AI and Disease Diagnosis: Legal Aspects*

Viviana Di Capua**

ABSTRACT:
Artificial intelligence (AI) and diagnostic medicine are topics linked by the concept of 'prediction'. Since good prediction enables accurate diagnosis, AI should serve to implement mathematical 'predictive models' that can identify a disease early. At present, AI has been applied in several areas of diagnostic medicine with positive results (e.g., in the field of lung or breast cancer identification and to support the diagnosis of Covid-19). If not adequately controlled and regulated, however, the use of AI in the field of medicine, and diagnostics in particular, can be a source of risks: for example, the use of AI systems without rigorous scientific validation, the lack of control over the data processed by expert systems, possible violations of user privacy, discrimination induced by algorithm programming, and illusory and misleading expectations for health care professionals and patients

---

* Contributo sottoposto a revisione tra pari in doppio cieco.

** Researcher of Istitutions of Public Law at the Department of Political Science of the University of Naples Federico II; viviana.dicapua@unina.it. The paper is a reworking of the report presented at the International Conference on the topic 'Application of Artificial Intelligence in the Health Sector' – A Multidisciplinary Perspective', held on 19 October 2023 at the University of Naples 'Parthenope, Palazzo Pakanowski, Generale Parisi Street, 13, 80132 Naples. I dedicate the paper to my father, Francesco Di Capua, Expert in Radiation Protection from the dangers of ionizing radiation and Specialist in Health Physics, who, patiently, discussed with me the technical aspects of the subject.

ISSN 2611-8882

resulting from the misuse of technologies[1]*. In recent years, the field of AI has been the subject of a series of interventions by the European legislature, aimed at outlining a common reference regulation through a progressive alignment of existing disciplines in member states.*
In the context of a varied and evolving scenario, the research aims to analyze the possible uses of AI systems in the field of diagnostic medicine, focusing on potential risks, European legislation inspired by a precautionary logic and its impact on the Italian legal system.

1. Disease diagnosis with Artificial Intelligence (AI): from the medical capsules of Elysium to a reality (still) under construction

In the dystopian reality of the science fiction film Elysium, only a few privileged citizens live in a space station orbiting the Earth, where, in addition to all kinds of luxuries, they can take advantage of medical capsules made with advanced digital technologies and installed in private homes, which can diagnose and heal any disease or physical harm, even very serious ones, in a matter of seconds, provided the patient's brain is not damaged.
Although artificial intelligence (AI) is rapidly penetrating all areas of society, facilitating complex tasks of daily life, the results from its application to diagnostic medicine are still far from Elysium's ideal model[2].
Every AI system entails risks for users, the jurist's attention will focus on how the law deals with risk, preparing analysis strategies and regulatory procedures, and on administrative decision-making in contexts of scientific uncertainty. Thus, the research aims to examine the possible uses of AI systems in the field of diagnostic medicine, the possible risks they pose, and the way these risks are regulated by the European Union. The final part of the analysis will be devoted to the proposed European Regulation (AI Act) establishing harmonized rules on AI, prepared by the European Commission, published on 21 April 2021 and recently approved by the Council of the European Union, and its impact on the Italian legal system.

[1] On these aspects, see C. Casonato, M. Fasan, L. Rinaldi, M. Tomasi, *IA e medicina: profili giuridici*, in A. Pajno, L. Violante (a cura di), *Biopolitica, pandemia e democrazia. Rule of Law nella società digitale*, Vol. II. *Etica, comunicazione e diritti*, Bologna, 2021, p. 43 ss.

[2] For a detailed analysis of the applications of AI to the healthcare sector, the state of the art and future developments, see the document *I sistemi di intelligenza artificiale come strumento di support alla diagnostica*, written by the Superior Council of Health - Section V, 9 November 2021, available on the institutional website of the Ministry of Health.

2. Definitions, technological aspects and early applications of AI to support diagnostics

AI is the branch of computer science that studies the simulation of intelligent behavior in computers; more specifically, the term AI refers to the ability of a machine to mimic intelligent human behavior[3].

From these simple definitions, it can be deduced that AI: has the purpose, through the use of algorithms, of extracting information from quantitatively numerous and qualitatively complex sets of data, which the individual human being would have difficulty in managing, in order to contribute to the production of new knowledge; It deals with activities, both abstract and concrete, that involve the production of judgments and/or predictions.

The application of AI in the medical sector is part of the broader digitalization project of the healthcare sector, which has become a priority for Europe after the Covid-19 emergency[4].

In the 2021 Accompanying Report on the State of Health in the European Union, it is highlighted that, before the pandemic, the widespread use of digital health tools was limited and uneven across Member States due to technical factors, inadequate regulatory framework, limited investment, poor staff training and administrative barriers. The Covid-19 pandemic has triggered significant changes in the way healthcare services are delivered. For example, to minimize physical contact between healthcare professionals and patients

[3] The definition is taken from the Merriam-Webster Dictionary, which can be found on the *https://www.merriam-webster.com/dictionary/dictionary website*. Cfr. Art. 3 of the AI Act, which defines an 'AI system' as «a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments».

[4] This issue has been at the heart of the European Union's political agenda for several years now. Among the most significant policy documents, cf. The State of Health in the EU: Accompanying Report 2019, Luxembourg, 2019; The State of Health in the EU: Accompanying Report 2017, Luxembourg, 2017, all available at: *https://health.ec.europa.eu/state-health-eu/synthesis-report_it*; COM(2018) 233 final of 25 April 2018, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society; COM(2012) 736 final of 6 December 2012, Communication from the Commission on an Action Plan eHealth 2012-2020 - Innovative Health for the 21st Century'; COM(2004) 356 final of 30 April 2004, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on eHealth - Improving healthcare for European citizens: an action plan for a European eHealth Area; Council conclusion on Health in the Digital Society – Advancing data-driven innovation in health, OJ 2017/C 440/05 of 21 December 2017; Council conclusions on personalised medicine for patients of 7 December 2015, OJ C 421, 17 December 2015. Council conclusions on the economic crisis and healthcare of 20 June 2014, OJ C 217, 10 July 2014; Council conclusions on the reflection process on modern, adequate and sustainable health systems, of 10 December 2013, OJ C 376, 21 December 2013; Council conclusions: Towards modern, adequate and sustainable health systems, of 6 June 2011, OJ C 202, 8 July 2011; Council conclusions of 10 December 2009 on the safety and efficiency of healthcare through eHealth, OJ C 302, 12 December 2009; European Parliament resolution on safer healthcare in Europe, P8_TA(2015) 197, 19 May 2015. For an analysis of the role of the European Union as a 'driver' of technological innovation in the health sector, see E.A. Ferioli, *L'intelligenza artificiale nei servizi socio-sanitari: una nuova sfida al ruolo delle istituzioni pubbliche nel welfare italiano?*, in *BioLaw Journal*, 2019, 1, p. 163 ss.

in need of non-urgent care, the use of technology for remote consultations has accelerated significantly in Member States[5].

The application of digital technologies to the healthcare sector does not exclude the direct interaction between doctor and patient, which is considered a unique and peculiar feature of healthcare[6]. Especially, the use of AI in healthcare has affected all areas in which medical knowledge needs to be represented and extended through different types of reasoning. Specifically, it considers the intelligent behaviors that underpin many decision-making activities in medicine, such as diagnosis, therapy, prognosis, and patient monitoring management. These activities involve the ability to merge and use basic knowledge and patient-specific knowledge, in order to make, within an acceptable timeframe, the best possible decision with respect to the evolution of the patient's (or entire groups of patients') state of health.

The first applications of AI in the medical sector resulted in the experimentation of techniques and software capable of simulating human reasoning compared to medical-clinical knowledge appropriately represented in a formal way. The areas of interest mainly concerned clinical decision support in specific contexts[7].

Subsequently, thanks to the evolution of information technology and the digitization of medicine, AI systems in medicine have increasingly begun to work on large amounts of data. In correspondence, the applications – defined as 'expert systems' – which were intended to support doctors with reasoning and related suggestions based on specialist knowledge have been replaced by applications that aim to support doctors' decision-making activities through the quick and usable identification of relevant information. This is *data mining*, which is a set of activities that aim to extract knowledge and implicit information from data. Among the main ones, it is possible to mention: classification, which consists in the placement of objects within a predefined class system, based on the available information; *clustering*, which makes it possible to identify homogeneous groups of objects; the derivation of *association rules*, which allows to extrapolate recurring associations in the data; *prediction,* which makes it possible to make predictions of future events on the basis of available data, descriptive of what happened in the past; What-if analysis, which makes

[5] The State of Health in the EU: Accompanying Report 2022, Luxembourg, 2022, available at: *https://health.ec.europa.eu/state-health-eu/synthesis-report_it*.

[6] In these terms, M. D'Arienzo, *Contributo allo studio dei modelli organizzativi in sanità*, Torino, 2022, p. 277, for which digital health and healthcare based on direct interaction between doctor and patient are two sides of the same coin, complementing each other and creating a unitary model. Previously, Ead., *Dimensioni organizzative e modelli culturali in sanità: stato dell'arte e prospettive evolutive*, in *Federalismi.it*, 2021, 1, p. 194 ss. See also R. Balduzzi, *Cinque cose da fare (e da non fare) in sanità nella (lunga e faticosa) transizione verso il post-pandemia*, in *Corti Supreme e Salute*, 2020, 2, p. 339 ss., p. 353.

[7] For example, an expert system developed at Stanford in the 1970s called MYCIN aimed to support specialists in defining patients with infections.

it possible to support hypothetical reasoning with respect to different situations envisaged; the *extraction of patterns*, or recurring configurations, from large amounts of data[8].
AI and diagnostic medicine are topics linked by the concept of *prediction*[9].
Since a good prediction makes it possible to formulate an accurate diagnosis, AI should be used to implement mathematical 'predictive models', capable of identifying a disease early and anticipating it[10].
The first studies on the applications of AI in this sector focused on the creation of 'expert systems', based on the split between the representation of medical knowledge – often described through *if-then production rules* – and the algorithms to be able to use this knowledge in the face of a clinical case. In other words, it is required, on the one hand, to represent in a formalized way the information concerning a specific clinical domain, and on the other hand, to define a strategy to use this information in the formulation of a diagnosis on the specific clinical case.
Although the use of these systems in practice has been very limited, however, the results obtained have been very important. The techniques of formalized representation of information have been used for the creation of classification systems or for the implementation of computerized guidelines included, at least in part, in electronic patient records or even in apps, or to obtain the formal and computerized representation of patient care flows of specific hospital facilities, which, representing the operation of a department or service, is of fundamental importance in the creation of decision-support systems[11].
Recently, the interest of scholars has shifted to the applications of *machine learning* systems to medical diagnosis: these systems learn or improve their performance using the data made available to them. The strategies for use in diagnostics are part of inductive

[8] U. Fayyad, G. Piatetsky-Shapiro, P. Smyth, *From data mining to knowledge discovery in databases*, in *AI magazine*, 1996, 17, 3, p. 37 ss.; M.T. Mitchell, *Machine learning*, New York, 1997; J. Han, M. Kamber, J. Pei, *Data mining: concepts and techniques*, San Francisco, 2011; T. Hastie, R. Tibshirani, J. Friedman, *The elements of statistical learning: data mining, inference, and prediction*, New York, 2009; M. Chen, J. Han, P.S. Yu, *Data mining: an overview from a database perspective*, in *IEEE Transactions on Knowledge and Data Engineering*, 2012, 24, 12, p. 2128 ss.; C.C. Aggarwal, *Data mining: the textbook*, New York, 2015; I.H. Witten, E. Frank, M.A. Hall, C.J. Pal, *Data Mining: Practical Machine Learning Tools and Techniques*, San Francisco, 2016.

[9] On the predictive capacity of algorithms, cfr. F. Costantino, *Lampi. Nuove frontiere delle decisioni amministrative tra* open *e* big data, in *Dir. Amm.*, 2017, p. 799 ss.;

[10] For an analysis of the phenomenon and its political-administrative implications, cfr. I. Martín Delgado, *Automazione, intelligenza artificiale e pubblica amministrazione: vecchie categorie concettuali per nuovi problemi?*, in *Ist. fed.*, 2019, p. 643 ss., spec. p. 645 ss.; G. Avanzini, *Decisioni amministrative e algoritmi informatici. Predeterminazione, analisi predittiva e nuove forme di intellegibilità*, Napoli, 2019, p. 10 ss.

[11] Cfr. A. Cassatella, *La discrezionalità amministrativa nell'età digitale*, in *Scritti per Franco Gaetano Scoca*, vol. I, Napoli, 2020, p. 675 ss., spec. p. 23 ss., which reports some virtuous examples of the use of algorithms to support clinical decisions. Especially, in the Emilia-Romagna Region, an algorithm was used that allowed Local Health Authorities (ASL) to manage certain categories of citizens at risk, through preventive medicine that aims to inhibit the onset of certain pathologies deriving from the patient's long-term hospitalization.

learning methods, in which objectives are pursued that can be classified into three areas: *i)* supervised learning; *(ii)* unsupervised learning; *iii)* reinforcement learning[12].
Supervised learning aims to relate a set of measured variables, such as a patient's clinical data, to a variable of interest, such as diagnosis. Learning is supervised because a 'supervisor' is supposed to have provided a database that contains a set of cases in which both the measured variables and the corresponding variable are present. If the variable of interest is discrete or categorical, in the sense that it can take on only one value within a set, as happens in the case of diagnostic problems, the problem is called a classification problem. On the other hand, if the variable has continuous values, such as a clinical parameter such as blood glucose, then the problem is defined as a regression problem. Although known to statisticians, recent developments in the field of *machine learning* have made it possible to expand the nature and quantity of input variables and, at the same time, to derive classification and prediction rules capable of capturing complex aspects in the available data.
Unsupervised learning, on the other hand, aims to find regularities in the input data, without a variable of interest having been defined *a priori*. In biomedical research, among *the data mining activities*, clustering has been widely used, which identifies groups of cases with similar characteristics to each other (*clusters*) and that are sufficiently distinct from the cases of other groups[13].
Finally, reinforcement learning deals with developing an artificial agent that must achieve a goal and, based on the stimuli provided by the environment and the outcome of its actions, learns the best strategy to achieve the goal itself.
In the field of clinical diagnostics, supervised classification methods are the most interesting for the implementation of AI systems.
A decisive aspect for the success of the application of any diagnostic procedure, and in general of any prediction method, is related to the choice of variables to be measured on the case in question. In *machine learning* approaches, variables are derived directly either from clinical data (e.g., laboratory data) or from measurements and extrapolations made by operators (e.g., observations made during diagnostic *imaging*).
In recent years, the process of data extrapolation has been greatly simplified using new artificial neural network architectures collectively referred to as *deep learning* methods[14]. These approaches perform two tasks together: they transform the input variables and, at the same time, they perform the classification (and, in general, any forecasting task)[15].

[12] V.L. Patel, E.H. Shortliffe, M. Stefanelli, P. Szolovits, M.R. Berthold, R. Bellazzi, A. Abu-Hanna, *The coming of age of artificial intelligence in medicine*, in *Artif. Intell. Med.*, 2009, 46, 1, p. 5 ss.

[13] For example, *clustering* has been widely used in the field of molecular diagnostics to discover subgroups in each disease based on data from *high-throughput measurement methods*, such as *Next Generation Sequencing*.

[14] G. Hinton, *Deep Learning. A Technology with the Potential to Transform Health Care*, in *JAMA*, 2018, 320, 11, p. 1101 ss.

[15] W.W. Stead, *Clinical Implications and Challenges of Artificial Intelligence and Deep Learning*, in *JAMA*, 2018, 320, 11, p. 1107 ss.

The high capacity of AI systems to recognize complex *patterns* in data, particularly in the field of diagnostic imaging, has created a strong expectation that it will be possible to create applications that can learn any type of clinical experience. However, it should be remembered that the successes of AI – about *machine learning* and *deep learning* systems – are strictly dependent on the ability of the systems to perform very specific tasks (such as the classification of images or text), downstream of a learning procedure based on large amounts of data. If these capabilities have to be placed in a broader system (for example, the creation of a clinical decision support system that must integrate multiple information sources and, above all, continuously adapt to the operational context of reference), the problem becomes much more complex and the number of success stories reported in the scientific literature is drastically reduced. AI systems will therefore have to be designed in such a way as to explicitly 'type' the patient care process, the information sources and their reference ontologies, be able to use high-quality data for the adaptation of decision-making rules and be equipped with self-diagnosis and performance monitoring tools.

Extensive medical scientific literature shows that, at present, AI has been applied in several areas of diagnostic medicine with positive results.

For example, in the field of lung cancer identification, machine learning algorithms were trained by scanning more than 34.000 chest X-rays, achieving a level of accuracy higher than 17 out of 18 radiologists used as a comparison[16].

Similar results were obtained in the identification of breast cancers, where a properly trained AI system led to an absolute reduction of 5.7% and 1.2%, respectively, in the United States and the United Kingdom, in false positives and 9.4% and 2.7% in false negatives, and an 11.5% increase in sensitivity compared to the work of 6 radiologists[17].

In radiology, the use of AI systems has made it possible to diagnose wrist fractures more accurately, increasing the sensitivity recorded in diagnosis by emergency room staff from 81% to 92% and reducing misinterpretations by 47%[18].

AI has also been employed to support the diagnosis of Covid-19. A study evaluated the performance of an AI system in detecting patients with Covid-19, analyzing chest X-rays and demonstrating its reliability compared to the work of 6 radiologists with a sensitivity

[16] J.G. Nam, S. Park, E.J. Hwang, J.H. Lee, K.-N. Jin, K.Y. Lim, T.H. Vu, J.H. Sohn, S. Hwang, J.M. Goo, C.M. Park, *Development and Validation of Deep Learning-based Automatic Detection Algorithm for Malignant Pulmonary Nodules on Chest Radiographs*, in *Radiology*, 2018, Vol. 290, no. 1.

[17] S.M. McKinney, M. Sieniek, V. Godbole, J. Godwin, N. Antropova, H. Ashrafian, T. Back, M. Chesus, G.S. Corrado, A. Darzi, M. Etemadi, F. Garcia-Vicente, F.J. Gilbert, M. Halling-Brown, D. Hassabis, S. Jansen, A. Karthikesalingam, C.J. Kelly, D. King, J.R. Ledsam, D. Melnick, H. Mostofi, L. Peng, J.J. Reicher, B. Romera-Paredes, R. Sidebottom, M. Tse D. Suleyman, K.C. Young, J. De Fauw, S. Shetty, *International evaluation of an AI system for breast cancer screening*, in *Nature*, 2020, 577, 7788, p. 89 ss.

[18] R. Lindsey, A. Daluiski, S. Chopra, A. Lachapelle, M. Mozer, S. Sicular, D. Hanel, M. Gardner, A. Gupta, R. Hotchkiss, H. Potter, *Deep neural network improves fracture detection by clinicians*, in *Proc Natl Acad Sci U S A.*, 2018, 115, 45, p. 11591 ss.

of 85% and with a specificity of 61%[19]. Another study, on the other hand, showed that a *deep learning* algorithm is able to recognize Covid-19 disease compared to other lung diseases by analyzing CT scans of patients' chests[20].

3. Risks arising from the use of AI in support of diagnostics and possible solutions

As anticipated, if not properly controlled and regulated, the use of AI in the field of diagnostic medicine can be a source of considerable risks[21]. Think, for example, of the use of AI systems without rigorous scientific validation, the lack of control over the data processed by expert systems, the possible violations of user *privacy*, the discrimination induced by the programming of algorithms and the illusory and misleading expectations for healthcare professionals and patients deriving from the improper use of technologies[22]. Ethical and legal issues involving professional responsibility and the role of the doctor in interacting with AI systems are therefore envisaged, with significant consequences in the relationship between doctor and patient[23].

The scientific validation of AI systems in medicine is a highly debated topic, as well as being an indispensable condition for their use in a healthcare context. This objective presupposes the existence of methodologically impeccable clinical studies to demonstrate that: a diagnosis made using an AI system is as reliable as that made by a specialized doctor; the *software* does not contain *selection biases* (e.g., avoiding that *machine learning* algorithms earn data only on certain categories of patients, ignoring others); the proposed solutions are generalizable and clinically safe and effective[24].

At national legal level, there is a need for regulatory authorities to govern AI systems used in the medical sector.

[19] K. Murphy, H. Smits, A.J.G. Knoops, M.B.J.M. Korst, T. Samson, E.T. Scholten, S. Schalekamp, C.M. Schaefer-Prokop, R.H.H.M. Philipsen, A. Meijers, J. Melendez, B. van Ginneken, M. Rutten, *COVID-19 on Chest Radiographs: A Multireader Evaluation of an Artificial Intelligence System*, in *Radiology*, 2020, 296, 3, p. 166 ss.

[20] L. Li, L. Qin, Z. Xu, Y. Yin, X. Wang, B. Kong, J. Bai, Y. Lu, Z. Fang, Q. Song, K. Cao, D. Liu, G. Wang, Q. Xu, X. Fang, S. Zhang, J. Xia, *Using Artificial Intelligence to Detect COVID-19 and Community-acquired Pneumonia Based on Pulmonary CT: Evaluation of the Diagnostic Accuracy*, in *Radiology*, 2020, 296, 2, p. 65 ss.

[21] On the relationship between risk and AI, cfr. A. Barone, *Amministrazione del rischio e intelligenza artificiale*, in *ERDAL*, 2020, 1-2, p. 63 ss.

[22] On this last aspect, in the medical scientific literature, cfr. A. Laghi, *Cautions about radiologic diagnosis of COVID-19 infection driven by artificial intelligence*, in *Lancet Digit Health*, 2020.

[23] Problems identified, in a general perspective, by A. Broadbent, *Approach to AI: An Analysis of Policy, Ethics and Regulation*, in *AI and Society*, 2021, 36, p. 59 ss.

[24] E. Santoro, *L'intelligenza artificiale in medicina: quali limiti, quali ostacoli, quali domande*, in *Recenti Prog. Med.*, 2017, 108, 12, p. 500 ss.

In the United States, for example, the Food & Drug Administration addressed the issue several years ago, adopting a regulation that submitted approval to the use of AI systems in medicine, like medical devices[25]. Public scrutiny does not, however, seem suitable to prevent any risk, especially considering that regulation becomes vulnerable – even if subject to updating – whenever retrospective studies or studies that provide weak evidence of efficacy are accepted for registration and approval of AI systems. The U.S. authority has, moreover, created some guidelines on the integration and correct use of AI in the diagnostic sector, helping to reduce the risks deriving from improper and incorrect use[26]. Compliance with procedural rules and adherence to guidelines is an important step, as it leads to the creation of reliable AI systems, correct use in diagnostics, and bringing out any critical issues.

In Italy, the D34Health project represents one of the successful cases of application of AI systems to diagnostic medicine. The project is coordinated by the Sapienza University of Rome, developed with the participation of the Polytechnic University of Turin, the University of Turin, the Vita-Salute San Raffaele University of Milan and other Universities and Hospitals and funded by the National Plan for Complementary Investments to the PNRR[27]. The aim is to identify new solutions for the diagnosis, monitoring and treatment of certain forms of cancer, multiple sclerosis and diabetes. Through a data mining approach, researchers will develop digital and biological models for the study of pathologies, i.e. 'digial twins' of patients and 'biological twins' of organs or tissues. The 'twins' will be created with similar characteristics to patients, to be used in wide-ranging tests that will provide reliable results without resorting to animal testing. The models will be developed starting from the collection of health data from many cases and from different hospitals, which will be analyzed through AI algorithms and integrated with data collected through innovative technologies such as wearable devices, sensors and organ-on-chips.

[25] The full list of AI systems in medicine approved by the Food & Drug Administration can be found at: *https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices*.

[26] Cfr. *Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff*, October 2017, available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device*.

[27] A summary of the project is available at: *https://www.iac.cnr.it/d3-4-health*.

4. The regulatory framework in the European Union and the new proposed European Regulation on Artificial Intelligence (AI Act)

In recent years, the AI sector has been the subject of a series of interventions by the European legislator, aimed at outlining a common reference regulation through a progressive alignment of the disciplines in force in the Member States.
First, a series of programmatic acts have been dedicated to the use of algorithms and, in general, of AI[28].
Subsequently, general legislative acts were adopted. With regard to the health sector, EU Regulation 2017/745 and EU Regulation 2017/746 were issued on 5 April 2017. The first regulates medical devices; while the second regulates *in vitro* medical-diagnostic devices. The aim of these regulations is to ensure a hard regulatory framework, suitable for maintaining a high level of security and transparency. The Regulation on *in vitro* medical-diagnostic devices classifies these devices into four classes of increasing risk: Class I; Class IIa; Class IIb; Class III. The classification is based on rules, contained in Annex VIII, which consider the duration of use (temporary, short-term and long-term), the intended use and the level of risk it entails (invasive and active devices, invasive devices, active devices, non-invasive devices). The determination of the risk class serves to identify the necessary steps for CE marking, especially with reference to the conformity and clinical needs assessment procedure.
In summary, the Regulation provides that the manufacturer must: assess whether or not the product falls within the notion of medical device; carry out risk analysis; carry out validation tests on compliance with safety and performance requirements (Annex 1); if the device falls into Class I, issue the declaration of conformity and affix the CE marking; for Classes IIa, IIb and III, involve a third party, called the Notified Body (ON), which carries out control activities; if the activity is successful, the NB issues the CE certification, the manufacturer issues the declaration of conformity and affixes the CE marking.
More recently, the European Commission presented a proposal for a Regulation of the European Parliament and of the Council, laying down harmonized rules on artificial intelligence (AI Act) and amending certain Union legislative acts, published on 21 April 2021 and recently approved by the Parliament of the European Union. This is the first attempt

[28] Among the most significant, cf. European Parliament resolution with recommendations to the Commission on 'Civil Law Rules on Robotics', 16 February 2017, COM(2018) 237; Communication from the European Commission on 'Artificial Intelligence in Europe', 25 April 2018, COM(2019) 168 final; Communication from the European Commission on Building Trust in Human-Centered Artificial Intelligence, 8 April 2018, COM(2020) 65 final; White Paper on the European Strategy for AI, entitled 'White Paper on Artificial Intelligence. A European approach to excellence and trust'. In addition, within the framework of the Council of Europe, the Committee of Experts on Internet Intermediaries published in March 2018 the study 'Algorithms and Human Rights'.

made to regulate AI in general terms, intervening in a context characterized by the substantial absence of regulatory disciplines of general application.
The AI Act sets itself the daunting task of balancing different interests pertaining to the sector. A legally and economically and ethically sustainable discipline: it must not inhibit AI research and development, for which economic investments of €20 billion are planned; it must affirm and consolidate the principles of the *rule of law*; it must be flexible and adaptable to technological changes and the rapid development that characterize technology, while ensuring the degree of certainty and predictability necessary for such a strategic and delicate field; it must not be inhibited by possible abuses in the use of AI systems, but must be able to courageously explore new benefits and domains, promoting and strengthening people's fundamental rights[29].
Like what happened with the adoption of the GDPR, the European Union chose to adopt the regulation instead of the directive. The legal basis is Article 114 of the Treaty on the Functioning of the European Union (TFUE), on the adoption of measures to ensure the establishment and functioning of the internal market, which may lead to such uniform and directly applicable constraints throughout the European territory, with the aim of creating a homogeneous and basically rigid regulatory framework for the Member States, except for some room for man oeuvre and appreciation for the discipline of *sandboxes*, codes of conduct, internal organization and sanctioning regime.
AI systems are classified according to a criterion that considers the risk associated with them, understood as the negative impact on values, fundamental rights, health, safety and transparency, and the severity of their impact, to which a different legal regulation is attached. In particular, a distinction is made between: systems with an unacceptable risk, for which a prohibition regime is provided for unless expressly derogated; high-risk systems, to which most of the discipline is dedicated; systems at risk of transparency, for which information obligations are envisaged; minimal risk systems, for which there are not only obligations, except for those imposed by sector regulations.
The subjective scope of application of the AI Act is very extensive. It applies: to providers that place on the market or put into service AI models for general purposes in the European Union, regardless of whether they are established or located in the Union or in a third country; deployers of AI systems that are established or located within the Union; providers and deployers of AI systems that have their place of establishment or are located within the Union; providers and deployers of AI systems that have their place of establishment

[29] C. Casonato, B. Marchetti, *Prime osservazioni sulla proposta di regolamento dell'Unione Europea in materia di intelligenza artificiale*, in *BioLaw Journal*, 2021, 3, p. 415 ss.; A. Adinolfi, *L'Unione europea dinanzi allo sviluppo dell'intelligenza artificiale: la costruzione di uno schema di regolamentazione europeo tra mercato unico digitale e tutela dei diritti fondamentali*, in S. Dorigo (a cura di), *Il ragionamento giuridico nell'era dell'intelligenza artificiale*, Pisa, 2020, p. 13 ss.; M. Zanichelli, *Ecosistemi, opacità, autonomia: le sfide dell'intelligenza artificiale in alcune proposte recenti della Commissione europea*, in A. D'Aloia (a cura di), *Intelligenza artificiale e diritto. Come regolare un mondo nuovo*, Milano, 2020, p. 67 ss.

or are located in a third country, where the output produced by the AI system is used in the Union; importers and distributors of AI systems; product manufacturers who place an AI system on the market or put into service together with their product and under their name or brand; authorized representatives of suppliers not established in the Union; data subjects who are in the Union[30].

The scope of the AI Act is also defined by the competences and territory of the European Union. Regarding the former, the AI Act does not apply to areas that do not fall within the exclusive competence of the European Union and, in any case, does not affect the competences of the Member States in the field of national security[31]. An area excluded from the scope of the Regulation could be, for example, healthcare services that presuppose a direct relationship between doctor and patient (e.g. consent to medical treatment, doctors' obligations to provide information, etc.).

The scope of the AI Act is limited to entities established or located in the territory of the European Union. However, its rules may also apply to entities outside the European Union that produce and place AI systems in the single market or that generate outputs that have effects on the territory of the European Union. Scholars have described this phenomenon as «Brussels Effect»[32], i.e. the territory of the European Union is always relevant as a parameter of validity and effectiveness of the rules of the AI Act, which, however, can also have extraterritorial application when AI systems generate significant effects in the European context.

The AI Act contains a few exclusions. For example, it does not apply to AI systems and their outputs specifically developed and put into service for the sole purpose of scientific research and development[33]. In addition, it also does not apply to research, testing or development activities related to AI systems prior to their placing on the market or putting into service. These activities are carried out in accordance with European law. However, real-world tests do not fall under this exclusion[34]. The goal of the AI Act is to promote scientific research and development; for this reason, all research and experimentation activities of AI systems are excluded from its scope (e.g. learning techniques). The AI Act only applies if and when the AI system is placed on the market or put into service as a result of the research activity. A case that falls within the scope of the provision is that of AI systems used in the medical and diagnostic fields. The AI Act does not apply to research activities, but only if and from the moment the AI system is put on the market. In addition, the provisions on regulatory sandboxes and real-world testing shall apply. For example, if a medical-diagnostic device that uses an AI system needs to be tested on a patient, the

[30] See Art. 2, par. 1, lett. a), b), c), d), e), f) and g), of the AI Act.

[31] See Art. 2, par. 3, of the AI Act.

[32] A. Bradford, *The Brussels Effect: How the European Union Rules the World*, Oxford, 2020.

[33] See Art. 2, par. 6, of the AI Act.

[34] See Art. 2, par. 8, of the AI Act.

AI Act allows it, provided that a protocol with application rules and informed consent of the patient is in place.
Another important aspect of the AI Act is definitions.
For the first time, a definition of 'AI system' is given, understood as an automated system designed to operate with varying levels of autonomy and which can present adaptability after dissemination and which, for explicit or implicit objectives, deduces from the input it receives how to generate outputs such as predictions, content, recommendations or decisions that may influence physical or virtual environments[35].
The AI Act also defines who is required to enforce it. These include a 'provider', i.e. a natural or legal person, public authority, agency or other body that develops an AI system or AI model for general purposes or that has an AI system or AI model developed for general purposes and places that system or model on the market or puts the AI system into service under its own name or trade mark, whether for a fee or free of charge[36]; and the 'deployer', i.e. a natural or legal person, public authority, agency or other body that uses an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity[37]. For the application of the AI Act, both the intention to develop an AI system and its placing on the market are therefore relevant.
The AI Act will become applicable 24 months after its entry into force, with some exceptions, for example, for Higth-Risk AI Systems, which will take place after 36 months[38]. Deferred application has the *ratio* of allowing manufacturers and developers of High-Risk AI Systems to progressively adapt to its rules.
Although the AI Act will become the reference legislation on the production and use of AI systems, its application does not exclude other sectoral European regulations on the subject. About AI systems used in the medical and diagnostic fields, the rules relating to the protection of personal data contained in EU Regulation 2016/679, of 24 April 2016 (so-called GDPR)[39]. In particular, art. 9, par. 1 means the consent of the data subject as a necessary legal condition for the lawful processing of personal data, except in cases where: the processing is necessary for the purposes of preventive or occupational medicine, as-

[35] See Art. 3, par. 1, n. 1), of the AI Act; see also the definition of 'general purpose AI model' in the Art. 3, par. 1, n. 63), of the AI Act.

[36] See Art. 3, par. 1, n. 3), of the AI Act.

[37] See Art. 3, par. 1, n. 4), of the AI Act.

[38] See Art. 113 of the AI Act.

[39] In fact, with regard to the relationship between the AI Act and the GDPR, Art. 2, par. 7, of the AI Act provides that: «Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect EU Regulation 2016/679 or EU 2018/1725, or Directive 2002/58/EC or EU 2016/680, without prejudice to Article 10, par. 5 and Article 59 of this Regulation». On these aspects, cfr. F. Pizzetti, *La protezione dei dati personali e la sfida dell'Intelligenza Artificiale*, p. 5 ss.; A. Spina, *La medicina degli algoritmi: Intelligenza Artificiale, medicina digitale e regolazione dei dati personali*, p. 319 ss., both in F. Pizzetti (a cura di), *Intelligenza artificiale, protezione dei dati personali e regolazione*, Torino, 2018.

sessment of the employee's ability to work, diagnosis, health or social care or treatment, or management of health or social systems and services on the basis of Union or Member State law or in accordance with a contract with a health care professionals (par. 2, lett. h); the processing is necessary for reasons of public interest in the field of public health, such as protection against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and medicinal products and medical devices, on the basis of Union or Member State law providing for appropriate and specific measures to protect the rights and freedoms of the data subject, in particular professional secrecy (par. 2, lett. i). In these cases, the processing is supported by special safeguards, since it is carried out by or under the responsibility of a professional subject to professional secrecy, in accordance with European or national law or the rules established by competent national bodies (par. 3).

The issue of data is also intercepted by EU Regulation 868/2022, of 30 May 2022 (so-called Data Governance Act or DGA), by means of which the European legislator has intended to facilitate data sharing in the internal market, by creating harmonized legal framework for data exchanges, without prejudice to data protection law (GDPR)[40]. The issue of data is also intercepted by EU Regulation 868/2022 (so-called Data Governance Act or DGA), by means of which the European legislator has intended to facilitate data sharing in the internal market, by creating harmonized legal framework for data exchanges, without prejudice to data protection law (GDPR). One of the critical aspects of the Regulation concerns precisely the reuse of personal data in sensitive sectors, including the health sector. According to the European Data Protection Board and the European Data Protection Supervisor, the ADI should have established, in these sectors, the necessary requirements for the protection of personal data, as well as the related conditions and specific data protection safeguards to be met for the reuse of data, including the data protection impact assessment (DPIA) under Article 35 GDPR, which is also necessary to ground the decision on reuse . The choice of the European legislator, in the ADI, was different: the obligation to conduct the DPIA was already provided for in the GDPR, which remains applicable to cases of reuse of personal data held by public bodies, and prevails in case of conflict with the provisions of the ADI. Since it is already regulated in the GDPR, there is no need to include a DPIA requirement in the GDPR as well for all data reuse possibilities. However, the application boundaries of this obligation will remain as outlined in the GDPR. In any case, the obligation to conduct DPIA to reuse non-anonymized personal data is mentioned in the recitals of the GDPR anyway.

Medical and *in vitro* diagnostic-medical devices will also be governed by the rules contained in the Regulation on the European Health Data Space (EHDS), which is currently

[40] See almost F. Bravo, *Data Governance Act and Re-Use of Data in the Public Sector*, in *ERDAL*, 2022, 3, 2, p. 13 ss.

being prepared[41]. The proposal introduces new rules for manufacturers of electronic health record systems (ECR systems) who intend to place their products and services on the EU market, complementing the Medical and Diagnostic Devices Regulations. In particular, Articles 14-27 of the Proposal set out a self-regulatory scheme that invites manufacturers to declare their conformity with the common specifications of the Proposal and its Annex, that are primarily linked to issues of interoperability and security. For example, manufactures of HER systems will have to draw a declaration of conformity to the common specifications and the essential requirements laid down in Article 23 of the Proposal, its Annex and any additional set of rules that will to follow by means of implementing acts[42].
In turn, entities that wish to import or distribute HER systems in the European market (e.g. Apple's AppStore or Google's Play Store) will then have to verify that all relevant declarations of conformity have been made and that the required information is provided by the manufacturer. If, however, they «consider or have reasons to believe» that an HER system is not in conformity with the Proposal, they can delay import or distribution until the system's parameters align with the scheme's requirements[43].
Some critical issues of the Proposal relate to the lack of mention of privacy and data protection in the essential requirements and common specifications for the declaration of conformity of CEE system manufacturers[44]. In addition, the Proposal does not adequately address the issues of user authorisation – i.e. who will be allowed to access which information through EEC systems – and audit of registers – i.e. who accesses what information[45]. This omission raises concerns considering that Article 31 allows developers of well-being-related applications to achieve interoperability with CEE systems through a self-declaring labelling scheme that would feed CEE systems with new data (i.e. well-being and lifestyle data generated by smart watches and IoT (Internet of Things devices). Thus, the exchange of data guided by formal and informal laws of the direct relationship between doctor and patient risks becoming a confusing framework in which information

[41] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, COM/2022/197 final, available: *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197*.

[42] Sulla Proposta di Regulation on the European Health Data Space (EHDS) see almost P. Terzis, (E.) OE Santamaria Echeverria, *Interoperability and governance in the European Health Data Space regulation*, in *Medical Law International*, 2023, 23, 4, p. 368 ss.; T. Petrocnik, *Health Data between Improving Health(Care) and Fuelling the Data Economy: Editorial*, in *Technology and Regulation*, 2022, p. 124 ss.; P. Terzis, *Compromises and Asymmetries in the European Health Data Space*, in *European Journal of Health Law*, 2022, 1, p. 1 ss.

[43] See indicatively, M.A. Rothstein, S.A. Tovino, *Privacy Risks of Interoperable Electronic Health Records: Segmentation of Sensitive Information Will Help*, in *Journal of Law, Medicine & Ethics*, 2019, 47, p. 771 ss.; G. Bincoletto, *Data Protection Issues in Cross-Border Interoperability of Electronic Health Record Systems within the European Union*, in *Data & Policy*, 2020, 2, p. 3 ss.

[44] P. Terzis, (E.) OE Santamaria Echeverria, *Interoperability and governance in the European Health Data Space regulation*, cit., p. 371.

[45] P. Terzis, (E.) OE Santamaria Echeverria, *Interoperability and governance in the European Health Data Space regulation*, cit., p. 371.

circulates between and through systems without patients' knowledge or without their implicit or explicit consent.

4.1. AI systems in diagnostic medicine as Higt-Risk AI Systems: analysis of the legal regime

The AI Act devotes a large part of the discipline to High-Risk AI Systems[46].
The identification of High-Risk AI Systems is based on a presumption of risk. The AI Act presumes such AI systems used in specific areas, considering their negative impact on fundamental rights protected by European law. In particular, High-Risk AI Systems are considered to be those that meet two conditions at the same time: they are used as a safety component of a product or they are themselves a product that falls within one of the areas governed by European regulations and listed in Annex I; are subject to a third-party conformity assessment in accordance with European legislation[47].
In addition to these, High-Risk AI Systems are also those used in the areas and intended uses indicated in Annex III[48].
However, this regulation has been mitigated thanks to the introduction of a 'filter rule' by the European Parliament: even if used in the sectors and with the intended uses indicated in Annex III, there may be AI systems that do not entail a significant risk of harm to protected interests in these sectors, as they do not materially influence the decision-making process[49]. This is the case for AI systems that perform a limited procedural task; it is intended for marginal improvement in the outcome of a human activity; it is intended to detect previous decision-making patterns and their deviations; they carry out a purely preparatory task.
The risk management system provided for by the AI Act is based on the consideration that not all concrete risks can be foreseen, mitigated and reduced to an acceptable social level through the provision of obligations. For this reason, every provider must adopt a risk management system, which must be maintained and updated throughout the system's lifecycle. It consists of: a process of identification and assessment of risks both known and foreseeable before marketing, and emerged during the post-market monitoring phase; management of the same in terms of elimination or reduction, as well as adequate information; appropriate testing procedures to ensure that it is used in accordance with the intended purposes and requirements of the AI Act. In particular, the following are required: a high-quality data set, the creation and maintenance of technical documentation, an ad-

[46] See Title III (High-Risk AI Systems) of the AI Act.
[47] See Art. 6, par. 1, of the AI Act.
[48] See Art. 6, par. 2, of the AI Act.
[49] See Art. 6, par. 3, of the AI Act.

equate level of transparency, human oversight and the guarantee of robustness, accuracy and security of the system[50].

The minimum requirements for the introduction of High-Risk AI Systems within the single market are[51]: the use of relevant, complete and error-free data[52]; the preparation of complete and constantly updated technical documentation, which also allows the assessment of their impact on fundamental rights[53]; the obligation to set up the functionality for the automatic recording of logs (a sort of logbook of navigation of the system), in order to keep track of the functioning of the system and the operations carried out, in order to verify its appropriateness throughout the life cycle[54].

The verification of the minimum requirements takes place through the European conformity marking procedure (CE marking), which has already been tested to regulate the circulation of numerous products on the European market. This procedure allows a product to circulate in the European market and in the European Economic Area (EEA)[55] only after the affixing of the conformity mark, consisting in the verification of the conformity of the product with European standards and rules carried out by the manufacturer himself or by a third-party certifying body. Unlike medicines or genetically modified organisms (GMOs), there is no provision for the issuance of an administrative, European or national authorization, but compliance with the requirements for the protection of the safety, health and fundamental rights of the citizen is ensured by a self-assessment by the person who has an interest in marketing the product.

This regulatory choice has undoubted advantages: administrative authorization gives greater certainty and guarantees on the safety of the product, but it is not exempt from economic and bureaucratic costs; the European conformity marking procedure makes it easier for the product to be placed on the market and shifts the responsibility for ensuring compliance with the safety requirements set out in the legislation to economic operators. It should be noted, however, that the internal conformity verification procedure, entrusted to the provider, is certainly less protective than the external conformity verification procedure, entrusted to a certifying body, independent of the provider. In any case, if the first system proves to be inadequate during the implementation of the AI Act, the Commission will be able to easily intervene, for example, by requiring Member States to entrust the conformity clearance procedure to an external party. In this sense, the AI Act represents a flexible legislative instrument that allows the Commission to make changes to the rules without having to redo the legislative process.

[50] See Art. 9 of the AI Act.

[51] See Chapter 2 (Requirements for High-Risk AI Systems) of Title III (High-Risk AI Systems) of the AI Act.

[52] See Art. 10 of the AI Act.

[53] See Art. 15 of the AI Act.

[54] See Art. 12 of the AI Act.

[55] This also includes non-EU countries such as Norway, Iceland and Lichtenstein.

In addition to the pre-market checks, a post-market monitoring system is also envisaged, which aims to ensure that the product complies with the requirements established by the regulations throughout the entire life cycle of AI systems[56]. It is therefore envisaged that each Member State must have an authority for the management of the post-market surveillance system; precise obligations are recognized for the user and the provider. The provider must keep automatically generated logs for an appropriate period of time, established on the basis of the characteristics of the AI system, which can be accessed by the competent national authorities for control purposes; in the event of non-compliance, it must immediately take the appropriate corrective measures and must notify the national competent authority – and possibly the certifying body – of the violations found in the operation of the system[57].

To ensure compliance with the requirements and obligations of providers, the national supervisory authority that becomes aware of a non-compliance of the AI system with the legal requirements may require the data subject to take appropriate measures to stop the infringement, order the withdrawal of the AI system from the market or a recall for a reasonable time proportionate to the nature of the risk[58]. The Commission and the other Member States must be notified of these actions with a view to the possible adoption of safeguard measures.

Detailed rules concern the certifying bodies and the relationship with the national notifying authorities. It is envisaged that each Member State should designate a notifying authority responsible for setting up and carrying out the procedures necessary for the assessment and notification of certifying bodies[59]; it should operate in a manner that ensures the absence of any conflict of interest with the certifying bodies, for which independence requirements are prescribed.

This regulatory choice has undoubted advantages: administrative authorization gives greater certainty and guarantees on the safety of the product, but it is not exempt from economic and bureaucratic costs; The European conformity marking procedure makes it easier for the product to be placed on the market and shifts the responsibility for ensuring compliance with the safety requirements set out in the legislation to economic operators.

In addition to the pre-market checks, a post-market monitoring system is also envisaged, which aims to ensure that the product complies with the requirements established by the regulations throughout the entire life cycle of AI systems[60]. It is therefore envisaged that each Member State must have an authority for the management of the post-market surveillance system; precise obligations are recognized for the user and the provider. The

[56] See Art. 61 of the AI Act.

[57] See Arttt. 20, 21, 22 and 23 of the AI Act.

[58] See Artt. 64 of the AI Act.

[59] See Artt. 30 of the AI Act.

[60] See Artt. 61 of the AI Act.

provider must keep automatically generated logs for an appropriate period of time, established on the basis of the characteristics of the AI system, which can be accessed by the competent national authorities for control purposes; in the event of non-compliance, it must immediately take the appropriate corrective measures and must notify the national competent authority – and possibly the certifying body – of the violations found in the operation of the system[61].

To ensure compliance with the requirements and obligations of providers, the national supervisory authority that becomes aware of a non-compliance of the AI system with the legal requirements may require the data subject to take appropriate measures to stop the infringement, order the withdrawal of the AI system from the market or a recall for a reasonable time proportionate to the nature of the risk[62]. The Commission and the other Member States must be notified of these actions with a view to the possible adoption of safeguard measures.

Detailed rules concern the certifying bodies and the relationship with the national notifying authorities. It is envisaged that each Member State should designate a notifying authority responsible for setting up and carrying out the procedures necessary for the assessment and notification of certifying bodies[63]; it should operate in a manner that ensures the absence of any conflict of interest with the certifying bodies, for which independence requirements are prescribed.

5. The impact on the Italian legal system

The AI Act will have a considerable impact on the legal system of the Member States.

First, it should be noted that the powers to implement the rules are vested in the national administrative authorities, in accordance with the well-known model of indirect European administration. The only exception is the rules on general purpose AI systems (GPAI), which are the sole responsibility of the AI Office, and therefore the European Commission.

The effectiveness of the AI Act will depend largely on the organizational solutions adopted by Member States. However, these solutions are, at least in part, conditioned by the Commission: for example, Member States can choose whether to establish a single authority with post-market notification and surveillance functions or to assign these powers to two different authorities[64]; however, both the responsibilities of these authorities and the staff to be employed by them shall be identified in detail. including «in-depth understanding of

[61] See Artt. 20, 21, 22 and 23 of the AI Act.

[62] See Art. 64 of the AI Act.

[63] See Art. 30 of the AI Act.

[64] Without prejudice to the burden of justifying in detail the administrative and organizational reasons for the designation of more than one authority (Art. 59, par. 2 and 3, of the AI Act).

artificial intelligence technologies', data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements»[65].
In Italy, the Council of Ministers, on the proposal of the President of the Council of Ministers and the Minister of Justice, approved a bill for the introduction of provisions and delegation to the government in the field of AI. The bill chose to entrust the notification and supervisory functions to two different authorities, namely the Agency for Digital Italy (AgId) and the National Cybersecurity Agency (ACN), which will operate under the direction of the Presidency of the Council of Ministers.
Specific provisions on the use of AI systems in the health and disability sectors are also introduced. In particular, it is stated that the use of AI systems cannot in any way restrict access to health services; whereas the data subject must be informed of the use of such technologies; whereas medical decision-making is the sole responsibility of medical professionals and that, at most, the use of AI systems can support the making of such decisions.
Some critical issues are presented by the provision on scientific research in the implementation of AI systems in the health sector, which declares «of significant public interest» the processing of data, including personal data, carried out by public and private non-profit entities for the performance of these activities. Coordination with the GDPR and the DGA certainly appears to be necessary.
Finally, the establishment of an AI platform is planned to support care purposes and territorial assistance.
More generally, the bill should consider the necessary actions, identified by the Superior Council of Health, to safely introduce AI systems into clinical practice[66]. The interventions to be implemented are: the creation of an organizational infrastructure, computerized, at local, regional or national level, of data stewardship and data governance; the creation of a governance structure for AI systems by Italian regulatory agencies, in particular the Ministry of Health for medical devices and AIFA for any therapeutic aspects, with the aim of establishing strict rules for the approval and registration of such systems; the preparation of national guidelines regarding the methods of integration and correct use of AI systems in diagnostics, in agreement with the relevant scientific societies; the creation of a permanent national observatory, at the Ministry of Health, to monitor the performance of AI systems placed on the market (post-market analysis); the preparation of undergraduate and postgraduate training modules to improve the knowledge and skills in the field of AI of medical personnel and health professions; the integration of methodological elements

[65] Cfr. Art. 59, par. 4, of the AI Act.

[66] Cfr. the document on *Artificial intelligence systems as a tool to support diagnostics*, cit., p. 3 ss. In doctrine, see R. Balduzzi, *Diritto alla salute e servizi sanitari tra consolidamento e indebolimento*, Bologna, 2017, which dedicates a broad analysis to healthcare in Italy.

in the field of AI within upper secondary school curricula and the creation of information content, including through IT channels, at the service of citizens.

6. A look into the future

AI systems are spreading rapidly in the medical sector, with the prospect of significantly changing diagnostic and therapeutic pathways, the decision-making methods of the specialist doctor and the doctor-patient relationship.
The use of such systems is the source of a number of significant risks, including: the lack of rigorous scientific validation; the lack of control over how data is processed by expert systems; possible violations of privacy by users; discrimination (e.g., racial and/or gender) introduced by algorithm programming; lack of information about safety and reproducibility in the use of AI systems; the lack of rules regarding the responsibility of the doctor in the interaction with algorithms; the unpreparedness of medical and healthcare staff for the correct use of AI systems and the appropriate way of communicating their use to patients; the difficulty of the user/citizen to grasp the real benefits and limitations of AI systems.
Since it is not possible to achieve zero risk, the real challenge of the law lies in introducing regulatory systems that bring the risk to a level deemed socially acceptable.
The AI Act seems to go in this direction, proposing to introduce a legally, economically and ethically sustainable regulation of AI systems. Its content is affected by the specific characteristics and complexity of the object to be adjusted. However, much will depend on the organisational choices of the Member States which, in their internal regulations, will have to identify the authorities to be entrusted with the functions of notification and post-market surveillance, and monitor the implementation of the discipline, in order to report any critical issues to the Commission.
Although the Elysium medical capsules are for now only an ideal model, however, technical-scientific progress, if adequately supported by adequate ethical-legal regulation, allows us to glimpse a reality not too far away that is not so different from the ideal model.