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Oficina C

# Artificial intelligence and health

## Potential and challenges

**Health is one of the areas where a significant contribution of artificial intelligence (AI) is expected, with implications for the cost, quality and efficiency of medical attention, including preparation and response capacities for health emergencies. Nevertheless, there are major challenges related to security, privacy and access to data, and the generation of inequalities. Legislation, regulation, evaluation and human supervision are key elements to facilitate its implementation in professional practice.**

Professional and social expectations worldwide see the potential of AI to produce a qualitative leap in healthcare. This is particularly the case for the diagnosis and treatment of patients, clinical management tasks and logistics, or in different aspects of public health.

The current clinical use and implementation of AI in prevention and healthcare on a global scale is severely limited due to social, technical and regulatory challenges.

In the clinical context, developments focus principally on support for healthcare professionals and respect for the autonomy of people, rather than seeking automation without human supervision. AI can also directly contribute to the self-care of people.

The development of new applications and their subsequent adoption by professionals requires collaboration between diverse sectors: research, industry, hospitals, the healthcare sector, regulation, assessment and legislation.

The availability of quality data is essential to develop AI applications. Despite the high degree of digitalisation of the health system in Spain, medical data are underused in R&D&i. The proposal for a European Health Data Space seeks to facilitate the use of this information.

The European Union fosters an ethical development of AI that benefits citizens and respects their rights. The latest proposals for European regulations on AI establish that high or limited risk applications must meet a series of requirements before and after entering the market.

## Production method

C Reports are brief documents on subjects chosen by the Bureau of the Congress of Deputies that contextualise and summarise the available scientific evidence on the analysed subject. They also inform about areas of agreement, disagreement, unknowns, and ongoing discussions. The reports are drafted based on an in-depth review of the literature, supplemented by interviews with experts on the subject and a two-round review process.

To produce this report the C Office referenced 270 documents and consulted 30 experts in the subject. Of this multi-disciplinary group, 50% belong to the field of life sciences (medicine, bioinformatics, biomedical engineering, health regulation and evaluation, and ecology), 26% come from physics and engineering sciences (informatics engineering, natural language processing, electronic engineering and robotics engineering) and 19% from social sciences and humanities (behavioural sciences, ethics, philosophy and law); 87% work in Spanish institutions or centres, whereas 13 % have affiliations abroad.

Oficina C is responsible for the publication of this report.

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*Graphical abstract*

## Introduction

Artificial intelligence (AI) is a science and a group of analytic and information science technologies that can achieve complex objectives based on information[1] (**Key point 1**). Although this field has existed since the end of the 1950s[2–4], new techniques, large volumes of data and high-capacity computing have brought about the disruptive innovation experienced in recent years[5–7]. The current interest in the application of AI is due to its capacity to perform particularly complex tasks on a large scale in a more efficient way than human intelligence; particularly: visual perception[8–10], processing spoken and written language[11–14] or physical interaction with the environment[15,16]. Nowadays, Health and medicine is one of the fields where the greatest impact is foreseen[5,17]. At the national level, the Digital Spain 2025 strategy[18], Digital Health Strategy[19], the Artificial Intelligence National Strategy (ENIA)[20] and the Spanish R&D&i Strategy in Artificial Intelligence[21] cover different aspects of the development of artificial intelligence in the field of health, among other subjects. The Strategic Projects for Recovery and Transformation (known as PERTE in Spanish) in Vanguard Health[22] and New Economics of Language[23] also cover developments in this field. At a European level, there are noteworthy initiatives and programmes like the Digital Europe Programme[24] or the EU4Health programme 2021-2027[25].

**Key point 1. What is artificial intelligence (AI)?**

**Objectives of using AI.** The original intention[2,3] was to achieve a general artificial intelligence, similar to or even greater than human intelligence: artificial superintelligence. As this proved too complex a task, most of the scientific effort in this field turned its focus on the development of specific artificial intelligence, which would be highly efficient in performing a single task under strictly controlled conditions, for instance, playing chess. The many techniques and focuses employed for widely varying purposes mean that defining AI is particularly difficult[1].

**Definition of AI.** The European Union has an umbrella definition as a basis for developing new regulations[26]. This defines the objective of AI as making recommendations or taking specific decisions that can directly influence the environment with which it interacts. This definition includes most sub-disciplines: from statistical methods and logic coding of knowledge to what is currently the most disruptive area, machine learning.

**Machine learning.** A sub-discipline of AI in which a programme “learns” based on experience (from databases or physical sensors). Such learning can be maintained over time as new experience is acquired[27] and enables the extraction of new patterns and information not previously known. There is a broad diversity of learning variants for different tasks and specific functions[28].

**Deep learning.** It is a variant of machine learning which uses multilevel neural networks. In a neural network, each neuron performs an operation and, when it connects with millions of other neurons with multiple processing layers and abstraction it forms a deep network[29,30], which can detect the characteristics of data by itself. In the field of medicine, this began to work well ten years ago with medical imaging, and this is the technique currently causing the greatest disruption[31]. It has also brought major advances in the modelling, use and digital processing of human language[32–34].

Professional and social expectations worldwide see the potential of AI to produce a qualitative leap in healthcare[35]. Among other possibilities is the potential to contribute to reducing the variability of healthcare between regions or countries[36–38], or improving the capacity to anticipate and prepare for health emergencies[39]. The development of new applications and their subsequent professional adaptation require collaboration between diverse sectors: research, industry, hospitals, the healthcare sector, regulation, assessment and legislation[5]. Despite the current worldwide momentum in this area and the existence of some successful projects, the deployment of these tools in healthcare and medicine is not widespread[5,17,40,41]. Nowadays, the complex technical, ethical, social and regulatory challenges necessary to achieve trustworthy AI are being resolved, both within Spain[20] and in the EU[42,43]. Finally, the availability of quality, interoperable data is essential to develop specific AI applications. The European Commission has highlighted the value of sensitive health data[44] and estimates that its re-use for R&D&i may amount to an economic value of some 25 to 30 billion euros per year[44]. Nevertheless, this potential is still underused in Europe.

## The potential of technologies with AI in healthcare

Among its benefits, AI can reduce the cost of some procedures while increasing their efficiency[9,45]. A 2017 report considered that including AI to combat diseases and conditions on the increase (specifically childhood obesity, breast cancer and dementia) could mean annual savings in Europe of 17,200 million euros[46]. Additionally, some degree of automation saves time, allowing healthcare professionals to devote more quality time to their patients[5].

According to a European-wide survey[47], current developments focus on tools for diagnosis (21%), self-care, early prevention and monitoring (14%) or as support systems for clinical decision-making (18%). But the focus of research covers more aspects of its potential use: AI can achieve major advances in biomedical and clinical research[17,48] and rare diseases[10,49], serve as support during surgical interventions in real time[50], predict a patient's clinical outcome[51,52] or expedite management of logistics and administrative tasks[53-55]. Likewise, it can contribute to decision-making in public health and in preparation and response to health emergencies (**Key point 2**). However, most of the applications described in the scientific literature have not been validated in a real-life clinical setting[53,56].

In addition, most of the development and introduction of this technology occurs outside Spain, with the USA and China at the forefront of knowledge transfer and investment in AI-based start-ups[45,47]. Some consortia and business associations highlight difficulties and delays in getting medical and healthcare products and devices on the market, in general due to the differences in interpretation of European regulations by member states, the complexity of reimbursement and acquisition[58], or a lack of speed in authorisations[59]. The objective of AI in the field of healthcare is to function as support for the worker, rather than generating automation without human supervision[53,60]. The following sections discuss applications that are at different stages of research and implementation. The focus is on applications that are closest to use in the short-term in real-life clinical practice, or ones with the greatest potential in healthcare.

**Support in prevention, self-care and wellness.** AI can quickly examine a large number of patients at a very low cost[41]. This helps in early risk prediction, for instance, in heart function[61,62] or in the diagnosis of tumours[63], lung cancer[64], skin cancer[65] or dangerous eye lesions[66-70]. Such early detection of different types of cancer is related with a better prognosis 71. On the one hand, some AI applications can be used directly by the patient. In this area, AI-based **digital assistants** have proved to be a useful aid to help improve the self-care of people who require follow-up[53], such as type 2 diabetes patients[72,73].

Digital assistant: a programme that undertakes tasks or provides a service to an individual based on guidelines or questions. A chatbot is an example of a conversation-based digital or virtual assistant.

**Diagnostic support.** In the USA, estimates suggest that one in twenty adults has suffered a diagnostic error[74], which would be avoidable with the help of AI[17]. Moreover, it has been shown that for different types of cancer it can enable more exact, quicker assessments[75-77], for instance, in breast[78,79], colorectal[80-82], or skin cancer[83]. Likewise, in the field of mental health, some studies have been able to predict the appearance of psychotic episodes based on language, with a reliability up to 93% under laboratory conditions[84,85]. Despite these successful examples, several studies indicate the difficulty of introducing AI-based diagnostic tools in real-life clinical practice. The appearance of COVID-19 spurred the search for diagnostic support tools in imaging. However, a systematic review of 62 methods (from 2212 scientific articles) showed that none were reproducible in a clinical setting, due to methodological shortfalls or data bias at origin[86].

Natural language processing (NLP): a type of AI that enables spoken or written human language to be automatically interpreted and/or generated by a computer.

**Logistic support. Natural language processing (NLP) technology**[87] enables simplification and a reduction in the length of medical texts. So, a long report with dozens of pages can be transformed into a brief synthesis, adapted so that non-specialists can understand it[88-91]. AI can also compose parts of medical discharge reports[92], or tag and generate radiology reports[93,94], freeing up the time of healthcare professionals. It can also automatically enrich **clinical terminology** databases and add knowledge to the most commonly used medical information systems 95. Initiatives are underway to optimise hospital management of resources and medical personnel in emergency situations that may occur in an emergency service 55. It has been shown that AI tools would help guarantee equity and a better quality of healthcare, reducing patient waiting times or improving response in situations of overload during waves of COVID-19[96,97].

Clinical terminology: a set of specific terms related with medical practice and based on healthcare provision for patients.One used in Spain is SNOMED-CT, a terminology that enables the input of standardised clinical information associated with codes.

**Therapeutic support.** AI plays an important role in developming and applying **personalised precision medicine**[22,98], with models tailored to each personal profile[99]. A study evaluating the use and dosage of different treatments found that patient mortality was lower when the procedure used coincided with the recommendations of an AI-based assistant[100]. Devices that use AI can also be prescribed in the same way as medication, in what is known as digital therapeutics[101,102]. AI can also be included in robots, where data arrives via sensors (from intelligent visual perception or spatial perception), resulting in direct physical interactions of the device with the patient's environment or the healthcare professional or assistants[103,104]. Finally, another tool that will be used in the future is digital twins: computer models of organs or even an entire person[105] that, among other functions, will enable simulation of response to treatment before it is administered[105]. This line of research has already received funding under the programme R&D Missions in AI, managed by the State Secretariat for Digitalization and Artificial Intelligence (SEDIA)[106].

Personalised precision medicine: personalised medical attention with decisions and treatments specifically tailored for each individual.

Digital therapeutics: programmes or devices that provide evidence-based medical intervention, prescribed and regulated in a similar way to medication.

**Drug discovery.** Finding new drugs and bioactive compounds has benefited from AI tools 107 and key advances like the understanding of the structure of proteins[108,109]. It is also possible to infer new properties of medicines using the scientific literature and applying natural language processing 110,111.

**Key point 2. Artificial intelligence in public health.**

Around 60% of deaths worldwide are due to a cause associated with the socio-economic and environmental context in which people live[112]. It is currently possible to assess these contexts and measure the associated risks by using information from social networks[113], meteorological agencies[114], citizen science[115], personal devices for health monitoring (wearable technologies)[116], or smartphones[117,118]. This work falls within the field of public health: the set of activities organised by public administrations, with the participation of society, to prevent illness and protect, promote and recover individual and collective health[119]. Among other actions, this includes monitoring risks that might have an impact on the health of the general public[120]. In this context, monitoring and managing epidemics and pandemics can potentially benefit from the use of artificial intelligence tools[117, 121].

**COVID-19.** During the COVID-19 pandemic, researchers around the world generated a multitude of tools based on AI capable of detecting outbreaks[122], automatically checking symptoms[123], predicting the number of cases[124] and tracing contacts[125]. These applications used data from collaborating citizens[126] and smartphones[117]. Although major limitations were found, future applications that use data from multiple sources could provide an adequate approximation to avoid both individual risk and the appearance of new outbreaks[117].

**Mosquito-borne diseases.** In Spain, there is a potential risk of the proliferation of tropical diseases transmitted by mosquitoes (dengue, yellow fever, White Nile virus, Zika or Chikungunya). Recent decades have seen larger and smaller outbreaks at different points in Spain[127–129]. Currently, the use of images collected with collaboration of the general public, provides important support data for monitoring, risk assessment, management and control of mosquitoes in cities[130]. The combination of this model with artificial intelligence[39,115] has the potential to expedite monitoring and cover larger geographical areas, both in Spain and internationally[39,127,131].

**Mental health and social networks.** Using sentiment analysis, language processing can detect behaviour patterns on social networks. Hence, AI can contribute to the prevention of cyberbullying, hate speech[132] or suicide, and detect anxiety or depression[133]. The use of smartphone data is also being considered to avoid suicide and assess emotional states[134,135].

**Links to precision medicine.** The social and environmental information traditionally associated with public health[118,136,137] could eventually contribute to precision medicine[136]. In the same way that genomics is used to perform highly tailored adjustments for each personal profile, it is also possible to identify specific environmental determinants for health and disease[138]. Work is also underway to predict clinical outcomes based on information obtained from personal devices[139].

## Towards implementation in healthcare

Despite a growing interest and research into AI applications in healthcare, even with the pilot projects undertaken by certain hospitals, there is no generalised transfer of this technology for use in clinical practice[140–143] due to a series of challenges[144,145]. The following section details the requirements necessary to achieve reliable, trustworthy AI[42,145–147], the challenge involved in the need for large amounts of quality health data[148,149], protection of patient privacy[150], and the need to create new frameworks for regulations and professional transformation[47,53,151]. The Artificial Intelligence National Strategy (ENIA, in Spanish), published in 2020[20], aims to tackle these challenges in Spain and to enable the development of inclusive, sustainable AI for all sectors that focuses on citizens.

### Achieving trustworthy AI

Reliability or trustworthiness is a prerequisite if people and societies are to develop, implement and use AI systems[145,152]. If this were not the case, undesirable consequences might arise that prevent its adoption or generate a perception of insecurity, discouraging its use[142,153]. According to recent studies, the attitude of society to the arrival of AI in medical practice is generally positive. Still, this research also indicates that there are different concerns and human supervision is preferable to full automation[154,155]. The following section provides details of some requirements necessary to achieve greater trust in AI in the healthcare sector.

Clinical prediction and decision-making: clinical prediction models are tools that allow the estimation of risk or the probability of having or developing a disease. They contribute to clinical decision-making.

**Human action and supervision.** Recommendations indicate that healthcare AI systems should support the autonomy and decision-making of people[42,53]. In particular, autonomous **clinical prediction and decision-making** could imply a risk for people unless there is human supervision[53]. In this context, some research has provided healthcare professionals with AI applications to monitor whether there is an improvement in the diagnostic process[156]. Among their conclusions, studies found that risks related to human error decrease[53] because a machine can automatically detect problems that a tired worker, for instance, might overlook[5, 53]. However, other research indicates that an excess of trust in an automated system can also lead to inappropriate decision-making[153].

**Safety and efficacy.** Tools based on AI should generate fair, robust, trustworthy predictions in the real-world clinical setting[157]. Nevertheless, much of the initial research worldwide has been conducted outside the clinical setting, from a technical perspective[153,158,159], with the available data, which may be limited, biased or not high quality[148,149, 158]. This makes it difficult to assess many of the imperfections and its effectiveness in real-life clinical practice[153]. Premature deployment of such systems may result in pressure on the health system, diagnostic error or stress for patients[142,153,158]. In order to prevent this scenario and accelerate the transfer of research to clinical practice, some scientific publications recommend considering ethical implications throughout the entire process of development, evaluation and implementation[160].

**Explainability.** Multiple reports highlight the importance of being able to explain AI-supported decisions when they have an impact on the lives of individuals[145,161], which often occurs in healthcare. This quality also means that an AI system can be audited in the case of legal requirements, errors or if harm has been caused[145]. However, there are times when it is not easy to explain how an outcome has been reached using algorithms, particularly those based on deep learning[29]. A currently active line of research is the creation of explainable models[162-164]. Nevertheless, some specialists cast doubt on explainability guaranteeing confidence in AI systems and support the idea of reinforcing the safety and efficacy of the systems[164,165].

**Avoiding the risk of discrimination and inequalities.** The risk of social discrimination exists for two reasons: the use of databases that do not equally represent specific groups of people[166], or due to decisions taken during the development and implementation of algorithms by the developers[167]. A development that does not consider diversity criteria results in devices that exacerbate the bias and discrimination already existing in society, such as prejudice related to racial origin[168,169], socio-economic situation[169,170], region of residence[171] or gender[167,172]. Experts indicate that this issue is particularly important in healthcare AI, since in this sector worldwide there are very few teams of developers headed by women[173]. Algorithmic bias produces more diagnostic errors for the discriminated groups 174 and may create a digital divide in healthcare[166]. To mitigate the risk, bias should be considered from the moment of technological development and throughout the processes of regulation and legislation[146], as should social context 175. For cases where it is difficult to achieve representative data, there is research underway that uses a focus with a smaller amount of data 176-178 or synthetic data (built using computer-based methods) [179-180].

**Minimising the risk of cyberattacks**. The increasing digitalisation of the health system opens the door to new vulnerabilities and an increase in cyberattacks[150,181,182]. Working environments that guarantee cybersecurity are a current area of research, although the European Commission affirms that there is still a long road ahead before achieving the cybersafe implementation of AI[44]. In addition to general vulnerabilities, applications based on AI in healthcare have specific ones[183]; for instance, in medical imaging analysis, a malicious alteration of pixels could lead an algorithm to reach completely erroneous conclusions about a patient[184,185]. Some attacks of this nature are easily detected with warning systems[186].

**Legal changes to civil liability.** Law is an area where AI has great impact[187-190]. The European Commission Expert Group on Liability and New Technologies concludes that, due to the characteristics of AI systems[191], it could be more difficult to decide damages for victims. Another hurdle could be the identification of the liable party and attribution of liability, which could be unjust or inefficient. To rectify this, the group argues for the need to make changes in civil liability legislation and regulations in the European Union and in member states[192]. The European Commission has prepared two initiatives to reform the Directive on Defective Products to include the particulars of smart products and products with AI systems (robot assistants, surgical robots, etc.) and propose common liability regulations in the case of harm caused by AI systems[193,194].

## Management and governance of health data

For AI-based systems to generate reliable results, large, high-quality databases are necessary at an initial training phase, as are validation of models and obtaining knowledge. Data can be obtained from images (radiological, dermatological, etc.) text (medical reports), genomics or other type of information, like social surroundings or the environment[195]. Improving management and governance is one requisite to expedite R&D&i and its implementation by the research, technology and business sectors. With this objective, progress should advance towards a greater availability, accessibility and **interoperability** of health data[44,196], while respecting the General Data Protection Regulation (GDPR)[197].

Interoperability: capacity of information systems and of the procedures they support to share data and enable the interchange of information and knowledge.

**Quantity and quality of data as the basis for trustworthy AI.** A European Commission study indicates that there is a loss of health efficiency in Spain and in Europe derived from a lack of interoperability, **standardisation** and semantics, or difficulties to access, interchange and analyse big data[198,199]. Among other difficulties, this complicates the reuse of data in R&D&i, which forms part of the Digital Health Strategy[19]. For data to be accessible and usable by a machine learning algorithm, they must be stored in a standard way[28,200]. Despite the high degree of digitalisation in Spain[198] and Spanish public sector initiatives to standardise the data of digital medical records[198,201] image repositories[202], genome biobanks[202] and cancer registries[203] health information is still underused in R&D&i[44,199]. However, it is essential for the development of personalised precision medicine[98]. The application of **FAIR principles**[200,204,205] alongside the knowledge and tools already available could facilitate the use of data for R&D&i in AI. It should be noted that databases with errors or incomplete data may lead to imprecise or erroneous indications[206].

Standardisation: the process of making, applying and improving different regulations to impose order on a specific activity.

FAIR principles: the FAIR principles are precise, measurable qualities for data publication. The acronym stands for findability, accessibility, interoperability, and reusability.

**Understanding the languages used by the population.** Approximately 40% of work in AI uses human language as its basis[207], and many healthcare applications could use the information contained in digital medical records[201]. However, much of this data is in unstructured text format that cannot be easily analysed (general calculations estimate this could be as much as 80%)[32]. For this data to be transformed into useful information requires l**inguistic resources** specific to healthcare, in the languages spoken by the target population[32]. Although Spanish is the second most spoken language in the world and holds fifth place in the number of scientific publications, English remains the dominant language of technical developments[208]. In Spain there is a movement to boost AI in Spanish, which is the aim of the MarIA project[23,34]. There are other initiatives with the same objectives in Spain's other co-official languages. AINA in Catalan[209-211], Nós in Galician[212] or the GAITU plan in Basque[213]. The PERTE of the New Economics of Language, which

Linguistic resources: datasets and their descriptors in electronic format to construct natural language processing systems and applications for specific areas (such as health). In simple terms, these resources are corpora of annotated and non-annotated texts (the words have tags with additional information), lexicons (ordered series of words), dictionaries or ontologies (relations between words).

continues the work undertaken in 2015's Promotion of Language Technologies Plan (Plan de Impulso de Las Tecnologías del Lenguaje), promotes the development of AI in the official languages in specific areas such as health, and also encourages pan-hispanism: progress in conjunction with the Spanish-speaking countries of the Americas and reinforcement of the use of Spanish in the digital world[23].

**Privacy and access.** In Europe and Spain, access to sensitive data about patients for R&D&i[150] must guarantee compliance with current regulations on privacy and data protection (GDPR)[214,215]. Health data protection is a legal requirement[215], which makes it important to consider privacy by design and by default when working with big data[216]. Nevertheless, implementation of the GDPR in the area of health is complex and would benefit from specific ethical, legal and operational guidelines when the data are for use in AI[217]. Specifically, at a technical level, to avoid **data re-identification**[218]. A specialist group report[47,217] recommends employing pseudonymisation[219], **encryption**, or **differential privacy**[220]. On the other hand, to conduct clinical trials based on real-world evidence it is necessary to decode the information in electronic health records. In this task, AI techniques can help hide personal or sensitive information[221].

**Interoperability.** Refers to the capacity of interchanging and using data from different sources in a simple, automated way. In Spain and in Europe, the use of medical information for R&D&i in AI has been hampered by unequal interoperability and by regional fragmentation[42,222]. In recent years, the healthcare and research communities have sought to reduce the heterogeneity of information by means of standardising knowledge in clinical terminology[223,224], and by aligning the formats and information contained in electronic health records[225,226]. In Spain, the current Digital Health Strategy includes the goal of having quality interoperable data at national and international levels 19. The Data Office (Oficina del Dato)[18,227], has participated in setting up the creation of a National Health **Data Space** to generate scientific knowledge[19,228]. This strategy is complementary to and forms part of the European proposal that follows[44,229].

**The European Health Data Space (EHDS).** The proposal of an EHDS seeks to improve healthcare and accelerate research in health. Among its objectives is facilitating access to sensitive health data to public and private R&D&i agents for the development of AI[44,229]. The governance, regulations, standard practices and infrastructures included cover the possibility of efficiently sharing health data. This regulation has its foundations in the NIS cybersecurity directive[230], the General Data Protection Regulation (GDPR)[219] and FAIR principles[204,205]. With the application of the Data Act, which the EHDS is also based on, the European Commission estimates savings of 120,00 million euros in the EU healthcare sector each year[231,232]. A pilot programme is scheduled for 2022 in which all European Union member countries must participate[44]. In Spain, actors related with ehealth have favourably received this proposal[58]. A national scale project, IMPaCT, is building the technical foundations to use health information in precision medicine and will be responsible for implementing EHDS recommendations in research[202]. Likewise, although at a much earlier stage, proposals exist for a European Language Data Space, aimed at compiling, creating and reusing language data for all industries, including healthcare[223].

**Machine learning adapted to the governance of health data.** AI can use the data stored in different infrastructures through **federated learning**[234,235], or its evolution, **swarm learning**[236]. Swarm learning, in particular, minimises the problems associated with privacy[220] and cybersecurity[237-239] by means of data **pseudonymisation** and encryption. The European Health Data Space will be a decentralised system with the potential for use by these types of AI[44].

**Data re-identification:** or de-anonymisation, is analysing anonymised data to discover the individual to whom data belong.

**Encryption:** representation of information in such a way that only authorised parties can decode it.

**Differential privacy:** system that enables the collection and analysis of data without compromising the identity and privacy of the data providers. Adding randomness to the data can make the relationship between the individual and the dataset less clear.

**Data space:** an ecosystem in which diverse independent actors safely and voluntarily give access to their data following common mechanisms of governance, organisation, regulations and techniques. This may be created at regional, national or international level. Adding randomness to the data can make the relationship between the individual and the dataset less clear.

**Pseudonymisation:** the process by which data is generated that cannot be attributed to a party without the use of additional personal information that must figure separately. This is different from data anonymisation, in which no personal information of any type exists.

**Federated learning:** a type of decentralised machine learning that works, for instance, in a data space. It has the advantage of not requiring data interchange or transfer, thus reducing privacy and security risks.

**Swarm learning:** a type of machine learning that builds models independently in a private data network. Its main advantages are its compatibility with cyber-secure technologies and guarantees of sovereignty, security and privacy.

### Regulatory framework

European regulation 2017/745 determines whether a tool is a medical device, and therefore, whether it is subject to having to obtain the CE mark (Conformité Européenne, in French) necessary for its sale within the European space[240]. In Spain, this certification is awarded by the Spanish Certification Agency of Medicines and Medical Products (Centro Nacional de Certificación de Productos Sanitarios - AEMPS). Current regulations on AI deal with software in a generalist way and do not contemplate all its particularities. This means that during the certification process the continuous learning capacity of some applications must be limited and only static models that have stopped learning can be approved, above all if the data is related to its use in a real-life clinical setting[241]. In consideration of the characteristics of these types of tools, in 2021 the European Commission made a proposal for the regulation of artificial intelligence (the AI Act)[242], which defines the European standards for the development, marketing and use of AI-based products in all industries throughout the European Union. It proposes a risk-based analysis, in which the uses or applications classified as high or limited risk have to meet a series of requirements related to security, efficacy and robustness before and after going on the market. Once on the market, these tools should have monitoring systems to ensure their application remains trustworthy[242]. The AI Act contemplates the designation of a competent national authority to supervise the application and implementation of market regulation and monitoring[242].

Regulatory sandbox: a safe space to test new regulatory processes. The concept comes from the financial sector, although it has expanded to other fields.

Although still at the planning stage, in 2022, Spain is promoting the creation of a Spanish Agency for Supervision of Artificial Intelligence (Agencia Española de Supervisión de Inteligencia Artificial - AESIA)[243]. Spain is also a pioneer in the creation of a **regulatory sandbox** for AI, which will enable the testing of technical and regulatory solutions related to the AI Act in a controlled environment[244,245].

Acquiring certification is an indispensable requirement to put a medical device on the market. However, for a device or product to be considered for inclusion in the Common Services Portfolio of the Spanish National Health System, like any other medical and healthcare device, those that include AI must be evaluated for its use in clinical practice[246]. Deployment of the current European regulations for health technology assessment will consider dimensions for assessment applicable to all countries in the European Union[247], and member states will be able to add any other dimensions they consider pertinent. In Spain, this assessment is made by the Health Technology Assessment Network (known as RedETS)[248], whose current manual relates to the general dimensions of health technologies: the health problem it is aimed at, a description of the technology, its safety, efficacy, effectiveness and cost-effectiveness[249]. RedETS has prepared a new framework for evaluation that includes the particularities of AI in a real-world clinical setting[250]. Among others, it includes the need to compare the performance of healthcare workers with and without the support of AI, since many tools are intended for use with, not substitution of, personnel[148,251,252].

### A new digitised healthcare professional environment

In Spain, 71% of the population believes that AI and automation will cause job loss in different industries[253] and, indeed, in the mid-term and only for certain applications, some studies suggest that professionals trained in digital health competence to use AI could replace those who are not[254]. A survey of 233 radiologists in Spain showed that there is a demand for training in artificial intelligence, computing and new technologies in medicine, and that this should be included in their medical specialisation[151]. Studies indicate that professional groups should be familiar with the limitations and strengths of a deep learning-based system, and therefore training syllabi should be updated[255]. Training is included as a priority in the Vanguard Health PERTE, and includes actions related with training in digital competencies[22] as well as specific postgraduate programmes in public administration and governance[256]. These new skills are essential to promote better cooperation between scientific data personnel and medical staff to obtain correct data and the successful development of applications[257]. This is also true for an integration in real-life clinical practice that includes security risk assessment[8,258]. In coming years, new specialist professions are expected to arise based on digitalisation and on the arrival of AI in the healthcare sector, and likewise AI will have an impact on the way we work and our cognitive skills[183,259]. The incorporation of these technologies should be associated with a cultural change and the evaluation of their acceptability for patients and healthcare professionals[260,261].

## AI in the social context of the future

Despite the fact that AI has the potential to contribute to improving health in tomorrow's societies[262], not all countries are committed to it in the same way. According to the AI Index[263], which evaluates the development of this technology in an international context for all sectors, the USA, China and the United Kingdom are the countries that predominate in international collaborations. In our context, France has made enormous advances, with[242] AI businesses set up between 2013 and 2021. Spain leads the EU ranking for mentions of AI in legislative procedures in the year 2021[263].

One of the social challenges faced by Spain is based on official demographic projections[264,265]. It is estimated that the population over the age of 64 in Spain will have increased by up to 5 million people by the year 2035 and could be double in 2050[266] with the consequent increase in healthcare pressure associated with old age and chronic disease. AI-based applications, both software and physical supports, are capable of performing tasks very efficiently and could therefore contribute to covering this demand[267]. In radiology, for instance, it would help to interpret a high volume of images, minimising the fatigue of professionals and the associated error[268]. In direct care, healthcare workers (nurses, auxiliary staff, carers) and older people could have the support of robotics to improve their autonomy and quality of life[15,262, 269,270]. Japan, whose demographic projections are similar to those of Spain, is making large investments in assistive robotics, support robotics and the automation of small tasks[16]. All of this has the potential to free up time for the corresponding professional groups 5. In Spain, therefore, there is a growing interest in AI-based technologies as they can contribute to sustaining the future healthcare of citizens[19,267].

similar a la española, se están invirtiendo grandes cantidades de dinero en robótica asistencial, de apoyo, y para la automatización de pequeñas tareas[16]. Todo ello con el potencial de dar más tiempo útil al colectivo profesional correspondiente[5]. En España, por tanto, el interés es creciente y radica en que las tecnologías basadas en IA pueden contribuir a sostener la salud de los ciudadanos en el futuro[19,267].

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