of breach of contract in accordance with Section 6:157 of the Civil Code[61] if he does not meet the quality requirements specified in the contract or by law at the time of performance. Based on his or her warranty rights, the injured party may request repair, replacement, and price reduction at his or her option. Alternatively, the developer could have someone else repaired the product, but since it is essentially software, even if the user obtained the source code, it would be impossible for someone else to repair it.[62]

Wearables should not be confused with wearables or invasive implanted devices ordered by a doctor, which are naturally certified in clinical research and approved by the authorities for therapeutic and diagnostic purposes.

The knowledge and scope of use of the two types of devices (wearables and medical devices) will probably get closer and closer to each other. One will learn from the other area. So, the demarcation will also become more and more difficult for licensing and legal judgment. The smart device is not a medical device, but it can provide a lot of very important data to the doctor. Data can be sent even through a telemedicine application in advance to the doctor. At the end, doctors are obliged to examine the patient in all cases independently what he/she had received in advance.

What if AI is only one component of the product, is the responsibility separated of the manufacturer regarding the hardware and the software? From the user point of view (hospital), it is certainly not, unless they are separate suppliers by contract. However, if there is a CT scan product, which is sold in conjunction with an imaging diagnostic AI system and which acts as a user system, the parties are contractually advised to settle their liability in a detailed contract, to the extent of it, and how to settle a dispute.

8.2. *Hospital's liability*

In the legal relationship between the institution and the patient, the doctor decides on the diagnosis and treatment since the AI

in *Nature*, vol. 594, 2021, 365.
[60] Act on Healthcare, Section 7 (2); 77 (3).
[61] Civil Code (2013. évi V.).
[62] Civil Code 6:159 §.

system currently only complements medical intelligence and facilitates the processing of information.

The mandate contract or an atypical "medical treatment" contract is concluded between the healthcare provider (hospital) and the patient.[63] The Act on Healthcare Section[64] 244 provides clear guidelines for the establishment of liability for damages, because according to subsection (2), the rules of the Civil Code on penalties for non-contractual damages and violations of personal rights apply. Who is liable on the care provider's side, as follows from paragraph 1, is the responsibility of the healthcare provider for damage caused in the context of institutional care and for violations of privacy and rights relating to personality.

In practical terms, therefore, the legal relationship between the hospital and the patient, or between the doctor and the patient acting on his own behalf, is governed by the contractual rules of the Civil Code, except in terms of tort, where the rules of tort liability shall be applied.

Section 6:519 of the Civil Code applies to the liability rules for damages without any contractual relationship. Anyone who unlawfully causes damage to another person is obliged to compensate. In connection with the involvement of the AI system, anyone who makes a claim for damages against the user of the system, i.e., the supplier, the doctor, and even jointly and severally the developer or manufacturer, must prove the unlawful tortious conduct, the occurrence of the damage and the causal link between the tortious conduct and the damage. The other party must prove that its conduct was not attributable to be exempted.

In the doctor-patient relationship, there is an information asymmetry that the legislature is trying to counteract in a lawsuit on the side of the injured patient. Such provisions include an obligation on the part of the respondent provider to provide information in the event of a statement emergency under Section 170 Subsection (5) Point (a) of the Civil Court Proceeding Act,[65] or the mandatory attachment of the means of proof in an evidentiary emergency under Point (b). When using the AI system, this information asymmetry can be further pushed back on the side of the supplier, and the supplier must even consider to be able to fulfill its obligations in this direction in a lawsuit. Thus, the developer, manufacturer, third-party operator of the AI system should provide the information or evidence.

For example, if, during an imaging diagnostic analysis, both the radiologist and the AI do not recognize the lesion, even though it was recognizable, it is an unlawful tortious behavior. The patients lose their chance for a speedy recovery or there is a deterioration in their health, they lose the earning capacity, there are costs for the care, this is the harm to the patient. If they had recognized it in time and started treating the patient, there would be no deterioration in the patient's condition, this is the causal relationship between the caregiver's behavior and the damage.

In order to be defensed, the health care provider must prove that the Healthcare Act Section 7 Subsection (2) he or she acted in accordance with the current professional and ethical rules and guidelines and with reasonable care, at the time of making the diagnosis, he or she could not have foreseen from any data, signs or information that the disease was developing, there was no reason to obtain another medical opinion, to request a consultation, or to recall the patient for control.

8.3. *Violation of personality rights*

According to Section 2:52 of the Civil Code, damages may be claimed from the infringer for violations of his personal rights in accordance with the rules of liability for damages caused unlawfully. Such a grievance fee may be claimed in connection with an AI system. For example, in relation to the right to inadequate and unindividualized information, where an AI-driven communication takes place in it. The same as in relation to a breach of the right to access the medical records of the patient, or if the data in the database used by the AI is lost, or the medical secret may also be breached, in the event of inadequate protection of such a database.

8.4. *Criminal Offence and Infringement*

In connection with the AI system,

[63] B. Kórodi, *Litigation emergencies in lawsuits for disadvantages related to health services,* in *Hungarian Legal Journal (Magyar Jog)*, 13 January 2020.
[64] Act on Helathcare (1997. évi CLIV.)
[65] Civil Court Proceeding Act (2016. évi CXXX.)

falsification of a health product within the meaning of Section 186 of the Criminal Code[66] can be considered by the implementation of a factual situation. Also, crimes committed in the context of an occupation where the AI system is used during the crime. Staying with the health product, by definition, a medical device falls within this category, and if not, the criminal conduct that falsifies the AI system itself, but its documentation, or is not allowed to be placed on the market or even to possess such a product, the facts of the case are realized and are punishable by imprisonment for up to three years. Health breach liability in connection with the AI system may arise, for example, in the case of false statistical reporting if the data processing is carried out using such a system.

8.5. *Market surveillance*

Chapter VII of the MDR provides for a post-market surveillance system that regulates the manufacturer's obligation to self-monitor and follow-up. The competent authority in Hungary is the National Institute of Pharmacy and Nutrition.[67] Thus, within the scope of the general control and supervision activities of the authority, the MDR market surveillance system is based on documentation testing, laboratory testing of sampling, conformity testing of devices, vigilance and complaint reports. It shall also carry out checks on the product of the manufacturer, importer or distributor in an individual market surveillance system in accordance.

Further actions can be taken with the help of consumer protection, for example with regard to wearable smart devices, may arise if an AI system is used by the service provider.

An infringement of advertising law or unfair market conduct may be considered if the promotion of the dissemination or use of the AI system conflicts with some prohibited advertising or is carried out in a way that influences the consumer through fraudulent means.

The data protection authority is key to the availability of data in relation to the AI system. The data subject will not have confidence in AI systems where data protection is inadequate, this lack of trust may even be a barrier to the development of the AI industry.

8.6. *Patient's complaints*

From the patient's point of view, what can be done to enforce patients' rights if they have a complaint during care? For example, he feels the AI technology used has not served his/her interests. Many patients need direct medical contact, and he/she is not happy when, during care, the doctor is pushing machines, staring at a screen and looking as if he does not care about the patient.

In many cases, the patient complaint is emotionally overheated, and in the event of the loss of a relative, the unprocessed grief drives the patient as a motivating force. The patient has the opportunity to complain to the care institution, it is possible to turn to the patient's representative for the patient's rights, to use the mediation advice and to take the dispute to the legal path.

The patient can also complain to various organizations.[68] Based on the complaint, the determining medical authority[69] exercises professional supervision and acts in accordance with the General Administrative Order (AKR), its sanctions may be warning, downgrading, suspension, withdrawal of license, imposition of fines.[70]

8.7. *Liability Insurance*

Through compulsory liability insurance in the field of healthcare, the compensation capacity of the provider and doctor operating in the care system is established. However, during the operation of an AI system, where there is necessarily a lot of patient diagnostics, a lot of therapeutic treatment, a lot of data management, even the highest amount of insurance available on the market may be scarce for coverage, so it is recommended to use additional insurance.

What happens after the cessation of activity? For example, the given AI system is outdated, it is disconnected, the product is no longer supported, but the damage happened earlier. The "Long Tail Liability" is becoming aware after a very long period of liability

[66] Criminal Code (2012. évi C.).
[67] Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYÉI) – after changes in 2023: (NNGYK).
[68] Chamber of Ethics Committee, OGYÉI, NEAK, NNK.
[69] Healthcare Act Section 123.
[70] Act on General Administration Procedure (2016. évi CL.).

enforcement and insurance liability even beyond the limitation period. It is therefore appropriate to expect that liability insurance will be maintained for an even longer period of time in order to mitigate the risk.

millions of lines, but so that we can explain how it works, and in case of doubt we can decrypt the causal chain in a documented way, finding the root cause of the problem.[71]

9. *Other achievements*

There are other achievements in digital healthcare. Like the National Ambulance introduced the 'Lifesaving Coronavirus' application.[72] Communication can help not only those involved in emergency care, but also those working in care in general. For example, through a specialist psychological emergency call service, you can manage the workload, burnout, depression, and psychological burden of individuals. Patients also feel the weight of this on the other side, and balanced service at the bedside increases the patient's sense of security, satisfaction, and thus the chances of recovery.[73]

There have also been COVID-induced developments in the wider healthcare system. For example, in wastewater-based epidemiology to predict the spread of the virus, algorithmic analysis was used to show the relationship between virus concentration and case count in wastewater using linear regression.[74]

In the field of infection control, not only developments are related to data processing, closing disinfectant cleaning to prevent COVID and other infections was carried out with non-contact surface disinfection technology, especially where units with high infection rates are located.[75]

Data-based clinical research is important according to the recommendation of the Health Science Council (ETT) because multicentre data collected online are collected in a structured way, making it easier to improve the efficiency of treatment through its analysis, and with the new concept of translational medicine, research on anti-COVID agents is a good example of the repositioning of previous pharmaceutical products.[76]

10. *Conclusions*

Declaring that COVID19 accelerated the development of digital toolkits in healthcare, the study assured that the proper legislation was evolved to use new healthtech achievements. The majority of doctors and patients are happy with the technology, so this trend is expected to spread further in the future. The study pointed out that patients accepted the new technology in general, though there are still some concerns for certain groups of people living with disabilities or in poor living standards or the lack of education becomes an obstacle. The current legislative system has clear definitions on medical devices. Both patients and clinical staff trust in systems as long as the technology is validated in clinical trials. Future prospects like the AI Act requires further risk assessments of medical systems.

The study showed that building trust in technology is in the interest of both the developer and the healthcare service providers, and patient is the one who enjoys the benefits. At the end, patients still must be protected against unlawful and malicious practices, like in any data protection incidents.

The need for the health data is growing. It is very difficult for a startup developer to get it. When planning an AI development, it must be clarified which institution, what patient data, under what conditions can be collected

[71] C. Bartneck (ed.), *An Introduction to Ethics in Robotics and AI*, Springer Briefs in Ethics, Cham, Springer, 2021, 36,37.

[72] Z. Győrffy (ed.). *Telemedicine During COVID-19 in International and Hungarian experiences and guidelines,* in *Medical Journal (Orvosi Hetilap)*, 2020, no. 24, vol. 161, 983-992.

[73] T. Irinyi, A. Németh, *Burn out and depression in the medical staff* , Study, Elitmed, 2022 https://elitmed.hu/kiadvanyaink/nover/kieges-es-depresszio-az-egeszsegugyi-szakdolgozoi-tarsadalomban/pdf-open.

[74] T. Pándics, E. Róka, J. Henczkó, B. Khayer, Z. Kis, T. Málnás, B. Pályi, E. Schuler and M. Vargha, *National forecast system on COVID-19 predictions using rest water – conclusions of 1,5 years,* Public Health Journal (NÉPEGÉSZSÉGÜGY a népegészségügyi képző- és kutatóhelyek országos egyesületének tudományos folyóirata, 99. évfolyam 1. szám.), Semmelweis University, Health and Technology Analytics Centre, 2022.

[75] I. Kopcsóné Németh, Cs. Dandárné Csabai, O. Bazsó, M. KÄFER, Zs. Biró Zs., M. Balogh, M. Csák and O. Csordásné Gergely, *Hospital infection controll during COVID-19, prevention of MRK infections in Honved Hospital,* Public Health Journal (NÉPEGÉSZSÉGÜGY a népegészségügyi képző- és kutatóhelyek országos egyesületének tudományos folyóirata, 99. évfolyam 1. szám.) Semmelweis University, Health and Technology Analytics Centre, 2022.

[76] ETT Guideline no. ETT IV/8537/2021/ETT.

and processed.

The final decision on the diagnosis, therapy and the liability for the decision remains on the doctor. So, the AI system does not replace medical intelligence, but rather it extends the intelligence, in the sense of a common medical knowledge and experience. What medical staff can do? Doctors must understand the logic of the system and its limitations, while the hospital must implement the system properly, constantly monitoring it in accordance with the given documentation.