Artificial Intelligence Strategy for the National Health System.

eIASNS

General Secretariat for Digital Health, Information and Innovation of the National Health System

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GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD
Estrategia de Salud Digital
Plan de Recuperación, Transformación y Resiliencia
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The challenges that the National Health System must address in the coming years (population ageing, chronicity, population mobility and its impact on global health, sustainability, multichannel care) require a change in the healthcare model, in which digital tools and therapies support the transformation process of the SNS to become "a dynamic system that learns".

The presence of Artificial Intelligence solutions in the health sector is growing, and the possibilities it offers to facilitate doctor-patient communication, optimise the professionals' time, involve people in their own health and eliminate management bureaucracy, is undeniable. Therefore, the implementation of this technology must be executed in a coordinated manner between the Autonomous Communities and the Ministry, each from their areas of competence, and within the framework of the Digital Health Strategy, with the aim that its availability is equitable and follows common and consensual criteria among all.

We are aware that AI must be adopted in compliance with current regulations, which in certain aspects are complex and whose details are still being defined by the EU, ensuring ethical, transparent, reliable and safe use.

The Artificial Intelligence Strategy – eIASNS*, establishes a defined and agreed scenario* in the Digital Health Commission within the IASNS program approved in July 2024, to establish AI governance in the SNS, the knowledge of the available solutions, the acquisition of the necessary skills for its development, management and deployment, and the development of use cases that are of interest to health services, with the collaborative model of shared leadership that has allowed us to execute different joint action plans in digital health since December 2021.

It is undoubtedly an opportunity to improve the health of our patients, reinforce and support our professionals and strengthen the capacities of our beloved SNS.

Mr. Juan Fernando Muñoz

Secretary General for Digital Health, Information and Innovation of the National Health System

Ministry of Health

GOBIERNO DE ESPAÑA
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"Quality in care, equity in access, trust in results: the foundations of the AI Strategy for the National Health System."

Promises

Realities

Challenges and risks

The time of AI in healthcare

The expectations offered by the application of Artificial Intelligence are promising, and some have already become realities, accompanied by challenges and risks involved in its use in the most delicate of scenarios, the care of our health.

In recent years, not only has the volume and intensity of these expectations increased, but algorithms and real use cases have been appearing where Artificial Intelligence supports healthcare professionals in health services around the world, and also in our National Health System.

Maybe we are in the time of AI.

1

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The **first system based on artificial intelligence** designed for medical use dates back to 1970. **MYCIN**[1], created at **Stanford University** for the **diagnosis** of bacterial infections and the generation of antibiotic treatment **recommendations** .

This innovative development for the time was based on two essential components: the **existing knowledge base**, generated by the diagnostic rules validated by a reduced group of infectious disease experts, and an **inference engine** that applied these rules to deduce appropriate diagnoses and treatments.

This structure, which allowed the system to **emulate a specialist's reasoning** with remarkable precision, was never used in healthcare practice although its **accuracy in recommendations was higher than the average** of expert doctors.

Despite this system's proven accuracy, a number of factors ruled out the use of MYCIN in **patient diagnosis:**

- **Legal concerns** about its use
- Arising with regard to the **responsibility** of the decisions
- **Lack of acceptance** by clinicians
- **Limited** explicability of results

Today, **55 years after MYCIN**, the **evolution** of systems' **computing** capabilities, the **availability** of large volumes of **data**, recent **advances in deep learning models** and **innovations in generative models** that create content autonomously, have placed **Artificial Intelligence applied to healthcare** in the priority focus **of investments by governments and companies**.
This advance in **technological capabilities** and the **prioritisation of AI in the budgets** of healthcare organisations, envision the beginning of a significant transformation in the prevention, diagnosis and treatment of patients. AI solutions will allow the **adaptation of the treatment to the individual characteristics of each patient,** leaving behind the traditional 'one-size-fits-all' and advancing in **personalised medicine**, adapted to each patient, which will allow significantly increasing the success in decision making throughout the **care process.**

Expectations and, in some cases, realities, **of the transformational impact of AI** in our daily lives and in our healthcare point towards a change in the delivery of healthcare as we know it. In this context, the evolution of algorithms and different AI techniques, together with the improvement **of computing capabilities**, are playing a key role in different areas of medicine:

The ability to **analyse huge volumes of data** and **perform complex calculations quickly** is revolutionising genetics research, making it possible to more accurately identify **rare diseases** and facilitating the **development of personalised treatments** in a faster and more flexible way.

In the **pharmaceutical field**, AI is transforming the way **new medicines** are discovered, by enabling **simultaneous analysis and complex simulations** with data from **millions of molecules**, significantly reducing development times and costs.

Incorporating **AI** into medical devices **optimises times in clinical care**, with advances in **early detection and diagnostic accuracy**, expanded simulation capabilities in **population health and health alerts**, improved **surgical techniques,** and improved patient interaction and care **management processes**.

Encouraged by this **expectation of transformation**, governments and companies develop millionaire investment plans around Artificial Intelligence.

The European Commission and member states also have plans to mobilise large investments in AI, articulated around the **InvestAI[2] initiative** in which the **collaborative development of complex models** is prioritised with the aspiration of turning Europe into a benchmark region in the development of **responsible Artificial Intelligence.**

The capabilities demonstrated by Artificial Intelligence, and its constant evolution, leave no doubt about impact it will have on our daily lives and on our healthcare, **although the initial concerns raised with the use of MYCIN, remain in force.**

> *"AI will improve our healthcare, spur our research and innovation and boost our competitiveness.*
>
> *Ursula von der Leyen*

The implementation of AI has **advanced significantly** in recent years in health providers globally and in the National Health System in particular, where different areas of healthcare already take advantage of its benefits, in **more accurate diagnoses**, **resource-efficient** management or **professional support**. At the European level, the European Commission is actively promoting funding and regulatory programmes to overcome the challenges and accelerate this integration that **will reshape care provision.**

The **pace and scope of AI integration in health depends on the complexity** of the sector, the **regulatory framework**, the **ethical** implications, and the **availability** of digital infrastructure.

Although there are differences in the degree of implementation, in different countries and healthcare providers, **sustained growth in use is observed,** giving way to AI solutions with already visible impacts in the **short term** and projected developments for the **medium and long term**, in **clinical**, **administrative** and **research environments**.

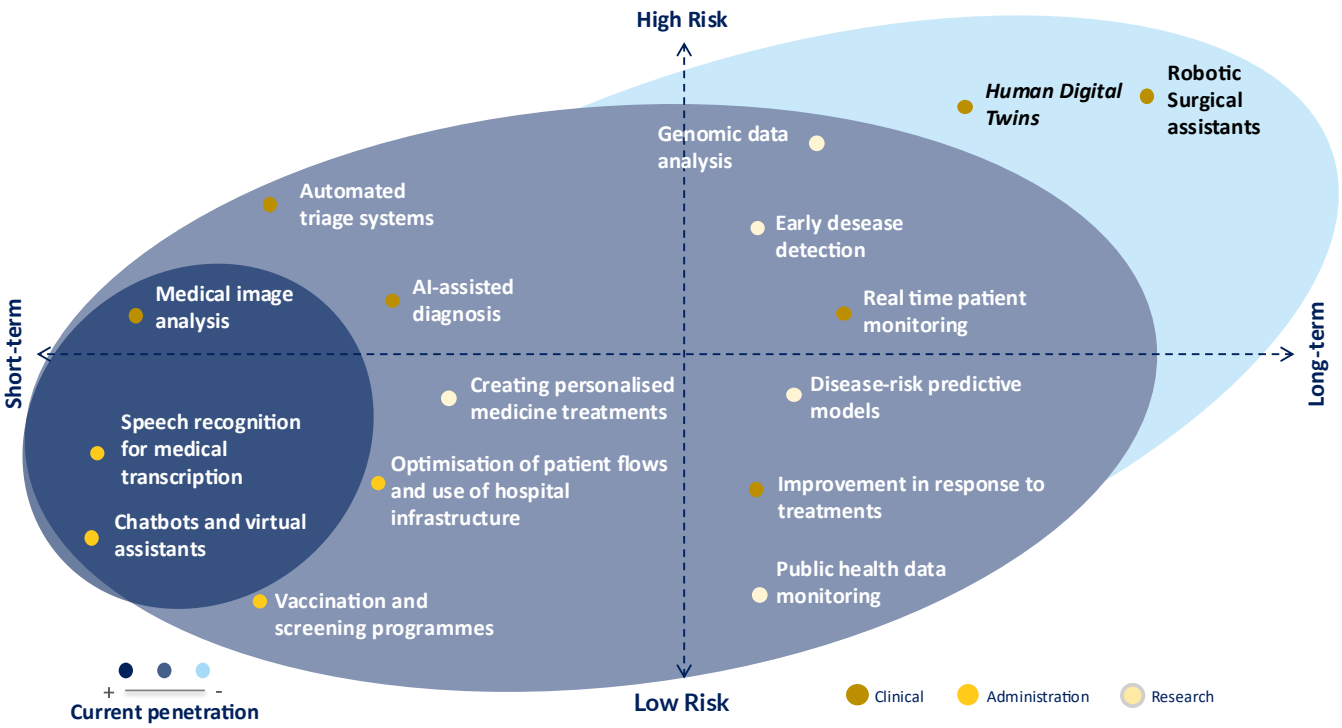


Fig. Penetration of AI solutions and estimated classification of risks of use in different areas of health provision (own data, based on analysis of solutions and reports on AI in health).

The deployment of AI tools in healthcare varies according to their maturity level: some of them are already widely deployed, while others are in emerging stages.

MATURE APPLICATION

- **Chatbots and virtual assistants,** which improve communication with patients and support professionals in daily care.
- **Speech recognition for medical transcription**, allowing the clinician to focus their attention on the patient, thanks to the automatic dictation of notes integrated into the medical record.
- **Medical image analysis to detect abnormalities** in X-rays, CT and MRI, increasing diagnostic accuracy.

APPLICATIONS IN CONSOLIDATION PHASE

- **Patient monitoring and improvement in response to treatments**, thanks to the constant **feedback** of **clinical data** and the dynamic adaptation of therapies.
- **AI-assisted diagnosis**, supporting physicians through clinical decision **support** systems**.**
- **Automated triage systems**, used in the emergency department to **classify patients** according to **severity** and **urgency**.
- AI-optimised **vaccination** and **screening** programs to identify at-risk populations, improve coverage, and plan preventive interventions.
- **Optimisation of patient flows and use of hospital infrastructure**, such as admissions prediction, health centre management and resource allocation.
- **Analysis of public health data**, useful for epidemiological surveillance, outbreak prediction and population health planning.
- **Prescription of personalised medicine treatments**, which adjust therapies and doses according to genomic data integrated into models that allow predicting risks, optimising treatments and anticipating adverse reactions.
- **Early detection of diseases**, through **predictive models** that analyse histories and **clinical parameters** alerting about early patterns of a pathology.

EMERGING APPLICATIONS

- **Robotic surgical assistants**, which combine **mechanical precision** with AI **algorithms** allowing complex minimally invasive interventions to be performed.
- **Human Digital Twins**, digital replicas of patients that enable **simulating responses** to **treatments** and clinical **scenarios and collecting data with the aim of improving processes and research.**

AI can detect pancreatic cancer up to 3 years early, increasing survival to 50%[3]

AI in cardiology automates tasks with over 95% accuracy.[3]

The application of AI in resonances allows diagnostics to be accelerated by 70%.[3]

Using AI to take clinical notes reduces staff burnout by 26%.[4]

AI relieves doctors of up to 10% of their day.[5]

"The application of AI contributes to the reduction of drug discovery time."

Streamlining flows with AI helps reduce waiting times in hospitals

AI in radiology makes it possible to work 26% faster and detect 29% more injuries.[3]

45% of doctors says that thanks to AI they can devote more time to patients.[5]

6 out of 10 professionals expect AI to allow them to focus more on direct care.[5]

"The application of AI is revolutionising genomics and the development of medical devices."

The emerging global data supports the evolution of AI in the healthcare environment, demonstrating that AI contributes to better decision-making and greater effectiveness in medical treatments.

2 out of 3 organisations in the health sector already actively use AI[22]

7 out of 10 healthcare professionals believe AI will reduce hospital admissions in the future[6]

8 out of 10 healthcare professionals say AI will be able to save lives by enabling earlier interventions[6]

Beyond improving diagnostic and therapeutic accuracy, the widespread use of AI in healthcare organisations will force the **redefinition of professional organisational models**. This transformation will require an evolution of traditional functions and the emergence of **new professional profiles**. AI acts as a support tool, allowing healthcare professionals to focus on the most complex, highest-value tasks such as making critical clinical decisions and directly interacting with patients.

This redesign does not imply a replacement but an **adaptation of their functions**, as well as the **need for training** in these competencies, the emergence of new roles in organisations and solid governance frameworks that ensure an ethical, safe and **patient-centered implementation:**

Developers of AI solutions in healthcare

They design and implement models for automated diagnosis, clinical event prediction, medical image classification, or treatment personalisation. They must work in coordination with clinicians and managers to adapt the solutions to the system's actual needs and to know the specific characteristics of clinical practice.

AI Trainers applied to health

Trainers are essential for staff to learn how to use AI-based tools. Ongoing training and knowledge of specific processes will be key to adaptation.

Healthcare professionals specialising in clinical AI

They integrate medical knowledge with skills in data interpretation and functional oversight of intelligent systems. They evaluate the performance of algorithms, interpret their results, and ensure that decisions are aligned with clinical ethics and practice.

Clinical data analysts

Mixed teams (clinical - ICT) for the extraction of useful knowledge for clinical decision-making, risk assessment and health planning. Their work is crucial in the validation and training of algorithms to ensure their applicability and reliability.

Health AI ethics and regulatory specialists

Ensure compliance with ethical principles, algorithmic transparency and patient data protection. They also address issues of legal liability for clinical errors arising from the use of AI.

*The global implementation of AI in health organisations will require the **creation of new profiles** and the **continuous training** of professionals.*

The **millions of data** that are generated daily in the **information systems of the SNS**, and in **patients' devices**, together with the digitisation and homogenisation of the information that the **implementations of the Electronic Health Records** have entailed in the autonomous communities, multiply the possibilities of integration of AI algorithms and solutions that can add to the work of health professionals in the **active care of our health.**

The mass use of AI in our health services can grant us great benefits, although it poses **risks** that require a **multidisciplinary approach** beyond the technological level.

Biases in data

AI learns from historical data, which can perpetuate inequalities in diagnoses and treatments if training data are biased.

Privacy and information protection

It requires large volumes of patient data, raising concerns about unauthorised use of sensitive information.

Quality and availability of data

The lack of standardisation in electronic medical records makes it difficult to train AI models.

Interoperability

AI systems must be integrated with multiple technology platforms in healthcare facilities and organisations, which is a technical challenge.

Automated decisions

The role of AI as a support to the medical decision raises dilemmas about liability in case of errors in diagnosis or treatment.

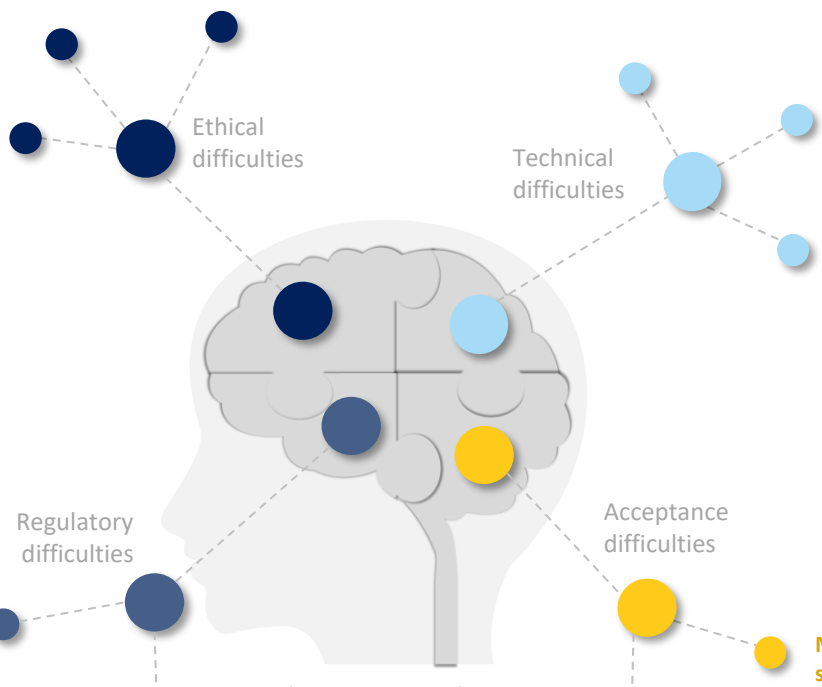


Fig. barriers to AI implementation (own data)

Reliability of algorithm performance

Some AI models can work well in test environments, but fail in real clinical situations due to the variability of the data.

Lack of specific regulations

Complex and dispersed regulation, the result of the coexistence of different regulations developed at different times and in different contexts, with heterogeneous approaches and unequal levels of technological maturity in the field of digital health.

Difficulty certifying algorithms as medical devices

Long, costly regulatory processes for solution certification.

Mistrust of automated systems

Errors in algorithm decision-making (especially false negatives) are a major obstacle to acceptance of their use in healthcare and give rise to mistrust in patients and professionals.

Lack of AI training for doctors and healthcare staff

AI is still perceived as a complex tool that requires an expensive learning curve.

Many professionals fear that AI will replace their work rather than complement it, which generates resistance to its adoption.

Challenges and Risks

The **adoption of AI** in the SNS must be based on essential principles such as **safety, equity, transparency and human oversight**.
The use of this technology in a particularly sensitive environment, such as healthcare, requires that the risks associated with its use must be **mitigated** in advance.

In this regard, the EU has established, in the recently published Artificial Intelligence regulation - *AI Act*[7], the rules that allow **these risks to be classified into** four levels (minimal, limited to lack of transparency, high and unacceptable) and to set the conditions of use in each case, based on the potential risk of the AI system.

The EU and its member states **promote the ethical and fair development and use** of AI **by protecting public interests and individual rights**, while seeking to foster trust in the technology. To this end, fundamental issues are identified as **ensuring the transparency** and **accountability of** algorithms, **preventing bias** or ensuring the protection of fundamental rights such as **the right to privacy** or **non-discrimination.**

The proper management of these risks and guarantees without delaying the **application of AI capabilities for the** transformation of the SNS, will require the involvement and coordination of all agents with competencies in the SNS and in the cross-cutting regulatory aspects for its **safe and reliable integration.**

93.4%
of Spaniards believe that programming and training AI systems should be regulated, according to a CIS survey[8]

309
cybersecurity incidents reported in 2023 in the health sector, in which 54% involve ransomware programs.[6]

+60%
of Spaniards are concerned about the use of their personal data by public or private entities.[8]

77%
of healthcare professionals support AI to improve patient outcomes.[6]

59%
of patients are confident that AI can improve healthcare.[6]

88%
of patients prefer to receive information and safety about AI from their healthcare professionals.[6]

Concerns about **privacy**, clinical data, and the increase in **cyberattacks** translate into **citizens' concerns about the safety of** the use of artificial intelligence in the health sector.

- *Ethics in the use of AI*
- *Legislation and associated regulation*
- *Obligations*

Ethical use and regulatory framework

It is necessary to harmonise the use of AI in health with data protection regulations, to base the application of the AI Act in the sector and to define principles of ethical use that guarantee its incorporation into the National Health System in a conscious, reasonable and safe way.

2

Ethics in the use of AI: context

Ethics and justice are concepts that have been debated throughout history; the emergence of Artificial Intelligence has revealed new aspects for analysis.

The rapid advancement of this technology, with the ability to process an enormous amount of information and make autonomous decisions in a **protected area such as health,** poses an **extraordinary risk due to its ability to acquire biases or transmit erroneous information.**

The problem in AI in health has been reflected in several publications of international organisations, which try to identify guidelines to incorporate ethical principles as an inescapable factor in the framework of the development of AI systems: WHO Ethics and Governance of Artificial Intelligence

for Health: WHO Guidance[11], OECD principles for responsible AI [12], Hiroshima principles agreed by G7 countries [13] …, which seek to ensure the continuity of the **person at the centre** of this trinomial formed by technology (continuous learning), ethics (conscience, critical thinking and moral judgement) and regulations (regulation of human oversight and responsibility over an AI system).

For its part, the **European Union** has gone further, not only being **active in proposing ethical guidelines** (Ethics Guidelines for Trustworthy AI [14], AI White Paper: Guidance on Accountability and Governance[15]) but also **regulating it legislatively** (AI Act).

Principles and dimensions for trustworthy AI

Indeed, if there is one area in which the importance of the ethical factor should be further emphasised, it is health.

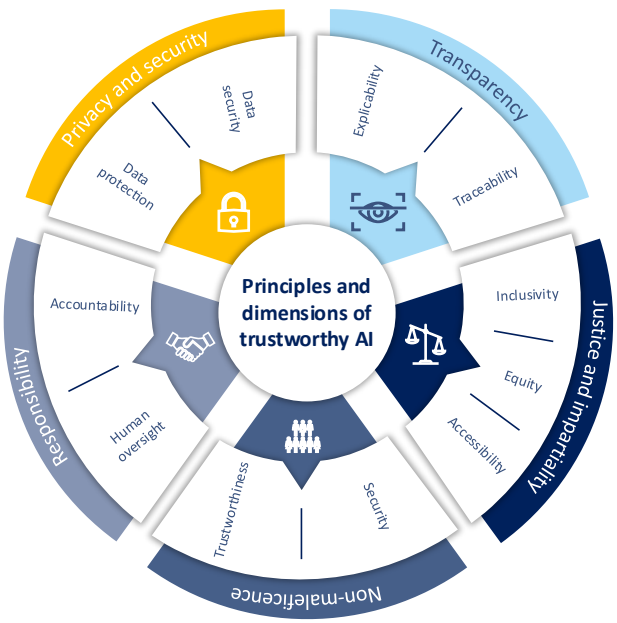


Fig. Principles and dimensions of trustworthy AI (own data)

> *"Ethics is indispensable for the person, so it must be an inseparable part of the use of any technology."*

AI can make differential contributions, improving diagnoses and treatments, but its **use** must **be transparent, safe and equitable** in order to protect the integrity, privacy and other fundamental rights of people.

It is essential for AI experts to be able to explain how and why they make decisions (traceability and explicability), allowing their understanding and continuous oversight, as well as considering other dimensions to ensure **a technology that is aligned with ethical values and principles.**

The literature review identifies the principles of **transparency, privacy, justice accountability and non-maleficence** as those under which a reliable use of AI systems is ensured.

AI Regulatory Framework

In relation to the trinomial formed by technology, ethics and regulations, the **European Union** has been **a pioneer in the complete regulation of algorithmic developments with AI,** including the aforementioned ethical principles.

Regulation **(EU) 2024/1689** of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules **on artificial intelligence** directly applicable to the Member States establishes a **comprehensive legal framework to regulate the use of artificial intelligence**, from research and development to implementation and final use.

However, the **regulations applicable to AI** in the **Community health context are not only limited to the** Artificial Intelligence Act, **but AI systems used in the health sector must simultaneously comply with the legislation of** Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR[16]) with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR[17]); together with Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on **health technology assessment** [18]; and with the CE Marking certification **associated with the MDR and the IVDR**. This regulation forms a complex regulatory framework, in addition to the European Health Data Space Regulation (**EHDS**[19]) and the General Data Protection Regulation (**GDPR**[20]).

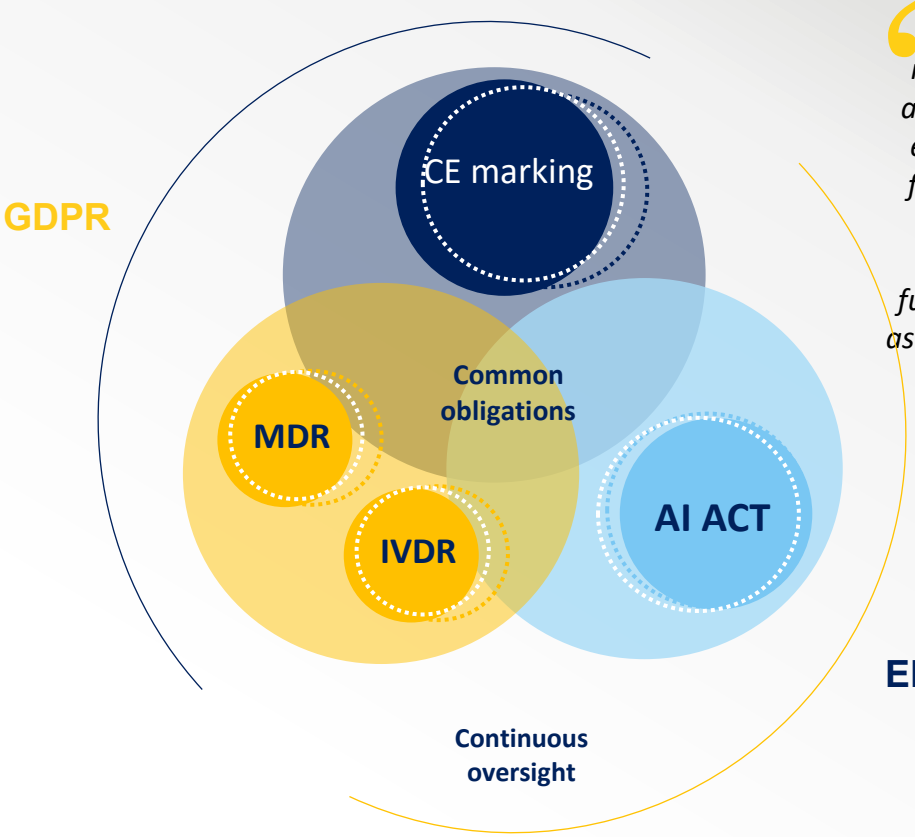


Fig. Regulatory corpus of application for the use of AI systems in health environments (own data)

> *European AI regulation is a complex and dynamic regulatory ecosystem, designed to find a balance between innovation and the protection of fundamental rights, and as a response to the risks that the use of AI generates in health.*

AI Risk Classification

The **use of AI** can be risky **and is therefore** regulated to **ensure the safety** of these systems.

Incremental levels of risk have **been established:**

Unacceptable risk: this type of risk will not be admitted.	AI systems considered **to be a threat to people's safety**, livelihoods or rights, such as *social scoring* or toys that use voice assistance that encourages dangerous behaviour.
High risk: if the system has the capacity to cause harm to people.	AI used in critical infrastructures, training, employment, essential services, judicial and democratic processes, border control, **medical products**...
Limited risk: if the system may not be transparent or help to obviate responsibilities.	Risks associated with the lack of transparency, such as informative text on topics of public interest drafted by AI or *chatbots*.
Minimal or no risk: systems not included in the above categories.	**Most of the systems** currently used in the EU, such as *spam* filters or video games with integrated AI.

Fig. Classification of AI systems according to their risk level

Unacceptable risk is materialised in a number of **banned practices**. They directly affect individual freedom and data protection and are incompatible **with the core values of the EU** and cannot be marketed or used within the European market. The **ban on** these **practices** came into force on **2 February 2025.**

Prohibited practices

Social behaviour-based assessments	**Recognising emotions** at work or in education	**Biomedical classification** by sensitive data	**Manipulation** and subliminal techniques
Real time **remote biometric identification**	Exploitation of **vulnerabilities**	Creation of **facial recognition databases**	**Assessment of the risk** of committing crimes

Medical Device Regulations

In the health sector, the AI Act is complementary to the sectoral ones: **Regulation (EU) 2017/745, (MDR)** and **Regulation (EU) 2017/746, (IVDR)**.

It is worth highlighting the need **to differentiate between the two**, because, although they regulate medical devices, they are not aimed at the same type of product.

MDR

Regulates

Medical devices, understood as that material, device, equipment, instrument or **software** that fulfils **functions of diagnosis, treatment, monitoring or prevention** of diseases, among other medical purposes, whose use may be intended for human beings.

Main objective

Ensure that products placed on the EU market are **safe, effective and traceable**, throughout their shelf life.

- **Implantable medical device** (pacemaker, prosthesis).
- **Non-implantable medical device** (thermometer...).
- **Devices combined** with medication.
- **Medical software** (diagnostic imaging algorithms).

IVDR

Regulates

Any medical device consisting of a **reagent, reagent product, computer program or system**, among others, used alone or in combination, intended by the manufacturer to be used *in vitro* for the **study of biological samples,** including blood and tissue donations.

Main objective

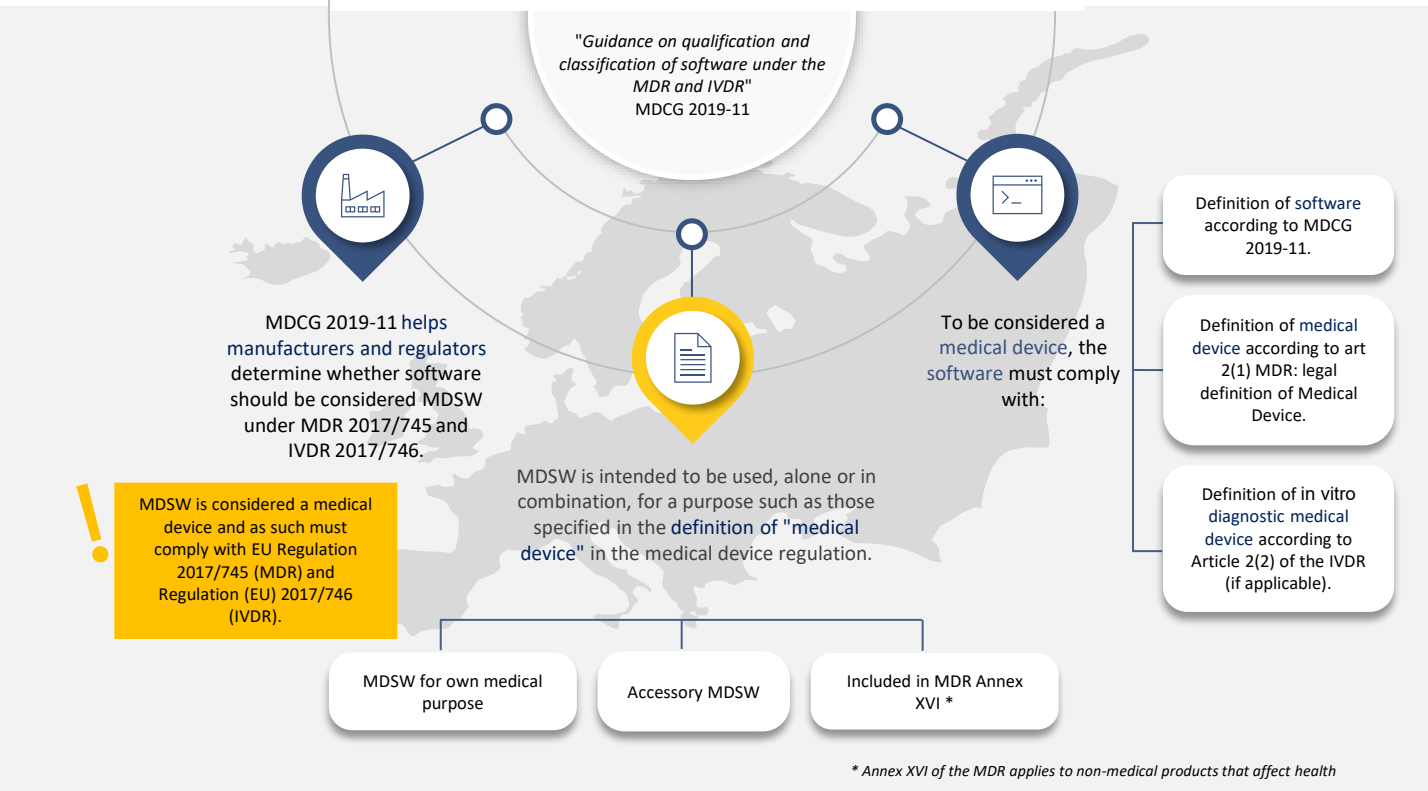
Ensure diagnostic products provide **clinically valid, reliable results without** undue risk to patients.

- **Laboratory test** that analyses human samples.
- **Genetic and molecular devices**.
- **Software** that interprets PCR, DNA analysis...
- AI-integrated **lab analysis** equipment

> *Both regulations require that, in order for a medical device to be marketed, it obtains the CE marking*.

Software as a medical device

Derived from the need to regulate all types of medical devices and, with the inclusion of new technologies, the legislation includes medical software with clear qualification and classification criteria, guaranteeing its safety and effectiveness in healthcare. In Europe, as Medical Device **Software (MDSW)-** it is considered a **medical device** and must comply with the **Medical Device Regulation (MDR) or the *I*n Vitro Diagnostic Regulation (IVDR 2017/746), as the case may be.**



MDCG 2019-11[21] is a **European Commission guide** entitled ***"Guidance on qualification and classification of software under the MDR and IVDR"***, published by the ***Medical Device Coordination Group*** **(MDCG)**. Its purpose is to assist manufacturers and regulators in determining whether software should be considered **Medical Device Software (MDSW)** under the Medical Device **Regulation (MDR 2017/745)** or the **In Vitro Diagnostic Regulation (IVDR 2017/746)**.

According to **MDCG 2019-11** medical device software is defined as:

"(…) software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the medical devices regulation or in vitro diagnostic medical devices regulation.

Classification of the medical device

Medical devices **will be classified** according to each regulation, MDR or IVDR, and, **according to their risk level**. When the product is **class IIa or higher** (MDR), or **class B or higher** (IVDR), they **will be equated** to the **high risk** level in relation to **AI regulations**.

The **medical device** is classified according to its impact on the patient and clinical use, following **Annex VIII of the MDR Regulation.**

Class III
Product that could cause death or irreversible deterioration if incorrect information is provided.

Assessment and certification:
Notified Body

Class IIb
Product that has an impact on critical health decisions.

Assessment and certification:
Notified Body

Class IIa
Product that provides information for medical decisions.

Assessment and certification:
Notified Body

Class I
It does not provide information for making medical decisions that affect health.

⚠ ***Exception:*** *monitoring of vital physiological information*

Assessment and certification:
Manufacturer

The in-vitro diagnostic **medical device** is classified according to the risk of its use for the patient and clinical use, following **Annex VIII.2 of the IVDR Regulation**. This annex establishes 7 classification rules and risk levels.

Class D
Products intended to detect the presence of transmissible agents in blood, tissue or organ donations.

Assessment and certification:
Notified Body

Class C
Products intended to detect transmissible agents in clinical samples or products to determine donor/recipient compatibility.

Assessment and certification:
Notified Body

Class B
Self-test, for example, pregnancy test.

Assessment and certification:
Notified Body

Class A
Low risk. General purpose laboratory products without direct medical function.

Assessment and certification:
Manufacturer

Obligations under the AI, MDR and IVDR Regulations.

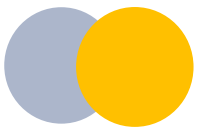
In view of the **casuistry** of **medical device used by AI** and, in relation to the **obligations** that **economic operators** will have during the life cycle of this product, it should be noted that the Artificial Intelligence Regulation clarifies that the basis of regulatory compliance, in this case, will be laid down by the medical device regulations through the **Medical Device Regulation (MDR)** or the ***In Vitro* Diagnostic Regulation (IVDR)**, and will be complemented by **the AI Act** (in accordance with Recital 124).

From the perspective of these three regulations, the **obligations of the most common economic operators are set out below.**

Manufacturer - MDR

- For the technical documentation, it must include: design, manufacture, verification and validation.
- The MDR imposes the obligation to include a clinical evaluation (studies, product bibliography, monitoring...).
- Intervention of a Notified Body (NB) is required for products of class IIa or higher.
- Post-marketing surveillance.
- The modifications and updates that are carried out on the product must be assessed according to the clinical impact.

OBLIGATIONS



- Manufacture the product safely.
- Unique identifier for the product.
- Incident reporting.
- Registration of the product in EUDAMED.
- Quality Management System.

Manufacturer - IVDR

- For the technical documentation, it must include: design, manufacture, verification and validation; and, a clinical validation together with a performance assessment.
- The IVDR requires a performance assessment divided into three parts: scientific, analytical and clinical.
- Intervention of a Notified Body (NB) for products of class B or higher, greater demand for intervention of the NB.
- Post-marketing surveillance. Requires ongoing clinical performance reporting.
- For modifications and updates, the IVDR also requires re-evaluating the diagnostic method, not just the technical impact.

> *"The obligations of the operators, together with the classification of the product, will lay the foundations so that the AI Act can regulate simultaneously and complementarily.*

COMMON OBLIGATIONS

1. AI literacy
2. AI recording
3. AI risk assessment
4. Technical documentation:
5. Event recording
6. Human oversight
7. Automatic record keeping
8. Cooperation

SUPPLIER

- Data governance
- Risk Management and Quality Management System
- Transparency, accuracy, robustness and cybersecurity
- Preservation of documents and recording of AI systems in EU database
- Serious incident reporting and corrective actions
- Conformity assessment, EU Declaration of Conformity, CE Marking
- PMS (post marketing surveillance)

Deployment manager

- Fundamental Rights Impact Assessment
- Responsible use of AI
- Instructions for use
- Relevant and representative data
- Report on AI usage in systems
- Request authorisation (*ex ante*) for remote biometric identification
- Do not use AI system if it is not in EU database

Starting situation in health services

The road to implementing AI in the SNS

Situation of Artificial Intelligence in the SNS

Today it would be difficult to find any health service in the SNS where AI has not arrived.
Many are the pilots, proofs of concept and also coordinated projects from the Health Services in which algorithms are being developed and using Artificial Intelligence solutions that support the day-to-day activity of professionals.

3

Within the framework of the program for the adoption of AI in the SNS (**IASNS**), a first diagnosis has been carried out to know the status of implementation in the health services of the SNS. The aim of the analysis has been to obtain a **clear and structured vision** of the current situation, identifying strengths, challenges and maturity levels in the use of AI. To this end, a methodology based on the collection, standardisation and evaluation of information from various sources has been adopted:

Bilateral sessions with each Autonomous Community, in which the current situation at the technical and organisational level in health services was addressed in detail.

Technical and regulatory assessment of AI algorithms, implemented in the Autonomous Communities based on questionnaires designed by the Ministry of Health and completed by the Autonomous Communities and their technology providers.

Analysis of projects and tenders for AI products and services in health services and hospitals, and study of regulatory initiatives in the Autonomous Community.

Aspects considered for maturity level assessment

Technical aspects

- **Algorithms** and implementation status.
- **Body responsible for** AI.
- **Assessment and validation** methodology.
- **Monitoring** and continuous improvement.
- **Infrastructure** and tools.
- Impact and measurement of **results**.
- **Training** and documentation.

Regulatory aspects

- **Knowledge** (MDR, IVDR, CE certification, AI Act and EHDS).
- **In-house training** (MDR, IVDR, CE certification, AI Act and EHDS).
- Defined **procedure** for compliance (MDR, IVDR, CE certification, AI

As a result of the analysis carried out, it is concluded that the starting point of the SNS in terms of artificial intelligence is in a state of **timely implementation** of Artificial Intelligence solutions with a considerable continuous evolution in their progress.

There are **notable differences between Health Services**, both in technical deployment and in knowledge of the applicable regulatory framework.

Analysis of existing algorithms in the SNS

As part of the starting point analysis, an **inventory of AI algorithms** has been drawn up in the Autonomous Communities, including both own developments and commercial solutions. These algorithms are in different phases of implementation, which has made it possible to quantify their degree of adoption.

The algorithms have been classified according to three main axes:

1. **Functional use case**, taking into account the specific objective they pursue.
2. **Clinical specialty** to which they are directed or in which they are being applied.
3. **Stage of the care process** in which they are defined (demand, diagnosis, treatment or prevention).

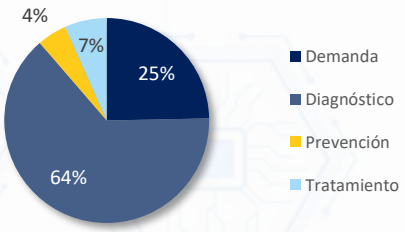
155 | algorithms

commercial | 81

56 | own development

unidentified | 18

Total number of algorithms, inventory performed with SNS health services in July 2025



Percentage of algorithms identified by stage of care

Main objectives of the AI strategy in the SNS

In the situation diagnosis process, the common interest in the SNS to advance in a coordinated way in the implementation of AI-based solutions and in the objectives to which the execution of the ***eIASNS*** strategy should be directed has been identified:

Methods of AI deployment and assessment

The proper assessment and deployment of AI models requires a robust, interoperable and secure infrastructure, as well as unified procedures for the identification, classification, validation and use of these solutions in the SNS.

AI governance models

To guarantee a safe and efficient development of AI in the SNS, it is necessary to establish governance structures with defined roles and services, supported by robust **data** management based on common quality policies, semantic interoperability, cataloguing and traceability.

Common and homogeneous vision

Promote a common and homogeneous vision regarding the capabilities and implications of AI and its use in the SNS, fostering an organisational culture that integrates AI as a strategic tool for the improvement of healthcare.

Use cases of common interest

In different Autonomous Communities, AI solutions are being implemented that respond to common SNS needs. Coordination of these projects and joint identification of use cases of common interest will optimise resource efficiency and advance federated governance.

Education and training

Understanding the capabilities and risks involved in the use of AI in the healthcare environment requires a multidisciplinary training and education process for professionals and patients, in ethical and regulatory aspects, as well as technical and usage issues.

The situation analysis in the SNS as a whole reflects the progress towards the adoption of AI capabilities. In some cases, health services have already passed the **exploration phase** in which the efficiency of solutions is demonstrated based on proofs of concept and limited projects, and in certain areas implementation projects in healthcare processes begin to be addressed (**timely implementation phase).** With the development of this strategy, the Ministry of Health aims to promote this progress towards the **widespread adoption** and **cultural acceptance** of AI in a coordinated manner and support health services in the multiple and diverse challenges posed by each of the stages:

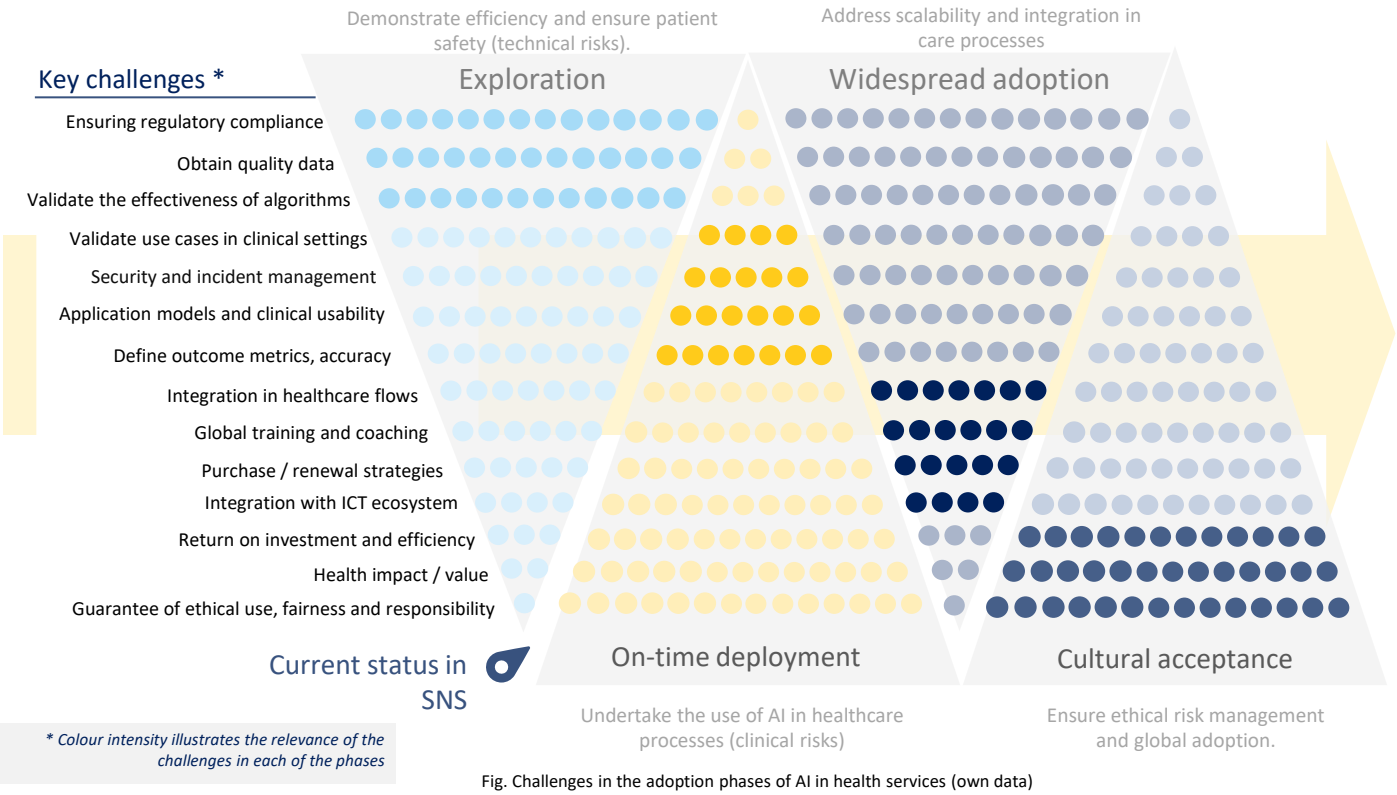


Fig. Challenges in the adoption phases of AI in health services (own data)

Progress in the adoption of AI, based on the conclusions drawn from the situation analysis, will require specific actions at the operational level. To this end, **six work dimensions** are identified in which initiatives will be defined and joint decisions will be prioritised in the SNS aligned with the **strategic objectives** of eIASNS:

01 AI strategy
- Roadmap
- Financing
- Governance
- Ethics

02 Use case development
- Identification
- Prioritisation
- Scalability

03 Infrastructure
- Software and hardware
- Storage
- Security and networking

04 Data
- Quality
- Governance
- Architecture
- Modelling

05 Governance
- Management structures
- Policies and processes
- Risk monitoring and management

06 Training
- Training
- Awareness-raising
- Dissemination

- *Context and purpose*
- *Lines of transformation*
- *Detail of initiatives and impact*
- *Financing*

eIASNS – Objectives and lines of action

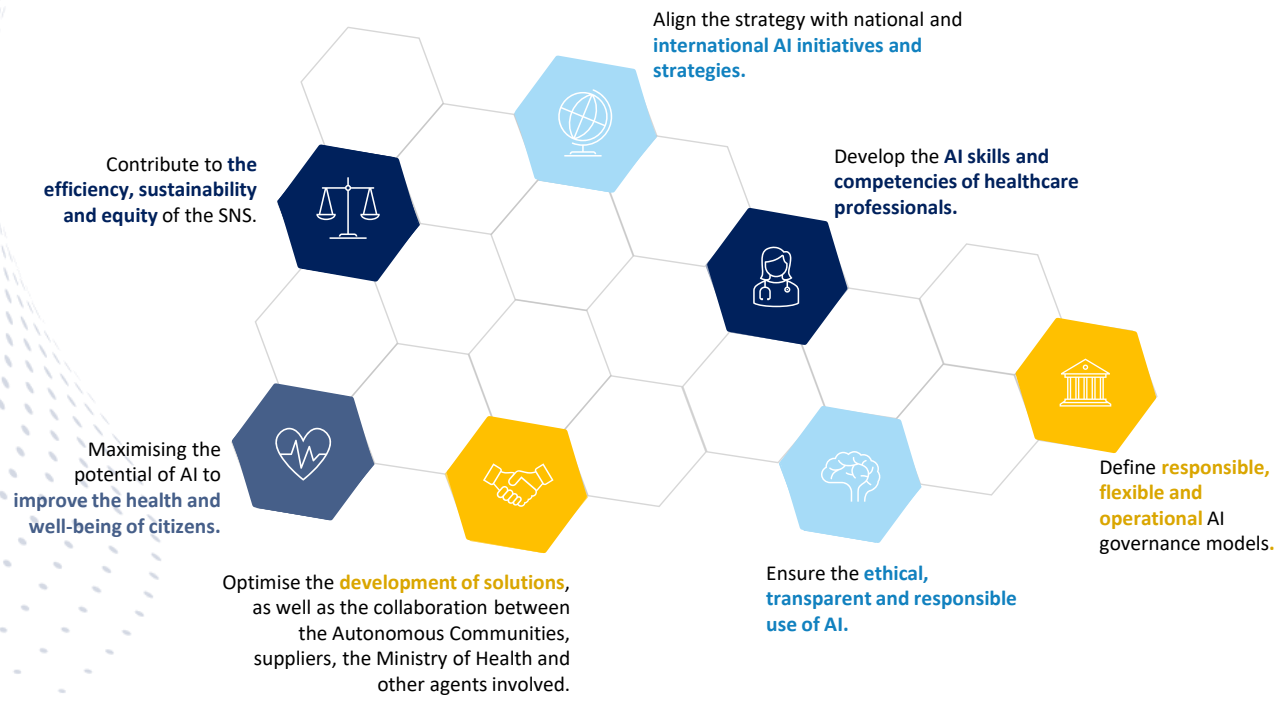
*The drive by the CISNS Digital Health Commission of this strategy, **eIASNS** will serve as a roadmap for the equitable deployment of AI in the SNS, monitor its implementation and measure its impact.*

4

AI **emerges as a technology with significant disruptive potential** to support the challenges that the SNS will have to face in the coming years (population longevity, chronicity, mobility, multichannel) and revolutionise the way healthcare is delivered.

However**, the adoption and effective integration of AI in the SNS requires a coordinated roadmap** that considers the specific characteristics of the Spanish health system, the ethical and legal aspects inherent in the use of sensitive health data, the need for interoperability and security of systems, the training and training of its professionals, as well as the active participation of both patients and professionals, and technology providers.

This is the main objective of **the SNS AI Strategy**, defined in the SNS Digital Health Strategy which also aims to:



eIASNS will promote **the implementation of discriminatory AI,** classification and pattern recognition, based on rules and models and especially of **generative AI solutions (IAGen)** that have shown great potential to improve the management and support tasks for **healthcare processes such as the automatic transcription of doctor-patient interactions**, the generation of clinical history summaries or the management of citations.

Generative AI can perform tasks that require human cognitive skills, such as responding to and formulating verbal or written commands, "learning" and "problem solving," or creating new content (text, images, audio, or synthetic data) in response to prompts instantaneously through very simple interfaces.

Mission

Integrating Artificial Intelligence into the National Health System in an ethical, equitable and coordinated manner, with the aim of supporting the healthcare of the population, empowering patients and professionals through its use and optimising system efficiency.

1 Healthcare support

Support the population's healthcare in a sustainable way through the **responsible, ethical and equitable adoption and use of Artificial Intelligence.**

2 Empowerment

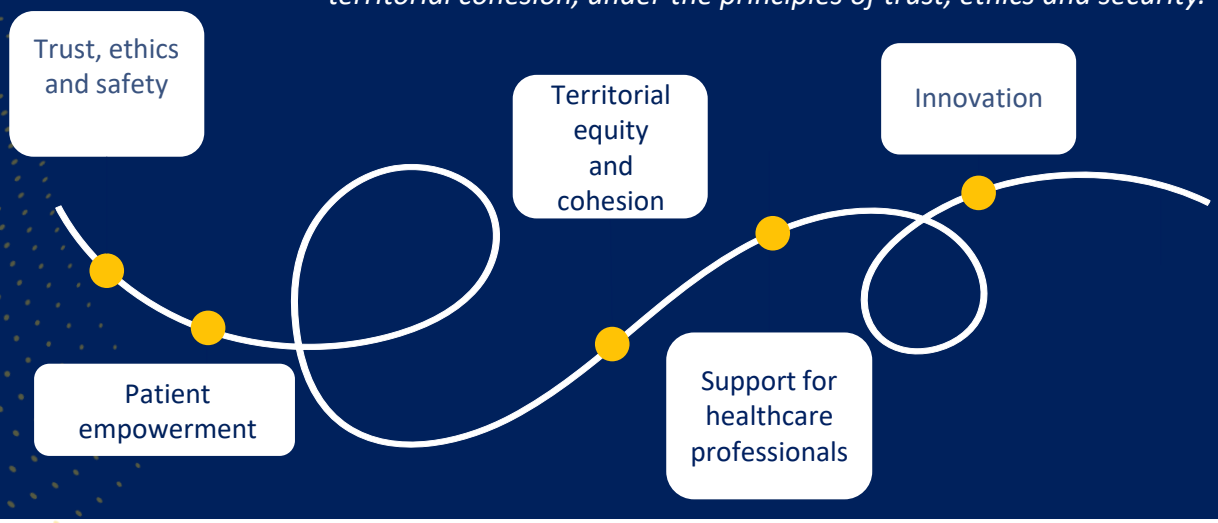
Empower patients and SNS professionals through reliable and efficient **AI tools**, to achieve personalised, preventive, proactive, safe and high-quality healthcare, fostering active prevention and proactivity in patients.

3 Optimise available resources

Integrate Artificial Intelligence in a coordinated way in the processes that make up the **care provision** and in management **and planning activities.**

Vision

*Promote the **equitable implementation of Artificial Intelligence in the SNS**, with the aim of incorporating the innovation involved in the healthcare life cycle, supporting its professionals and strengthening territorial cohesion, under the principles of trust, ethics and security.*



The strategy is based on **4 lines of transformation:**

Line 1
Reliability

The trust of citizens and professionals will be maximum when the **ethical, regulatory and transparency** principles are rigorously applied; guaranteeing security and privacy from the design and throughout the life cycle of AI.

Line 2
Utility

Healthcare professionals will work with the **support of reliable AI tools that add value, optimising their time and updating their clinical knowledge** to enable higher quality care and proximity to the patient.

Line 3
Humanism

Each user will be able to receive **personalised, predictive, preventive and participatory healthcare** thanks to the use of AI, which will allow them **to assume a more active and responsible role in the care of their own health.**

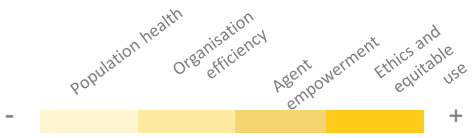
Line 4
Universality

AI will actively contribute to **reducing health inequalities**, helping to ensure **equitable access to innovative diagnostics and treatments,** regardless of location or socioeconomic status, with sustainable solutions.

The definition of **global objectives and evaluation** metrics for the use of AI in care settings and management processes in the SNS will be addressed.

Projects for the controlled implementation of specific AI **solutions** will be jointly executed in a coordinated manner between the Autonomous Communities (ongoing transcription agents).

Reliability Line 1



Initiatives

- AI Governance: regulatory compliance and technical and functional quality assurance.
- Algorithms and solution marketplace.
- Assessment of technical and legal characteristics.
- Controlled collaborative testing spaces.
- Training, change management and awareness for the reliable and ethical use of AI.
- Continuous risk monitoring and surveillance.

Line 2 Utility

Use of digital assistants and AI agents * for professional clinical, administrative and management support.
AI for diagnostic support.
AI for precision medicine and therapeutic decision support.
AI for simulation and training of professionals.

Initiatives

*Assistant: **Support** tool that assists HCPs in reducing low clinical value tasks.
*Agent: they automate tasks such as **transcription, report generation and appointment management**, de-bureaucratising care, among others.

Humanism Line 3

Initiatives

- Patient and user empowerment.
- AI for literacy and health training and psycho-emotional accompaniment.
- Promotion of therapeutic adherence and personalised care plans.
- Personalised digital assistants for navigation, information and self-care.

Line 4 Universality

Equitable demand planning and efficient resource allocation.
Predictive modelling for strategic planning and population health.
AI for early detection of public health alerts and health crisis management.
Process automation to remove barriers to access and optimise service provision.
AI for energy optimisation in health infrastructures.

Initiatives

Line 1 Reliability

1.1 AI Governance: Regulatory compliance and technical and functional quality assurance

Establish a clear governance framework that defines policies, responsibilities and processes. Ensure strict regulatory compliance throughout the AI life cycle. Implement a robust methodology for continuous evaluation of the safety, efficacy and ethics of algorithms and their economic impact.

1.2 Algorithm and solution marketplace

Create a centralised inventory of the AI algorithms validated and in use in the SNS, detailing their characteristics and performance and risk level in accordance with regulations.

1.3 Evaluation of technical and legal characteristics

Constitute a centralised unit to guide, support and facilitate the collaborative development of AI algorithms and solutions by SNS teams. Provide expert technical, methodological and regulatory advice.

1.4 Controlled collaborative test spaces

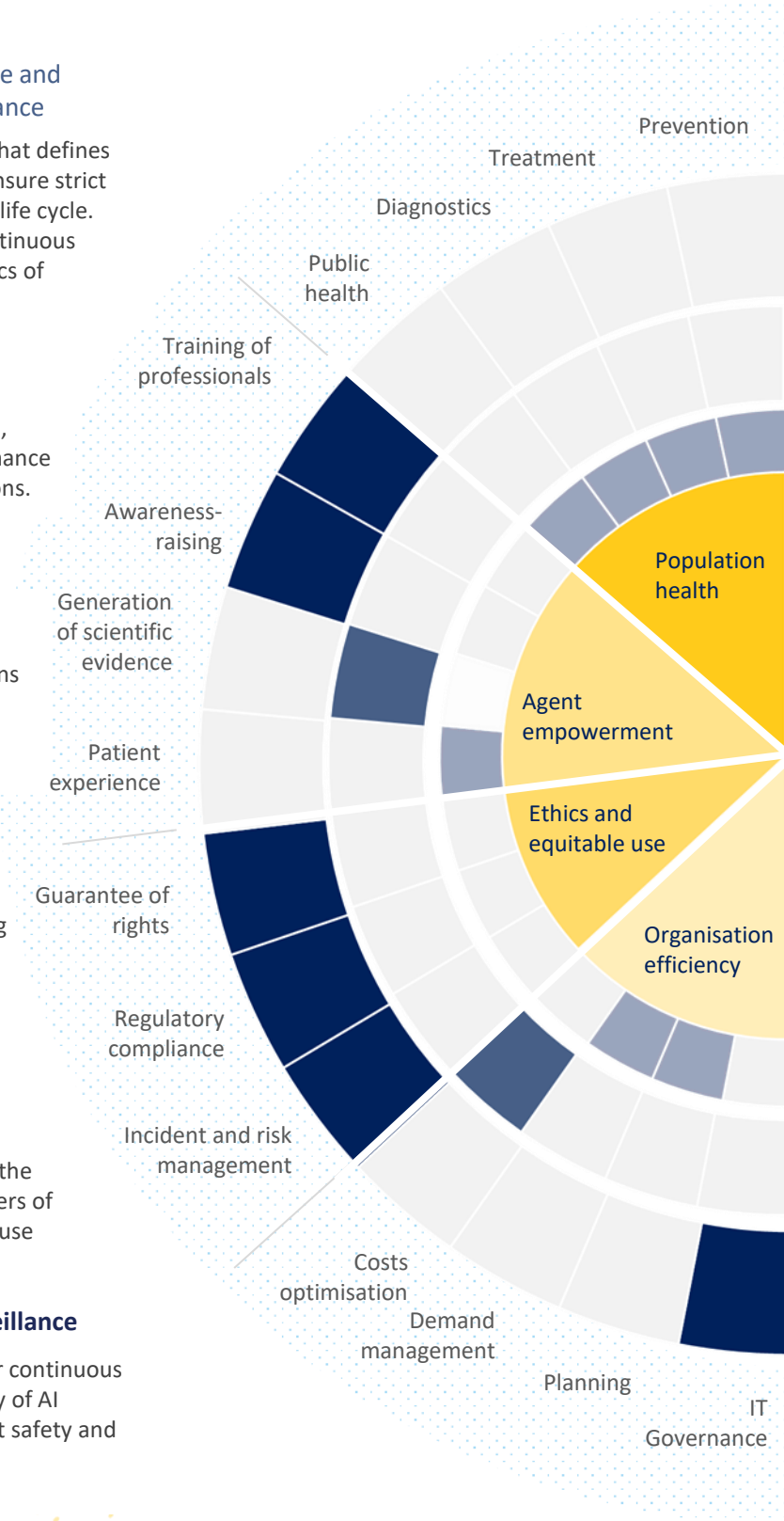
Develop and maintain secure, controlled environments to test and validate new AI solutions prior to clinical use, encouraging federated training of collaborative development algorithms and models.

1.5 Training, change management and awareness-raising for the reliable and ethical use of AI

Implement training programs adapted to the different professional profiles and managers of the SNS on the safe, effective and ethical use of AI.

1.6 Continuous risk monitoring and surveillance

Establish an active surveillance system for continuous monitoring of the performance and safety of AI algorithms in clinical use, ensuring patient safety and continuous improvement of solutions.



Line 2 Utility

2.1 Use of digital assistants [1] and AI agents [2] for professional clinical, administrative and management support

Transparently implement and integrate solutions into the daily routine of professionals that transform the way they interact with information, providing immediate access to unidentified alerts or interactions that require assessment, automating repetitive processes or de-bureaucratising administrative tasks.

2.2 AI for diagnostic support

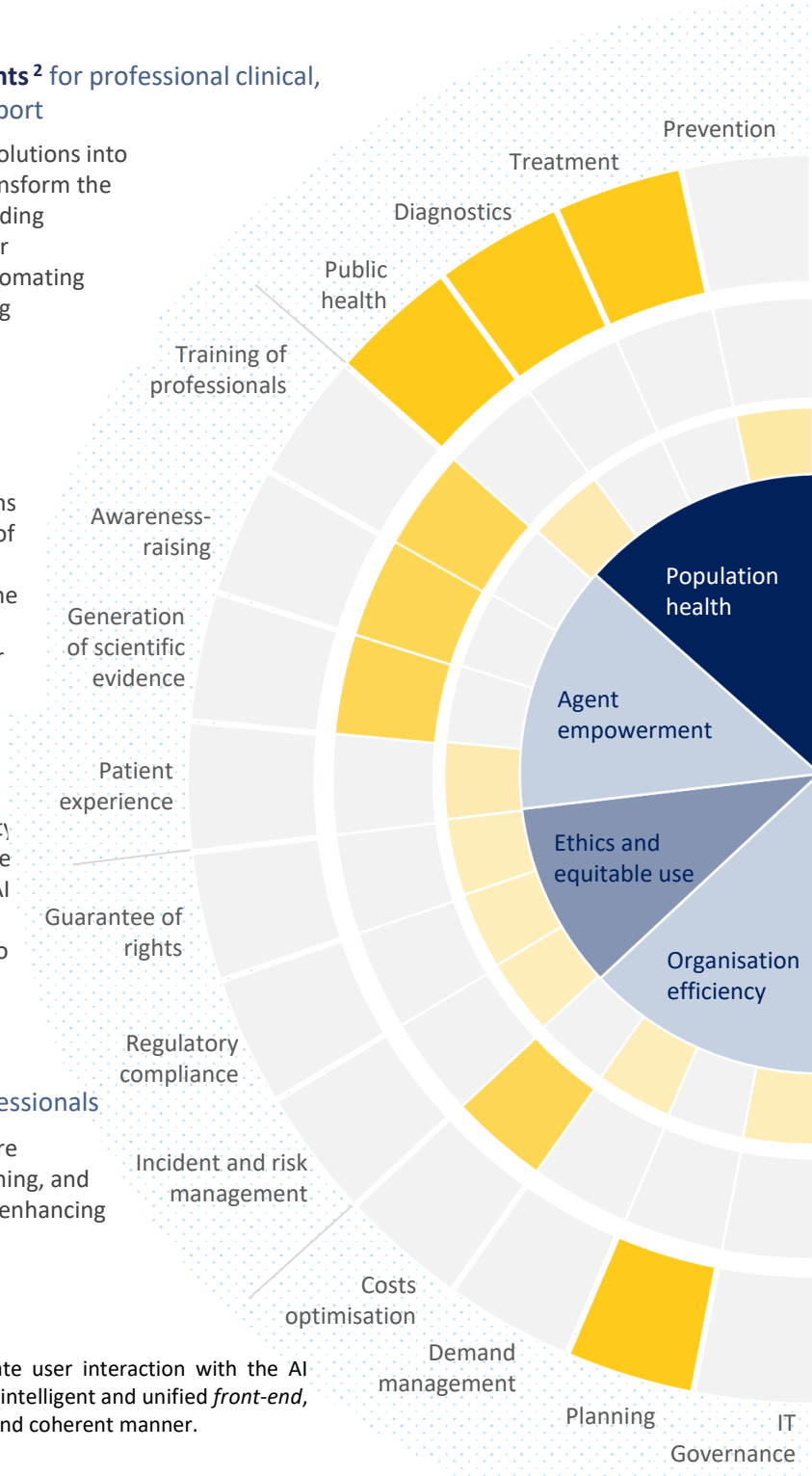
Develop and implement AI algorithms capable of analysing medical images, detecting anomalies and classifying lesions automatically or prioritising the analysis of the professional, and advance in a multimodal diagnosis that will increase the success rate and accelerate the early detection and improvement of results for the patient.

2.3 AI for precision medicine and therapeutic decision support

Use AI to fuse genomic, clinical, and lifesty data into analyses that enable personalise treatments and prevention, integrating AI into clinical pathways and therapeutic decision systems, and “co-pilot” agents to support practitioners in selecting highly tailored interventions for each patient.

2.4 AI for simulation and training of professionals

Provide and integrate tools that drive more personalised, efficient and accessible training, and collaborative agents for research directly enhancing clinical competencies and patient safety.



[1] **Digital assistant:** Main interface to facilitate user interaction with the AI ecosystem. Its primary function is to act as an intelligent and unified *front-end*, managing interaction with the user in a fluid and coherent manner.

[2] AI **Agent:** Specialised and autonomous AI solution designed to resolve a specific use case or perform a specific task. Agents reside "below" the digital assistant, operating in the background and being invoked by the orchestrator when their specific capabilities are required

Line 3 Humanism

3.1 Patient and user empowerment

Develop and provide AI-driven digital tools that give patients an active and proactive role in the management of their own health, facilitating safe and personalised access to their clinical information, promoting effective communication with health professionals, and offering personalised educational resources for individuals and adapted to the needs of groups, which promote prevention and self-care.

3.2 AI for literacy and health training and psycho-emotional accompaniment

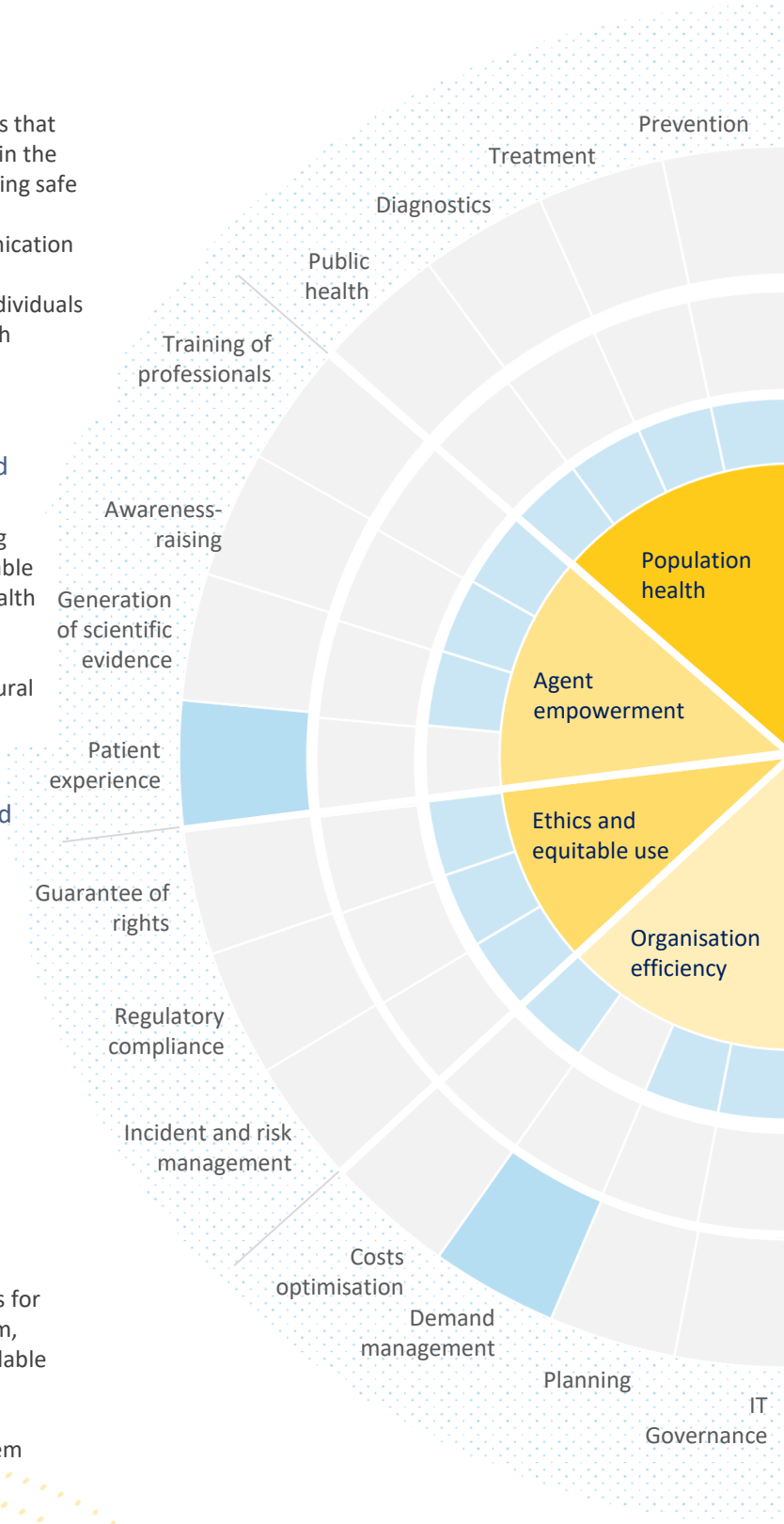
Develop AI solutions capable of generating personalised, interactive and understandable educational content that improves the health literacy of patients and caregivers, dynamically adapting to the level of knowledge, learning preferences and cultural context of each user.

3.3 Promoting therapeutic adherence and personalised care plans with AI

Implement AI systems capable of predicting and addressing the factors that influence adherence to treatment, generating personalised reminders, offering emotional and motivational support, and dynamically adjusting care plans based on the individual evolution of each patient.

3.4 Personalised digital assistants for navigation, information and self-care

Create AI-enabled virtual assistants and *chatbots* that serve as personalised guides for patients throughout the healthcare system, providing them with clear and understandable information about their appointments, treatments, available services, and administrative processes, and offering them self-care tools and healthy lifestyle recommendations.



Line 4 Universality

4.1 **Equitable forecast demand planning** and efficient resource allocation

Implement AI algorithms and the use of 'Digital Twins' of healthcare infrastructure and processes to predict healthcare demand and manage the allocation of resources (staff, beds, equipment) in an equitable and efficient manner, optimising scheduling, reducing waiting times and improving the use of available resources.

4.2 **Predictive modelling** for strategic planning and population health

Using AI-based predictive models capable of analysing demographic and epidemiological data, as already implemented during COVID, to inform strategic health policy planning and anticipate population trends and risks.

4.3 **AI for early health alert detection** and health crisis management

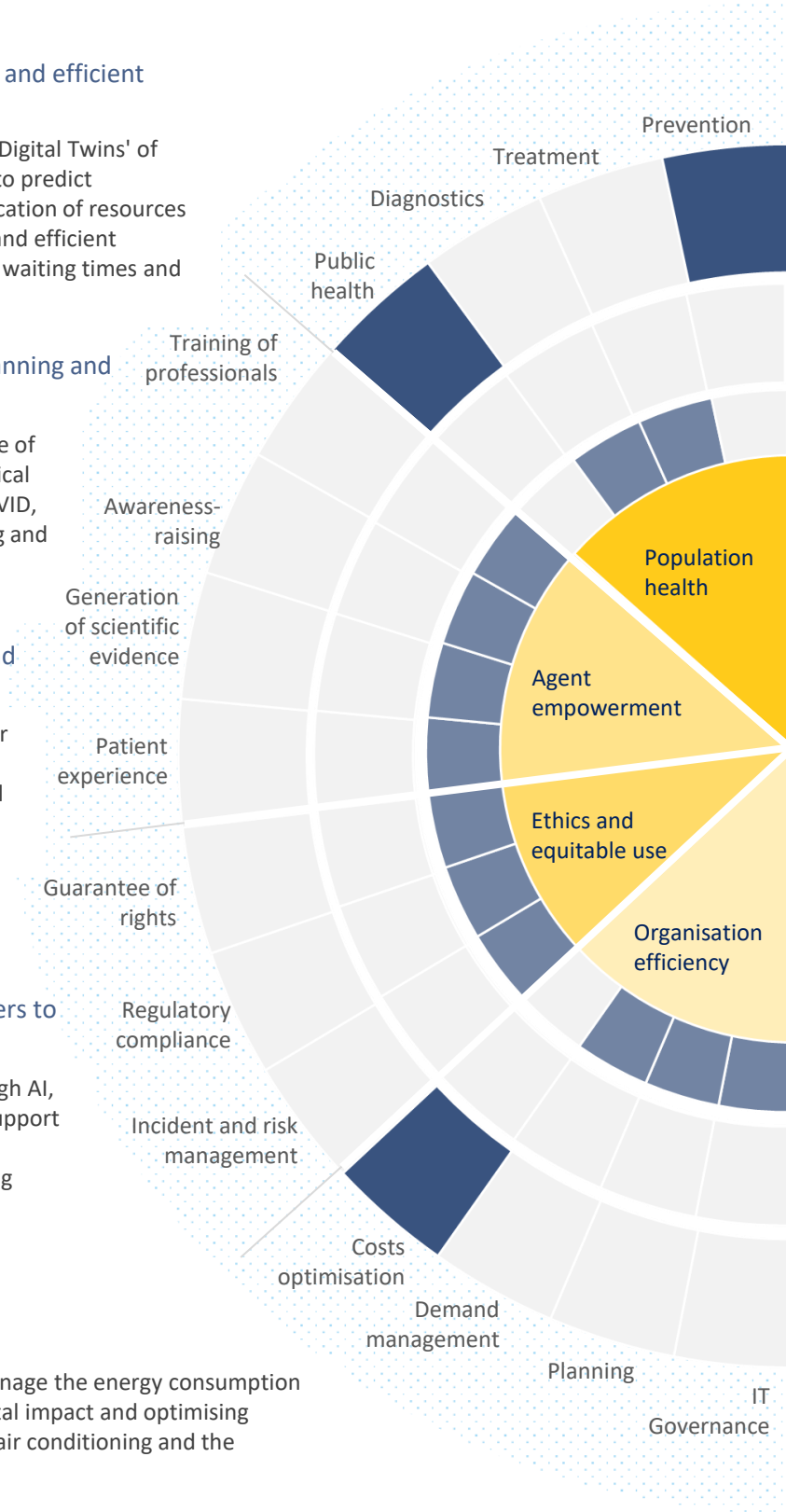
Develop AI tools to monitor population or collective data, detecting early alerts of infectious outbreaks and providing useful information for better decision-making during health emergencies.

4.4 **Process automation** to remove barriers to access and optimise service delivery

Implement intelligent automation, through AI, of administrative, logistical and clinical support processes, streamlining repetitive tasks, reducing operational costs and minimising possible errors.

4.5 **AI for energy optimisation in health infrastructures –** Green AI

Implement AI systems to analyse and manage the energy consumption of health facilities, reducing environmental impact and optimising energy costs through the automation of air conditioning and the efficient use of lighting.



The investment comes from **different funding sources and programs** deployed in the SNS Digital Health Strategy.

Allocated budget
(2020-2030)

€297M

€40M
Boosting data analytics
AI applied to medical imaging

2021
Sustainability, efficiency improvement, and equitable access to SNS

2022
Primary Care Transformation Plan

€26M
Data standardisation
Process reengineering
GT7: Use case development

€11M
PT3 - Data standardisation and normalisation
Advanced analytics

2022
Personalised Digital Care Plan

2023
National Health Data Space

€100M
Data analytics and information exploitation
Information interoperability

€120M[1]
Algorithms
AI Governance - Infrastructure
Training – Change Management

2025-2029
IASNS

[1] It is estimated that 45% of the amount of the 2021-2027 ERDF Healthcare pathway amounting to €223M will be dedicated to the implementation of AI solutions.

- *Global governance model*
- *Planning instruments*
- *Governance structures*
- *Cooperation tools*

AI governance in the National Health System

To ensure that the application of AI in the SNS is aligned with the fundamental principles of equity, quality, safety and sustainability, it is essential to establish a governance model that effectively articulates the joint action of all the stakeholders involved. This federated model aligned with the competency configuration of the SNS, must allow not only to coordinate the implementation of AI solutions, but also to regulate, monitor and evaluate them in a coherent, agile and transparent way

5

AI governance in the national health system

Global governance model

"The safe, coordinated and equitable deployment of AI in the SNS requires a federated model of governance that guarantees the coordination of the different s involved in the implementation, regulation and oversight of technological solutions.

1 Planning instruments

eIASNS

Strategy for the implementation of AI in the SNS: strategic objectives, governance model and impact indicators.

SNS coordinated programs

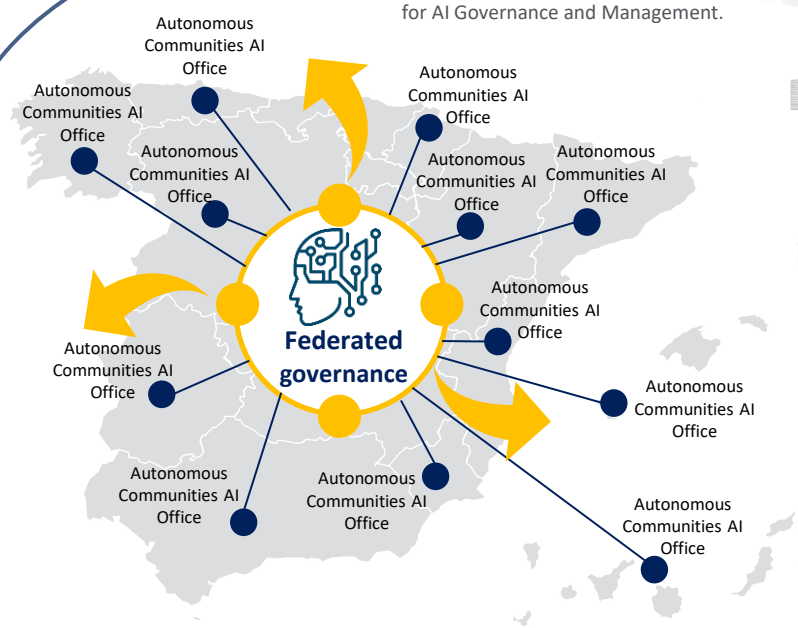
Collaborative execution programs with AI deployment projects in: IASNS, GT7 PTDAP, ADP, Sustainability...

Global Guidelines and European Initiatives

Applicable European regulations and coordinated programmes at national and international level.

Autonomous Community Initiatives

Governance initiatives and Health Services and Autonomous Communities projects for AI Governance and Management.



SNS AI Office

Support and coordination in the development of algorithms and the implementation of AI systems. Definition of tools and methodology. Monitoring and tracking the use of AI.
Coordination with supervisory bodies (AESIA, AEPD, COM).

2 Governance structures for AI

Autonomous Communities AI Offices

Deployment of AI in Health Services. Risk monitoring and management.
Coordination with MSAN (Ministry of Health) and national entities.

3 Cooperation and collaboration tools

Test space

Environments for algorithm validation and controlled testing, data access, and model training. Access from the Marketplace.

Marketplace

Repository of algorithms catalogued according to the methodology and standards defined in the SNS; and creation of environments for the validation and controlled testing of algorithms, access to data and training of models

Assessment and regulations

Tools and methodology for the validation of regulatory compliance and evaluation of the use of algorithms.

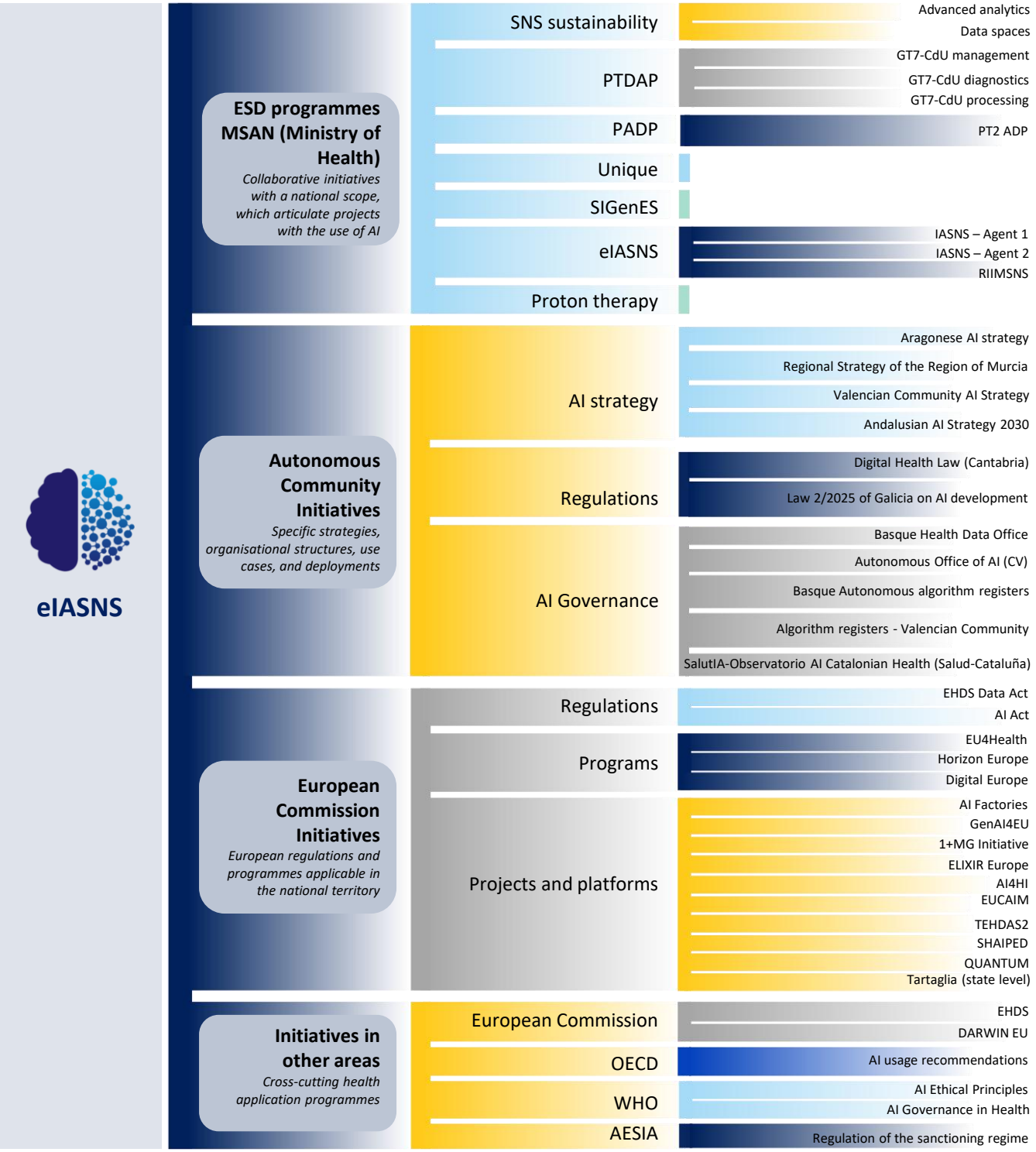
Education / training

Itineraries of training in application regulations, challenges of use and technical capabilities of AI in health.

Agents involved MSAN (Ministry of Health) Autonomous Communities

Planning instruments: Strategic guidance for coordinated AI deployment in the SNS

With the eIASNS strategy as a framework, **a shared vision** will be established, common objectives will be set and coherence between regional and national initiatives will be ensured



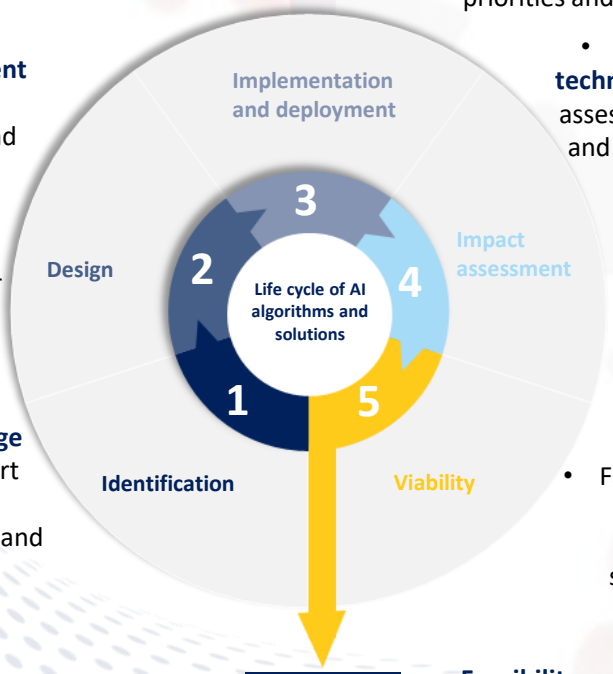
AI governance structures **will enable operational decisions to be aligned** with agreed strategic objectives.

SNS

IASNS Office

Support for equitable coordination of AI in the SNS.

- Coordinate, monitor and update the progress of the **AI strategy** in the SNS. Ensure its alignment with national and regional programmes and European guidelines.
- Ensure a **homogeneous, equitable and coordinated incorporation** of AI solutions in the SNS, supporting administrations in their deployment and use.
- **Coordinate the development** of AI algorithms through common methodologies and frameworks.
- Support the **regulatory oversight** of AI solutions, offering guidelines for their accreditation and risk assessment in accordance with the ENS.
- Foster **structured knowledge about AI** in health to support evidence-based decisions through reports, indicators and best practices.
- Support and provide resources to **ensure regulatory and ethical compliance** in the use of AI solutions, especially in high-risk cases.
- Define metrics and perform monitoring and **economic impact** of AI implementation in the SNS



Autonomous Community AI Office

Autonomous Communities

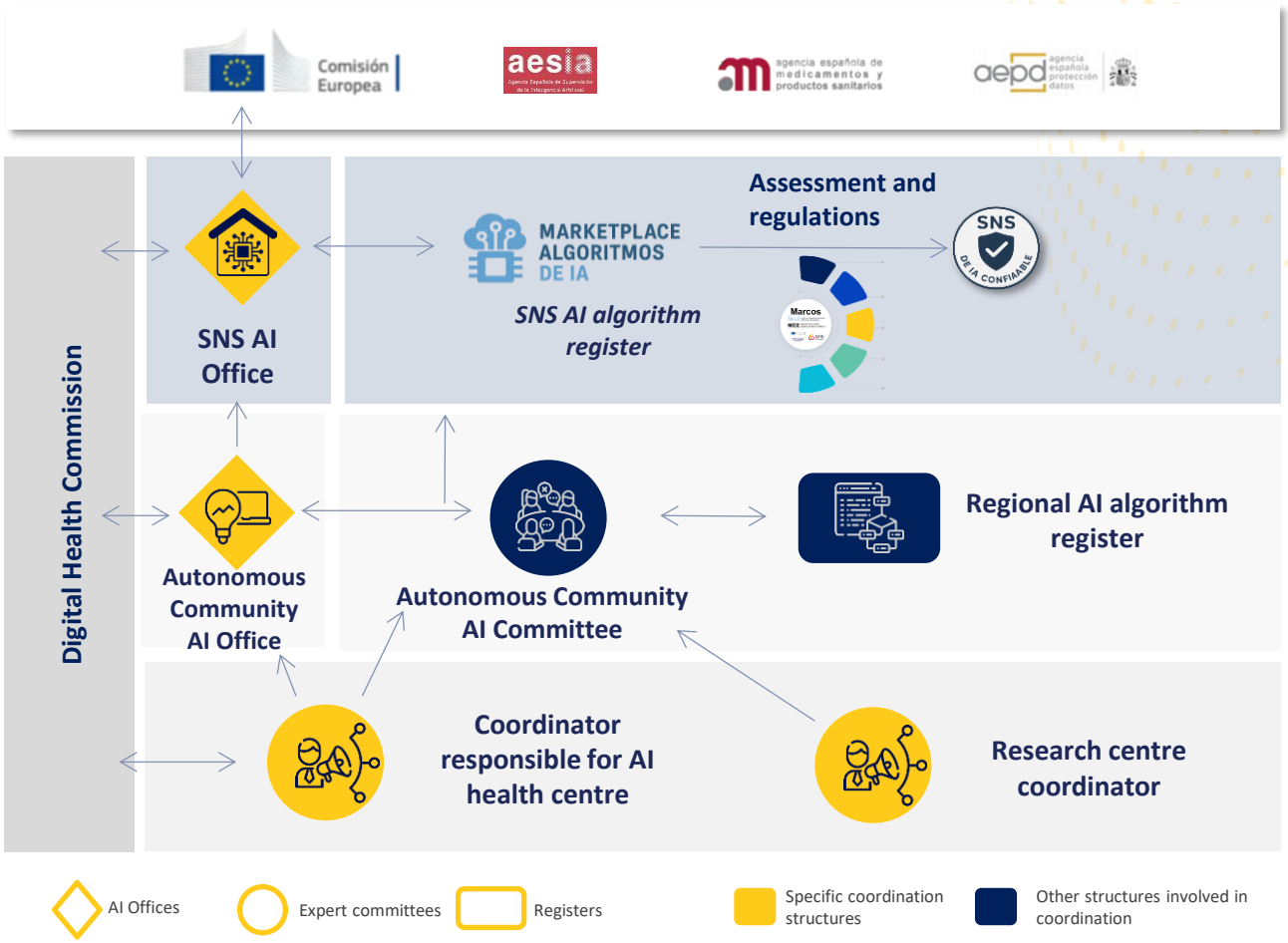
Body responsible for overseeing the incorporation of AI into the health service, ensuring its alignment with European, national and regional guidelines.

- **Coordinate the Autonomous Communities' AI in Health plans**, ensuring their alignment with the national strategy, the eIASNS program, and their adaptation to regional priorities and capacities and stakeholders.
- Provide **methodological and technical support** to AI initiatives, assessing and prioritising projects and providing resources for their comprehensive analysis.
- Promote the **governance and monitoring** of the life cycle of AI solutions in health, from their implementation to their retirement.
- Facilitate resources to **ensure regulatory and ethical compliance** in the use of AI solutions, **model monitoring** and incident reporting.
- **Feasibility and security analysis** of new AI solutions and coordinate their planning, deployment and monitoring.
- **Promote and lead the training of professionals** in the safe and responsible use of AI, in coordination with national and regional training plans.
- Perform monitoring and **economic impact** of the implementation of AI in regional health systems.

The Autonomous Communities' AI governance structures and the IASNS office will cooperate at different stages of the life cycle of AI algorithms and solutions, ensuring regulatory compliance and alignment with global guidelines and programs.

The AI governance structures in the SNS must establish **coordination mechanisms between different entities.**

The IASNS Office will support coordination and dialogue with the entities and bodies that the European Commission defines for the governance and control of AI, as well as with the state agencies with competence in the matter: AEMPS (Spanish Agency of Medicines and Medical Devices), AEPD (Spanish Data Protection Agency), and the newly created Spanish Artificial Intelligence Supervision Agency. In the Autonomous Communities, AI committees are already being articulated **at the regional level and AI governing bodies** in health that channel the needs and demands of health centres and research entities.



Governance structures will need **tools for cooperation and** collaboration to facilitate **coordination** between the different levels and stakeholders of the SNS, align initiatives, exchange good practices, and the progressive and coherent integration of AI into the health system.

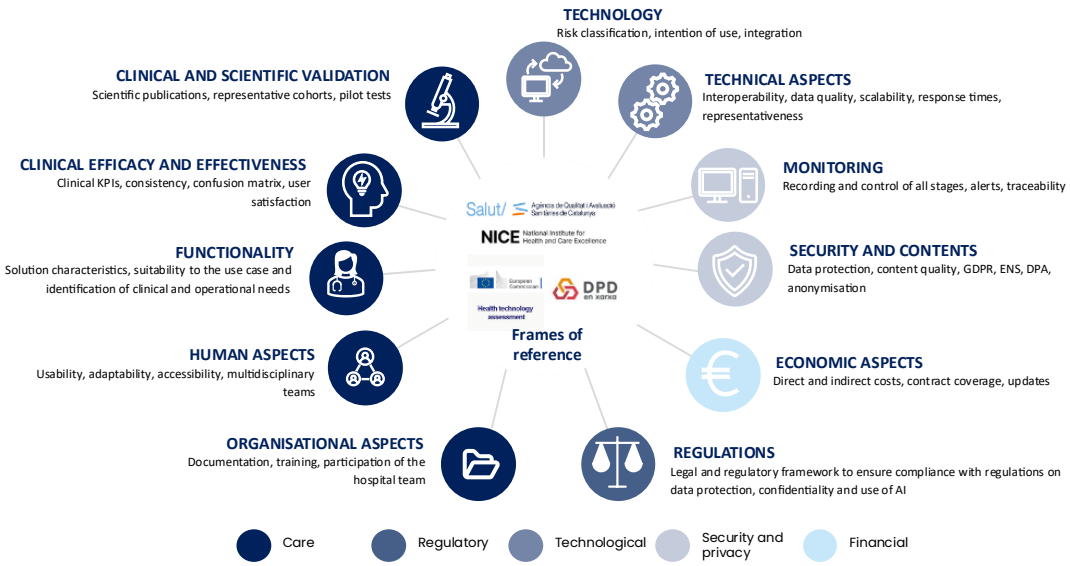
1. ***Marketplace* algorithms**
2. **Assessment and regulations**
3. **Education / training**

SNS Seal (algorithm valuation)

The assessment of the **algorithms implemented in the SNS** based on a common methodology and ensuring compliance with the applicable regulatory framework according to their category and use, will be one of the cooperation instruments that will be enabled within this strategy.

This process, **based on national and international reference frameworks**, establishes the following valuation dimensions: **regulatory, technological, care, safety and economic.**

Based on this process, the solutions will be awarded the **SNS Seal**, a badge of conformity that will differentiate the algorithms that **satisfactorily pass the proposed technical and regulatory assessment process.** The SNS seal does not limit publication in the Marketplace, acquisition and implementation to those solutions that have it, but means that the validation, whose criteria will be public, has taken place**. It is an instrument that makes it easier for the Autonomous Communities to know the characteristics of the AI tool,** although it does not exempt or replace any other validation or evaluation process required by the applicable regulations.



Education and training

The **education and training of SNS professionals** in AI, in addition to responding to the literacy obligation determined in the AI Act, is a key need for the promotion and adoption of artificial intelligence, as has been prioritised by the Autonomous Communities in the previous analysis process carried out.

The knowledge of the possibilities of AI and **use cases** applicable in the different healthcare areas, the **regulatory** derivatives, or the **technical and use aspects** of the algorithms, will allow the advancement of the adoption of solutions in the SNS.

*Within the **eIASNS framework**, training and education initiatives will be promoted in virtual and face-to-face format to advance knowledge of the multiple dimensions in which the use of AI in the SNS impacts.*

IASNS Marketplace

The IASNS Marketplace will constitute a centralised digital platform that will allow the Autonomous Communities to access an inventory of **AI tools, algorithms, models and technological resources** in a structured and transparent way. It will collect, among others, the identification and classification data required by the AI Act, and will implement the process of obtaining the SNS seal, so it will act as a register of artificial intelligence solutions for the SNS, without prejudice to the existence of regional registers.

Centralised access to a **catalogue of commercial algorithms developed by the Autonomous Communities** previously validated as a resource for the SNS as a whole.

Common governance and good practices model for the implementation and management of AI solutions in the SNS

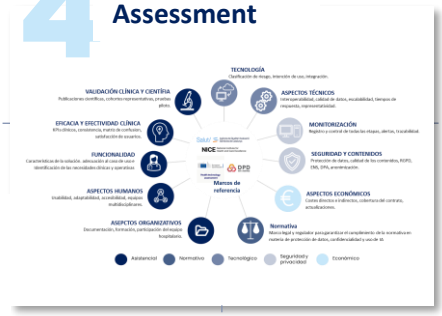
Process of incorporation of algorithms into the Marketplace and obtaining the SNS seal

1 Algorithm identification
Self-development algorithms

2 Initial profiling
Business algorithms

3 Publication of algorithms in the Marketplace

4 Assessment



5 Obtaining the SNS seal

The **technical assessment** process aims to verify the **level of compliance with requirements of transparency, security and regulatory adequacy**, economic assessment and **licensing model of** the algorithms.

In a second phase, the Marketplace will incorporate AI solution governance capabilities, allowing access to test environments and data sets for algorithm training.

AI Indicators and impact

Investments in Artificial Intelligence will transform healthcare organisations and optimise current delivery models.

The impact of its application in the SNS must be monitored based on a set of indicators that enable offering a joint vision of its contribution and measure whether the objectives set out in the eIASNS have been achieved.

6

The implementation of the **eIASNS** Action Plan initiatives will be assessed through a set of indicators designed to measure the degree of progress and impact on the **four lines of transformation** that make up the strategy:

reliability, professionals, patients and sustainability. To monitor the progress of the implementation of AI in the SNS, indicators are proposed with an **intermediate milestone** in 2027 and a **final goal in 2030.**

Reliability

		2027	2030
1	Artificial Intelligence algorithms evaluated and catalogued based on the ethical, regulatory, clinical and safety criteria established in the SNS.	200	500
2	Health professionals from the SNS who have received specific training in the technical, regulatory, ethical and safety dimensions of Artificial Intelligence.	50,000	87,500
3	Degree of adoption and use of collaborative testing controlled spaces.	25%	60%

Utility

1	Percentage of SNS health professionals who have access to Artificial Intelligence in making personalised clinical and therapeutic decisions.	10%	>60%
2	Number of medical images analysed using Artificial Intelligence algorithms to contribute to early detection and diagnostic accuracy.	1 MM	25 MM
3	Number of agents based on Artificial Intelligence used by professionals to support the management and optimisation of their daily activity.	50	250

Humanism

1	Patients who have access to AI tools in the NHS for personalised monitoring and remote monitoring of their chronic pathologies.	20,000	500,000
2	Patients who have benefited from personalised diagnoses, interventions, or treatments supported with the use of AI tools.	100,000	500,000
3	Interactions of patients with virtual assistants for the resolution of doubts, appointment management and healthcare.	10 MM	40 MM

Universality

1	Automated administrative and logistical processes using Artificial Intelligence to improve the management and optimisation of resources.	50	200
2	Predictive models and tools based on Artificial Intelligence to support possible public health alerts.	15	50
3	Number of healthcare facilities using AI for intelligent consumption management such as HVAC and lighting and other supplies.	75	150

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