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*The AI in Healthcare: Balancing the Right to Health and Boosting Administrative Innovation in the Italian National Health Service (SSN)**

Alessia Monica
(Researcher in Tenure Track in Administrative Law)

ABSTRACT Italy's Law 132/2025 on Artificial Intelligence (AI) introduces significant changes to the healthcare system, transforming administrative processes and the organisation of the National Health Service (SSN). Implementing Regulation (EU) 2024/1689 (the AI Act), the law ensures that the adoption of AI complies with Article 32 of the Constitution, which protects health as both an individual right and a collective interest. Article 8 recognises the processing of data for AI-based scientific research as being of significant public interest, in line with the European Health Data Space (EHDS) and the General Data Protection Regulation (GDPR). Additionally, a national AI platform, managed by AGENAS, supports healthcare objectives, particularly with regard to local care. Against this backdrop, the EU principle of good administration aims to ensure that digital transformation in healthcare remains aligned with the community care and the protection of human rights.

KEYWORDS: Healthcare - AI Act – Platform - Good administration - Data space - National Health Service

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1. *The Italian Law on AI in Relation to the EU AI ACT Regulation*

The Italian law on Artificial Intelligence (n. 132/2025) falls within the framework of Regulation (EU) 2024/1689 (*AI Act*). Specifically, the national text is subordinated to, and should be interpreted in accordance with. Shortly, a few points about the EU reference framework need clarification. Due to the risk-based approach, whereby the type and content of the rules should be tailored to the intensity and scope of the risks that AI systems can generate, the risk categories for AI systems defined by the AI Act remain the reference grid. The risks posed by AI can be characterised and classified according to the severity, probability and frequency of the potential harm they may cause, and classified in 3 different level of risk: high, medium or low. Obviously high risk is not only linked to emergency healthcare patient triage systems involving AI, but also with the determination of essential public assistance, which significantly impacts people's livelihoods and may infringe their fundamental rights.[1] Again, the use of AI for healthcare purposes is governed by a complex legal framework which encompasses also overlapping and complementary rules such as the *Medical Device Regulation* (MDV)[2] or *In Vitro Diagnostic Regulation* (IVDR).[3] All these regulations prevent Member States from adopting measures that would jeopardize the effective free movement of these products.

Although inspired by the principle of the free movement of AI systems within the internal market, the AI Act complies with both the legal basis of Article 114 TFEU and that of Article 16 TFEU. It defines a regulatory framework of principles and standards covering various potential uses of artificial intelligence across different sectors, excluding transport and national security.[4] This includes the use of AI tools and systems in medicine, ranging from apps that promote healthy lifestyles to those that directly perform healthcare services, as well as AI systems that improve the management of healthcare services. An immediate clarification of a misleading confusion is required. The use of ICT in healthcare has progressively improved

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[1] Recital 58, Regulation (EU) No. 2024/1689.
[2] Regulation (EU) No. 2017/745 on Medical Device.
[3] Regulation (EU) No. 2017/746 on In Vitro Diagnostic.
[4] As for the national security, see article 2(3) AI Act.

the prevention, diagnosis and monitoring of illnesses, as well as the promotion of healthy lifestyles. *E-health* is primarily employed via telemedicine which enables the provision of remote healthcare services.[5] Again, it encompasses the *automation and digitisation of procedures* (ADMs). ADMs are also used to create algorithms that improve decision-making.[6] Against this backdrop, it must be remarked that AI is something else entirely, even though it is often difficult to define satisfactorily[7] by listing uncontroversial necessary and sufficient conditions.[8] The use of ICT involves imitating certain aspects of human intelligence in order to develop IT products or machines that can interact with and learn from their external environment. These machines are capable of making increasingly autonomous decisions in the health sector. On this path, the AI ACT also provides the protection of fundamental rights against the harmful effects of AI. Therefore, EU Regulation applies to both private and public entities to prevent any adverse impact on fundamental rights. Consequently, public administrations are not exempt from the obligation to comply with it, both in case it plays as a provider or as a deployer of AI systems.

From the patient's perspective, the AI Act says rather little about their specific rights. Apart from the AI practices contrary to EU values set in article 2 TEU,[9] once the risk of AI use has been assessed and accepted, the protection mostly concern the right to an explanation of individual decision-making. This applies to high-risk AI systems listed in Annex III that have an adverse impact on health, safety or fundamental rights.[10] Besides, with regard to the use of AI in healthcare, Italian national legislation introduces more stringent obligations than the AIA's provisions. Above all, this is a direct consequence of the lack of a specific competence concerning health at the EU level. Despite the fact that health is primarily considered a 'negative' right under European Union law, in the sense that EU action does not overlap or interfere with the competences of Member States, it assumes the characteristics of a 'cross-cutting' right covering multiple areas. For this reason, effective guarantees – both at individual and collective level – require concrete and targeted interventions in a variety of sectors and public policies that are increasingly interdependent and interconnected. According to article 168 TFEU, the Union action shall respect the responsibilities of Member States for the definition of their health policy and for the organisation or the delivery of health services and medical care. In other words, Member States health policies cannot be harmonized but they can progressively be guided to converge. Indeed, the exclusion of harmonisation contained in Article 168(5) TFEU did not limit the possibility for other harmonisation measures, adopted under other legal bases, to have an impact on the protection of health, 'to the condition that such legal bases are not used in order to circumvent the exclusion of Article 168(5) TFEU'.[11]

In this light, it is possible to recognise the common value of the right to healthcare at EU level, as set out in article 35 of the CFREU, which fosters cooperation and the subsequent rights of protection, particularly in cross-border areas.[12] Therefore, article 35 of the CFREU can be considered a guarantee of adequate 'protection' of health in the social sense,[13] as set out in Article 9 TFEU. This

[5] M. Campagna, *Linee guida per la Telemedicina: considerazioni alla luce dell'emergenza Covid-19*, in *Corti supreme e salute*, no. 3, 2020, 599-618; A. Mazza Laboccetta, *Telemedicina: sfide, problemi, opportunità*, in *Federalismi.it*, no. 22, 2023, 135-182.

[6] H. C. Hofmann and D.U. Galetta, *Evolving AI-based Automation: the Continuing Relevance of Good Administration*, in *European Law Review*, vol. 48, 2023, 617- 635.

[7] See the list of 68 definitions of AI at art. 3 of *AI Act*. On this purpose, L. Cotino Hueso, *What is "Artificial Intelligence" for the regulation? Analysis, delimitation and practical applications*, in D.U. Galetta and L. Cotino Hueso (eds.), *The European Union Artificial Intelligence Act*, Naples, Editoriale Scientifica, 2025, 109.

[8] L. Floridi, *The Ethics of Artificial Intelligence: Principles, Challenges, and Opportunities*, Oxford, Oxford University Press, 2023, 16.

[9] M. Ho - Dac, *The EU AI ACT and the challenge of protecting fundamental rights*, in *Common Market Law Review*, vol. 62, Issue 5, 2025, 1305.

[10] See article 86 AI Act. Cfr., H. Van Kolfschooten, *EU regulation of artificial intelligence: Challenges for patients' rights*, in *Common Market Law Review*, vol. 59, Issue 1, 2022, 81-112.

[11] V. Delhomme, *Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health*, in *The European Journal of Risk Regulation,* no. 11, 2020, 749.

[12] T. Hervey and J. McHale, *Article 35 – The Right to Health Care*, in S. Peers (ed.), *The EU Charter of Fundamental Rights*, Hart, Bloomsbury, 2021, 952.

[13] A.G. Kokott, Conclusions, C-358/14 *Polonia c. EU*

provision represents a cross-cutting constraint that applies to all Union policies and actions.

Turning to Italian legislation, it has regulated the adoption of AI systems, primarily ensuring compliance with the right to health under Article 32 of the Constitution, which is at the same time recognised as both an individual advantage and a collective interest.[14] The latter is defined as the development of various public interests, and it is necessary to consistently provide legal recognition and protection for these interests.[15] Consequently, public administration provides healthcare services to private individuals through material actions that are always governed by the law following administrative procedures obligations.[16] These material actions presuppose the exercise of a duty of power to provide for the public interest, such as health protection. Also, innovation in the healthcare sector affects the performance of administrative duties and the organisation of the National Health Service.[17] In the healthcare sector, which is heavily supported by ICT and AI, it is now more important than ever to adapt general, abstract rules to individual cases. For example, using AI systems, it is also important to understand the extent to which human intelligence is no longer involved in decision-making, and how much administrative discretion is effectively still exercised. Finally, the AI Act is part of the broader strategy for *European data spaces* (EDS), which aims to establish the EU as a leader in a data-driven society grounded on trust among 'public and private organizations and individuals to be confident in allowing their data to be shared in data spaces'.[18] This strategy also encompasses the *EU Health Data Space* Regulation (EHDS) which is due to come into force in March 2027 and covers the primary and secondary use of health data.[19] It also includes the *Digital Governance Act (DGA),*[20] the *Open Data Directive*[21] and the *Data Act.*[22] They are all components of this comprehensive, multifaceted data strategy, as do special legislation dealing with cybersecurity,[23] as is the GDPR.

2. *The Novelties Introduced by the Italian Law on Artificial Intelligence*

The use of AI is inevitably revolutionising and integrating national healthcare services in Member States. It is the case of AI for reading X-rays, mammograms, CT scans, or dermatological images supporting doctors in early diagnosis.[24] AI is not only introducing qualitative improvements in performance that are transforming healthcare practices and organisations into intelligent systems (*i-Health*),[25] but it is also progressively intersecting with different sectorial legislation, such as the Directive 2011/24/EU on cross-border assistance,[26] the GDPR, the MDR and the IDR, towards a '*Europeanisation of health AI*'.[27] Clearly, this process should be observed following two directions: first, in a vertical sense, between institutions and Member

Parliament, ECLI:EU:C:2015:848: 'It should be borne in mind, however, that the protection of human health has considerably greater importance in the value system under EU law than such essentially economic interests (see Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights), with the result that health protection may justify even substantial negative economic consequences for certain economic operators', para 130.

[14] R. Cavallo Perin, *L'interesse delle collettività alla tutela della salute*, in *Diritto amministrativo*, no. 3, 2024, 745-759.

[15] N. Aicardi, *La sanità*, in S. Cassese (ed.), *Trattato di diritto amministrativo* – spec. part, vol. 1, Milan, 2003,627-630; R. Ferrara, *L'ordinamento della sanità*, 3rd ed., Turin, Giappichelli, 2025, 47-48.

[16] G. Corso, *Manuale di diritto amministrativo*, 4th ed., Turin, Giappichelli, 2013, 188.

[17] F. Cimbali, *La governance della sanità digitale*, Padua, Wolters-Kluwer, 2023, 37-53.

[18] J. Reichel, *The European Strategy for Data and Trust in EU Governance. The Case of Access to Publicly Held Data*, in *CERIDAP*, no. 4, 2023, 132.

[19] Regulation (EU) No. 2025/327 on the European Health Data Space.

[20] Regulation (UE) No. 2022/868 (*DGA*).

[21] Directive (UE) 2019/1024 on open data and the re-use of public sector information.

[22] Regulation (EU) No. 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act).

[23] Regulation (EU) No. 2024/2847 (*Cyber Resilience Act*) and Regulation (EU) No. 2025/38 (*Cyber Solidarity Act*).

[24] YA. Fahim, IW. Hasani, S. Kabba and WM. Ragab, *Artificial intelligence in healthcare and medicine: clinical applications, therapeutic advances, and future perspectives*, in *European Journal of Medical Research*, vol. 30, issue 1, 2025, 1-21.

[25] J. Vida Fernandez, *Regulation of Artificial Intelligence in Healthcare within the European Union*, in *European Review of Digital Administration & Law*, vol. 4, issue 1, 2023, 33-48.

[26] Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

[27] H. Van Kolfschooten, *EU regulation of artificial intelligence: Challenges for patients' rights*, in *Common Market Law Review*, cit., 84.

States; and second, in terms of the internal organisation of health services implementing the EU law.

At first glance, it seems that the Italian law has created a complex and centralised governance system involving multiple authorities and extensive executive powers, which slows down the effective implementation of the AI Act and its first pillar, which is the assessment of the level of risk. According to article 7 of Italian law, AI systems in healthcare 'assist in prevention, diagnosis, treatment and therapeutic choice processes, while the final decision always remains with medical professionals'.[28] Nevertheless, there is a need to ensure that medical oversight is always guaranteed, as it has the ultimate authority. Article 8 is also noteworthy as it is dedicated to scientific research and experimentation in the development of AI systems in the healthcare sector.

The secondary use of data shifts the focus of the discussion from the inherent risks of the AI system to the value of the data and the implications of its use, according to article 53 of EHDS.[29] Again, article 8 in particular declares that processing data for scientific research involving AI in the healthcare sector is of 'significant public interest', in compliance with EU Regulation 679/2016 (GDPR) and data protection principles. In fact, the lawful processing of sensitive data (article 9 of GDPR) must comply with the 'principle of minimisation', as well as specific enhanced security measures derived from cyber security obligations. On this purpose, a decree from the Minister of Health, to be issued within 120 days after the entry into force of this law, will govern the processing of personal data. This will be done after consultation with the *Italian Data Protection Authority*, research bodies, health authorities, and other relevant bodies and individuals in the sector. It seems that there is ample room for unnecessary regulatory overlap, which can potentially lead to confusion.[30]

2.1. *The Crucial Role of the Consensus*

From this outlook, consensus plays a crucial role for a human-centred AI. First and foremost, informed consent is needed as to receive treatment, not only as for the understanding of the medical process, but also for exercising the rights of self-determination.[31] Obviously, understanding process becomes more blurred when AI is implied and the consent process is under severe challenge. Scholarship and national legislators have explored different solutions. For example, the Italian approach aims to foster a doctor-patient relationship by recognising the central role of the doctor as the final decision-maker, thereby ensuring that the human remains in the loop. In addition to informed consent affecting issues concerning freedom of treatment- and therefore the self-determination of the individual with regard to therapeutic choices-[32] 'consent to data processing' is equally important. Such processing is closely linked to the specific service provided and, in turn, to health protection as a public interest which also implies the access to treatment on equal terms. Consent on data processing gives rise to other considerations. These are related to the general value of data, its reuse and its relationship with the GDPR. As is well known, recital 10 of the GDPR recognises that Member States have the discretion to maintain or introduce national provisions that further specify the application of the rules set out in the Regulation itself.[33] When exercising these powers, a Member State is permitted to process personal data independently of the data subject's wishes, and conversely, the data subject has no discretion regarding consent, as it is not required for public interest's matter.

The GDPR also allows Member States to specify their own rules, including those relating to the processing of special categories of personal data, such as sensitive data. To this extent, the GDPR does not preclude

[28] Author's translation.
[29] Article 53: *Access to cross-border sources of electronic health data for secondary use*.
[30] G. Gallone, *Intelligenza artificiale. La legge italiana rischia di doppiare le norme unionali*, in *Il Sole 24* ore, 11 November 2025.
[31] E. Wesołowska, *Traveling with or without informed consent?*, in *Corti Supreme e salute*, no. 1, 2024, 532.
[32] T. Balduzzi, D. Morana and F. Morganti, *La salute "intelligente": eHealth, consenso informato e principio di non discriminazione*, in *Federalismi.it,* no. 34, 2022, 128.
[33] '[…] This Regulation also provides a margin of manoeuvre for Member States to specify its rules, including for the processing of special categories of personal data ("sensitive data"). To that extent, this Regulation does not exclude Member State law that sets out the circumstances for specific processing situations, including determining more precisely the conditions under which the processing of personal data is lawful': Recital 10, GDPR.

Member State legislation setting out the circumstances for specific processing situations, including the precise conditions under which the processing of personal data is lawful when exercising an authoritative power, such as in the case of health protection. On the basis of this provision, it follows that the administration may process personal data when exercising its powers of authority, independently of the data subject's wishes. Conversely, the latter has no discretion regarding consent, as it is not required.[34] The same applies to the processing of sensitive data for reasons of substantial public interest, preventive or occupational medicine, or public health (Article 9(g), (h), (i) of GDPR). This has implications in relation to the right to be forgotten (Article 17 of the GDPR) and the right to object to processing (Article 21 of the GDPR). Whenever processing is lawful under Article 6(1)(e), the administration could oppose a request for erasure on the basis of a ground for exclusion under Article 17(3), providing that the condition of lawfulness is met. This is particularly evident in the enforcement of the *Italian Privacy Code*:[35] Article 2-ter (1-bis) of Legislative Decree 196/2003 states that processing is permitted 'if it is necessary for the performance of a task carried out in the public interest or for the exercise of official authority'.[36] Although consent for the processing of health-related data is mandatory, administrations clearly have broad powers to process personal data at all times and in all circumstances while carrying out their duties, thereby overcoming the need for consent.[37]

Actually, this issue presents a conundrum regarding the use of secondary data, as governed by the EHDS. This Regulation is supposed to transform the governance of electronic health data across EU. The process may encounter various obstacles due to the right to opt-out of the processing of personal electronic health data for secondary use (which encompass different purposes from education, statistics to research and policymaking). Anyway, a Member State may establish a mechanism in its national law to make available data for which the right of exclusion has been exercised. In this regard, the EHDS stands as a complement to the GDPR and must be applied in light of a thorough understanding of data protection legislation.[38] Again, not only the GDPR, but also the EHDS include multiple mechanisms for informal and soft loyal cooperation for the institutions and public bodies involved,[39] or private sectors such as assessment bodies, insurance companies and healthcare providers.[40] At a national level, *Health Data Access Bodies* are responsible for receiving and evaluating applications for secondary data access, issuing data permits, supervising secure processing environments and enforcing sector-specific obligations alongside the GDPR.

The first step is to make primary use of health data, as set out in the EHDS. This Regulation enables individuals to access, control and share their electronic health data across borders. It also facilitates the provision of healthcare and requires trust in innovation. As formats for presenting and processing data, as well as digitalisation practices, vary greatly between Member States, this approach implies a significant change in how health data is digitised and how interoperability is correctly applied (under the Commission's control). Additionally, the implementation of the Open Data Directive cannot be ignored.[41]

Against this backdrop, the cross-border

[34] G. Carullo, *Diritto all'oblio e dovere di provvedere delle pubbliche amministrazioni*, in *EUROJUS*, special issue "*Mercato Unico Digitale, dati personali e diritti fondamentali*", 2020, 174.

[35] Legislative Decree no. 196 of 30 June 2003.

[36] S. D'Ancona, *Trattamento e scambio di dati e documenti tra pubbliche amministrazioni, utilizzo delle nuove tecnologie e tutela della riservatezza tra diritto nazionale e diritto europeo*, in *Rivista italiana di diritto pubblico comunitario*, no. 3, 2018, 587-627; G. Carullo, *Dati personali e fini pubblici: dubbi di compatibilità europea del Codice Privacy*, no. 3, 2024, 37-50.

[37] F. Cascini, *L'uso dei dati nel nuovo Regolamento (UE) 2025/327 sullo spazio europeo dei dati sanitari. Finalità primarie e secondarie e loro implicazioni per gli Stati membri*, in F. Trubiani (ed.), S*istemi di intelligenza artificiale in medicina verso lo spazio europeo dei dati sanitari*, Turin, Giappichelli, 2025, 135-148.

[38] C. Di Somma, *European Health Data Space: opportunità e sfide per il riuso dei dati sanitari in ambito di ricerca scientifica*, in F. Trubiani (ed.), S*istemi di intelligenza artificiale in medicina verso lo spazio europeo dei dati sanitari*, cit., 175.

[39] J. Reichel, *The European Strategy for Data and Trust in EU Governance. The Case of Access to Publicly Held Data*, cit., 148.

[40] F. Cascini, *L'uso dei dati nel nuovo Regolamento (UE) 2025/327 sullo spazio europeo dei dati sanitari. Finalità primarie e secondarie e loro implicazioni per gli Stati membri*, cit., 140.

[41] A. Monica, *L'utilizzo degli Open Data per l'effettività dell'azione amministrativa nei procedimenti compositi europei (tra piattaforme digitali, intelligenza artificiale e space economy)*, in *CERIDAP*, no. 2, 2024, 10-32.

nature of health data processing and the resulting multi-level governance structure can make it challenging for data subjects or operators to identify the relevant supervisory body and obtain effective judicial protection in cases where the body fails to impose penalties for breaches of legal obligations. Moreover, even though the cross-border healthcare Directive 2011/24/EU is chiefly concerned with cross-border healthcare as a direct result of the freedom of movement in the EU, the assistance provided is also impacted by changes brought about by AI. For example, the *eHealth Network* set in article 14 a voluntary network connecting national authorities responsible for online healthcare designated by Member States. This network provides non-binding guidance to help Member States establish technical and semantic interoperability in their health information systems, with a view to ensuring secure and efficient cross-border data exchange. On this purpose, Member States could use AI to perform the information function of *National Contact Points* (NCP). NCP are 'valuable intermediary in providing information' and they 'have a strong potential to contribute to realization of EU human rights protection objectives, also those included in the AIA'.[42] Predictive algorithms are used in *Business Intelligence*[43] to analyse and transform raw data into meaningful, operational information for managing organised processes. Therefore, AI tools could also be used to list available treatments and their availability, manage authorisation and access to treatment procedures, and conduct epidemiological surveillance, which is a matter of common cross-border interest.

2.2. *An AI Platform to Support Healthcare Objectives*

As anticipated, national law on AI has provided for the development of a national platform for support services in healthcare, particularly local assistance. The *National Agency for Digital Health Services* (AGENAS),[44] is responsible for designing, implementing and operating this platform, as well as assuming related responsibilities. The law also specifies that the platform is fuelled by data which are strictly necessary for providing predetermined services. In a nutshell, platforms in public administrations can be conceived as architectures with distinctive and classifiable features or, at least, with differentiating characteristics compared to other network makers – among these, the coexistence of components with both stable and dynamic designs – capable, through digital technologies, of generating complex ecosystems. The potential of such platforms is self-evident, as it is set on the effective implementation of the aforementioned principle of interoperability.[45] First, this principle serves to facilitate citizens' access to information, procedures, and services while reducing administrative burdens (including those borne by public administrations themselves). Secondly, interoperability enables the optimal use of data to support evidence-based and informed decision-making both for doctors and for patients. On this path, the concept of government as a platform has evolved beyond an idea.[46] The government has embraced a strategic approach focused on steering and customizing various policies within a new administrative ecosystem centred around interconnected digital platforms and nationally significant infrastructures. These platforms and infrastructures exhibit increasing interdependence and complementarity among products, as well as between public and private services.[47] As far as health is

[42] E. Wesołowska, *Traveling with or without informed consent?*, in *Corti Supreme e salute*, no. 1, 2024, 532.

[43] L. J. Basile, N. Carbonara, R. Pellegrino and U. Panniello, *Business intelligence in the healthcare industry: The utilization of a data-driven approach to support clinical decision making,* in *Technovation*, vol. 120, 2023, 1-11.

[44] AGENAS, is rather playing a dual role as both a technical and operational agency supporting State and Regions (see dal Legislative Decree no. 266, 1993) and as the *National Agency for Digital Health*, is tasked with strengthening the digitalisation of healthcare services and processes (Decree-Law No. 4 of 27 January 2022).

[45] G. Carullo, *L'amministrazione quale piattaforma di servizi digitali*, Naples, Editoriale Scientifica, 2023, 3.

[46] T. O' Reill, *Government as a platform*, in *Innovations: Technology, Governance, Globalization*, 2011, vol. 6, issue 1, 13-40.

[47] A Brown, J. Fishenden, M. Thompson, and W. Venters, *Appraising the impact and role of platform models and Government as a Platform (GaaP) in UK Government public service reform: towards a Platform Assessment Framework (PAF)*, in *Government Information Quarterly*, vol. 34, no. 2, 2017, 167-182; B. Boschetti, *L'amministrazione pubblica nell'era digitale,* in A. Lalli (ed.), *La transizione della pubblica amministrazione verso il modello Government as a platform,* in A. Lalli, (ed.), *L'amministrazione pubblica nell'era digitale,* Turin, Giappichelli, 2022, 1-44.

concerned, the *Italian National Recovery and Resilience Plan* (PNRR) in Italy dedicates a specific mission to healthcare, dividing interventions into strengthening local healthcare services and innovation, the latter of which encompasses AI.[48] It provides specific funding for the application of AI to the reorganization of local healthcare services. The two components, assistance and AI, are not to be interpreted as opposed to each other. For example, different databases are already in operation, but they only record data from healthcare services provided in a specific area or hospital.[49] Therefore, the main challenge facing AI-based healthcare platforms is the slow implementation of such measures and the risk of their excessive proliferation. The Italian Decree No. 73/2024, which aims to reduce waiting times for healthcare services, frequently refers to soft law acts, such as guidelines and recommendations. While these acts should not be underestimated in terms of their practical effectiveness, the Decree itself does not provide regulatory instruments capable of ensuring the consistency of AI assessment mechanisms with these non-binding instruments. It should also be noted that the use of the AI tool on this attendance platform is subject to the National Law on Artificial Intelligence, even though the latter was approved after the aforementioned decree. However, the AI-powered waiting list platform must operate similarly as the support platform set out in Article 10 of the National AI Law. Using multiple platforms to process common and intra-organisational data can lead to delays and hinder the integration, operational efficiency and effectiveness of these tools. AI-powered platforms are, in fact, optimisation support services that assist patients. They must always comply with the general principles of administrative law, including the principle of good administration, as set out in Article 41 of the Charter,[50] as confirmed by the EU Court of Justice in case C-604/12 *H.N*[51] Furthermore, all the shortcomings already highlighted with regard to human rights in the context of the AI Act are relevant here. Lastly, the recent appointment of a commissioner to AGENAS to temporarily replace and oversee the agency's ordinary governance is worth mentioning, as it may slow down and congest its activities.[52]

3. *Concluding Remarks: The Right to Health in the Context of Digital Health Innovations*

As it is well known, the adoption of AI in healthcare is revolutionizing the traditional healthcare assistance both from the side of medical action and from the side of administrative organization. It must necessarily guarantee respect for fundamental human rights, including the fundamental right to health as stated in article 32 of Italian Constitution. This right has a dual nature that cannot be overlooked in today's risk society. It is not only an individual right, but also a right that determines the need to consider healthcare as a matter of public interest, because it affects the community as a whole. This raises issues that must be examined in relation to the most advanced digital technologies, far beyond a mere discussion about algorithm-based decision-making and its implications. Not only that. The fundamental nature of the right supports the thesis of the 'incompressible nature of the right' which refers to a level of protection below which the law cannot fall,[53] even when facing financial constraints and organizational limitations.[54] National Health Service (SSN) in Italy was established in 1978 by Law No. 833/1978. Its guiding principles are still centred on equality, universality and fairness throughout the country, guaranteeing a

[48] The PNRR aims to foster the promotion of research and innovation, technological and digital upgrading, and the strengthening of local healthcare. See, A. Pioggia, L*a sanità nel Piano Nazionale di Ripresa e Resilienza,* in *Giornale di diritto amministrativo*, no. 2, 2022, 165 – 173.

[49] R. Cavallo Perin and C. Jacod (with C. Perrone), *I servizi pubblici con intelligenza artificiale*, in D.U. Galetta and R.C. Perin (eds.), *Il Diritto dell'amministrazione pubblica digitale*, Turin, Giappichelli, 2025, 73.

[50] D.U. Galetta*, Il diritto ad una buona amministrazione nei procedimenti amministrativi oggi (anche alla luce delle discussioni sull'ambito di applicazione dell'art. 41 della Carta dei diritti UE),* in M.C. Pierro (ed.), *Il diritto a una buona amministrazione nei procedimenti tributari*, Milan, Giuffré, 2019, 23.

[51] EU Court of Justice, judgment 8 May 2014, C-604/12, *H.N*, ECLI:EU:C:2014:302, para 49.

[52] The commissioner was appointed by DPCM on 5 August 2025, until 31 December 2025.

[53] As far as the right to health protection is concerned with a 'minimum core' see the Italian Constitutional Court, 16 July 1999, no. 309.

[54] G.M. Napolitano, *Nucleo minimo di un diritto vs Livelli essenziali delle prestazioni: la Corte ritorna sulla questione,* in *Dirittifondamentali*.it, no. 2, 2025, 201-205.

universal service.[55] It is also dedicated to local healthcare, which is understood as a means of linking the democratic principle of care with the concept of community care. The monitoring of LEA is conducted through a dedicated platform known as the *New Guarantee System* (*Nuovo Sistema di garanzia*- NSG),[56] which integrates extensive health data from the *National Health Information System* (*Sistema Informativo Sanitario Nazionale, SISN*). The NSG evaluates and verifies that all citizens have equitable access to healthcare services according to principles of equity, effectiveness, and appropriateness. In this context, predictive AI models can be employed to monitor LEA and support the planning of healthcare services for the population. The medicine of the future, also financed by the PNRR,[57] thus emerges not only from technological evolution but also from clear regulatory choices inspired by shared values. These values are reflected in coherent and equitable organisational models that rely on data. Clearly, in addition to interoperability, data must be user-friendly to facilitate the generation of high-quality native digital data. Enhancing the value of health data within the *EHDS* allows not only the cognitive potential of the data itself to be exploited,[58] but also to compete in the data market. Once again, the pivotal role of public entities operating as part of an open government platform cannot be overstated. Subject to informed consent, data collection thus becomes a means of training models and creating public value. As data are an exchangeable asset, it becomes not only a 'public' good, but also a service that enables the production of other services.[59]

In this context, also innovation plays its part. It is worthwhile to consider the legal basis of the Treaties. Innovation falls within the EU's coordination and support competences only (art. 179 TFEU). The EU coordinates research and technological development activities with its Member States to ensure that their policies are aligned and consistent (art. 180 TFEU). The EU Commission plays a pivotal role in this process, initiating activities such as establishing guidelines and indicators, organising best practice exchanges, and preparing the necessary elements for periodic monitoring and evaluation (art. 181 TFEU). This approach strengthens collaboration between countries, promotes shared objectives and ensures effective oversight without infringing national autonomy, thereby supporting a cohesive and unified research and innovation landscape within the EU. Moreover, the EU Commission assumes a steering role in the effective implementation of the AI Act. It is indeed tasked with detailing and specifying particular aspects of the regulations through implementing measures, as well as updating and renewing them in response to technological and digital innovation.[60]To this end, the *Digital Omnibus Act*[61] has recently been approved with the goal to contribute to the coherent development of the EU's data governance framework. It facilitates interaction between the AI Act, the *European Health Data Space* (EHDS), the *Data Act* and other digital legislation prompting the adoption of harmonised standards and implementation measures alongside the development of these pieces of legislation.

[55] Article 1, Italian Law no. 833, 1978.

[56] The New Guarantee System (NSG), supported by the wealth of information now available on the New Health Information System (NSIS), enables the verification of the fairness, effectiveness and appropriateness of care and services provided to all Italian citizens under the Essential Levels of Care (LEA). See www.salute.gov.it /new/it/tema/livelli-essenziali-di-assistenza/il-nuovo-sistema-di-garanzia-nsg.

[57] S. Battilomo, G. Arbia and N. Salvini, *Potenziamento del FSE e rafforzamento dell'infrastruttura tecnologica e degli strumenti di raccolta, elaborazione e analisi dei dati e simulazione*, in A. Cicchetti and F. Morandi (eds.), *PNRR Missione salute: una missione possibile?*, Turin, Giappichelli, 2022, 73-82.

[58] M. Falcone, *Le potenzialità conoscitive dei dati amministrativi nell'era della "rivoluzione dei dati": il caso delle politiche di eradicazione dell'epatite C*, in *Istituzioni del federalismo*, no. 2, 2017, 421 – 446.

[59] M. Gurstein, *Should "Open Government Data" be a product or a service (and why does it matter)?,* in *Gurstein's Community Informatics*, 03 February 2013, in https://gurstein.wordpress.com/2013/02/03/is-open-government-data-a-product-or-a-service-and-why-does-it-matter.

[60] C. Burelli, *La scelta dell'atto da parte del legislatore dell'UE: il mercato unico digitale alla prova della qualità della legislazione*, in *Federalismi.it*, no. 28, 2025, 34.

[61] Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as regards the simplification of the digital legislative framework, and repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868, and Directive (EU) 2019/1024 (Digital Omnibus)COM(2025) 837 final.

To conclude, the AI Act and its implementation in Member States is essential for enabling the coexistence of anthropocentric AI and ensuring the proper functioning of the internal market while protecting human rights. Despite the complex intersection of field of policies and the level of their implementation, the EU can use its powers more effectively through administrative cooperation. Indeed, cooperation is an instrument for strengthening the administrative capacity of Member States[62] implementing the EU law, inspired and leaded toward the guarantee of the right of good administration (art. 41 CFREU).

Specifically, in terms of national and cross-border healthcare administration, this effort includes information exchange, streamlined procedures based on system interoperability, and personalised care. Again, information and data must be gathered in order to make lawful and legitimate decisions[63] that ensure the promise of accessible preventive healthcare and beneficial medical treatment[64] set out in Article 35 of the CFREU. The aim is to improve healthcare systems and enhance the quality of healthcare for European citizens, as well as fostering innovation.

Against this backdrop, advanced digital cooperation inspired by the EU principle of good administration may be functional to the achievement and the protection of right to health. The attempt is to address the complexity of the regulatory framework the Italian national healthcare system encompasses. This includes the multilevel laws governing the organisation of the SSN and the essential service levels (LEA), not least the risk assessment which follows the use of high-risk AI and digital health governance. Following this path, already the national law on AI can truly be integrated with the ongoing transformation of the SSN fostered by the PNRR, with the final goal to give full protection to the right to health, as defined in Article 32 of the Italian Constitution. Indeed, the significance of the right to health becomes clear once it is considered in terms of both the subjective legal situation of the individual, informed consent and responsibility; as well as the objective dimension of the situation as a whole. Therefore, in the context of digitalised healthcare, concerns currently stem from the implementation of innovative systems that employ AI to take care of individuals and their communities, while protecting fundamental rights and utilising platforms to exploit the cognitive power of owned and exchangeable data.

[62] R. Cavallo Perin and G. M. Racca, *La cooperazione amministrativa: dai gruppi alle reti d'amministrazioni pubblica*, in *CERIDAP*, Special Issue 5, 2025, XXX.
[63] D.U. Galetta, *Public Administration in the Era of Database and Information Exchange Networks: Empowering Administrative Power or Just Better Serving the Citizens?*, in *European Public Law,* vol. 25, no. 2, 2019, 173.
[64] H. Botterill, *Patient mobility, the EU Charter's 'right to health care', and Member State competence: Towards a new role for fundamental rights*, in *Maastricht Journal of European and Comparative Law*, vol. 32, no. 44, 2025,472.