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Interconnecting Innovation Ecosystems for Common European Data Space in Health



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Executive Summary

The present Deliverable 2.5 “Case Study Spain” has been developed within the framework of WP2 “Analysis of ecosystems and innovation agendas” of **EDAH**.

EDAH (Interconnecting innovation ecosystems for common European data space in Health) is a 2-year preparatory action funded by Horizon Europe that aims to contribute to the development of the European Health Data Space. The 4-partners-consortium seeks to establish close collaborations with the EU presidencies during the project’s lifetime, to help prioritise EHDA in their successive agendas. EDAH also seeks to engage a wide range of quadruple helix stakeholders from diverse innovation ecosystems across Europe in identifying barriers and enablers to EHDS, channelling the different Member States’ inputs into EU policy processes. By bridging the current digital health divide in Europe, EDAH contributes to the New European Innovation Agenda with more inclusive, dynamic, diverse and interconnected European innovation ecosystems.

EDAH aims to unlock the power of health data for innovative medicines and future healthcare by helping develop the European Health Data Space.

The project’s key milestones are:

1. Set an open dialogue to facilitate the agreement among Member States, Associated Countries and EU Regions about key aspects related to EHDS.
2. Advancing towards common legal, governance, data quality and interoperability framework to facilitate the advancement of EHDS.
3. Scaling up good practices and addressing important gaps in the regional and national innovation ecosystems, through a better understanding of the digital health innovation landscape.

The following report is the fifth of a series of 7 case studies envisaged in this project (namely Portugal, Czech Republic, Sweden, Bulgaria, Spain, Belgium and Hungary). The studies are connected to the EU presidencies happening during the timespan of this preparatory action, from September 2022 to August 2024, corresponding to the end of Czech Republic’s, Swedish, Spanish, Belgian and the initial weeks of Hungarian Presidency.

Spain assumed the rotating presidency of the Council of the European Union on July 1st until December 30th, 2023, the fifth time that Spain takes this role since it became a member of the EU in 1986. Belgium and Hungary will hold the presidency in 2024. The “trio” formed by these three consecutive presidencies has adopted a joint programme with some priorities related to health: “The trio will work to further strengthen the **EU Health Union and the resilience of health systems** that are accessible to all”, “reinforcing the EU’s global competitiveness by strengthening our industrial base in line with the accelerated twin green and **digital transitions** and making use of innovation”. No direct reference to digital health or health data in the 18-month Programme of the Council (1 July 2023 - 31 December 2024)¹. The Spanish presidency programme is more explicit in priorities related to health data and digital transformation of

¹ <https://data.consilium.europa.eu/doc/document/ST-10597-2023-INIT/en/pdf>

health systems. The third priority, “Promote greater social and economic justice” includes as a line of action “Complete the European Health Union, creating a European Health Data Space and strengthening EU action on caregiving and mental health”.²

The present case study provides an overview of the Spanish health innovation ecosystem, the legal framework EHDS regulation will face, Spain’s innovation agenda, good practices, synergies with other initiatives and a SWOT analysis of Spain’s readiness to adopt EHDS.

As a summary, Spain is situated in the south-west of Europe, sharing borders with Portugal, France, and Andorra. With an area of 505,990 km², this is the 6th largest country in Europe, and one with a high share of EU27 population (over 10%, with its 47.4 million³) and a per capita GDP of approximately €50,506.64.⁴

The political form of the Spanish State is a parliamentary monarchy. The exercise of the legislative authority of the State belongs to the General Courts, composed of two Chambers: The Congress of Deputies and the Senate. The Spanish State comprises three levels of governance: central, regional and local (Provinces and Municipalities). It is territorially organized into 17 self-governing regions (autonomous communities), 2 autonomous cities (Ceuta and Melilla), 50 provinces and 8.131 municipalities. The so-called “Autonomies” have a autonomy for the management of their respective interests.^{5,6}

Spain is considered one of the healthiest countries in the World.⁷

The **Spanish National Health System (SNS)**, operating under statutory regulations, offers nearly universal coverage, primarily funded through taxes, and delivers care predominantly through the public sector. Services are provided free of charge at the point of delivery, except for certain outpatient pharmaceutical prescriptions and specific orthoses and orthopaedic prostheses.

Since 2020 there has been a significant progress in Spain towards EHDS, with the creation of specific Government units for digital health, launching of funds and instruments like the “Vanguard Health” PERTE (special strategic projects of interest) and the proposal for a creation of a Spanish Data Lake. The following report reviews the main assets, needs and opportunities towards EHDS for Spain as a case study for EDAH.

² <https://spanish-presidency.consilium.europa.eu/media/e4ujaagg/the-spanish-presidency-programme.pdf>

³ <https://www.ine.es/>

⁴ <https://data.oecd.org/spain.htm#profile-health>

⁵ <https://www.lamoncloa.gob.es/espana/organizacionestado/Paginas/index.aspx>

⁶ <https://portal.cor.europa.eu/divisionpowers/Pages/Spain-intro.aspx>

⁷ <https://www.statista.com/statistics/979667/20-healthiest-countries/>

Introduction to this report

Specific objectives of EDAH

The partnership implementing EDAH has five specific objectives:

- O1 – Ensuring a coherent overview of the (ongoing) strategic developments related to the European Health Data Space (EU level policy processes, important initiatives and projects) and developing a deeper understanding of seven important EU ecosystems (innovation agendas and ecosystem stakeholders) represented by clusters/networks from Portugal, Czech Republic, Sweden, Bulgaria, Spain, Belgium, and Hungary.
- O2 – Setting up a coordination mechanism to connect important stakeholders from innovation ecosystems all around Europe and engage them in focused dialogue around key challenges and opportunities related to advancing the EHDS.
- O3 – Scaling up the dialogue at the EU level via developing further collaboration pathways with EU presidencies.
- O4 – All of the above will be used for, step-by-step, developing, validating and finalising the Joint Action Plan (JAP) for synergetic work in the interconnected ecosystems of EU health-related clusters/ networks (facilitated by the dialogue mechanisms and collaboration frameworks developed in this project) to jointly advance the development of the EHDS.

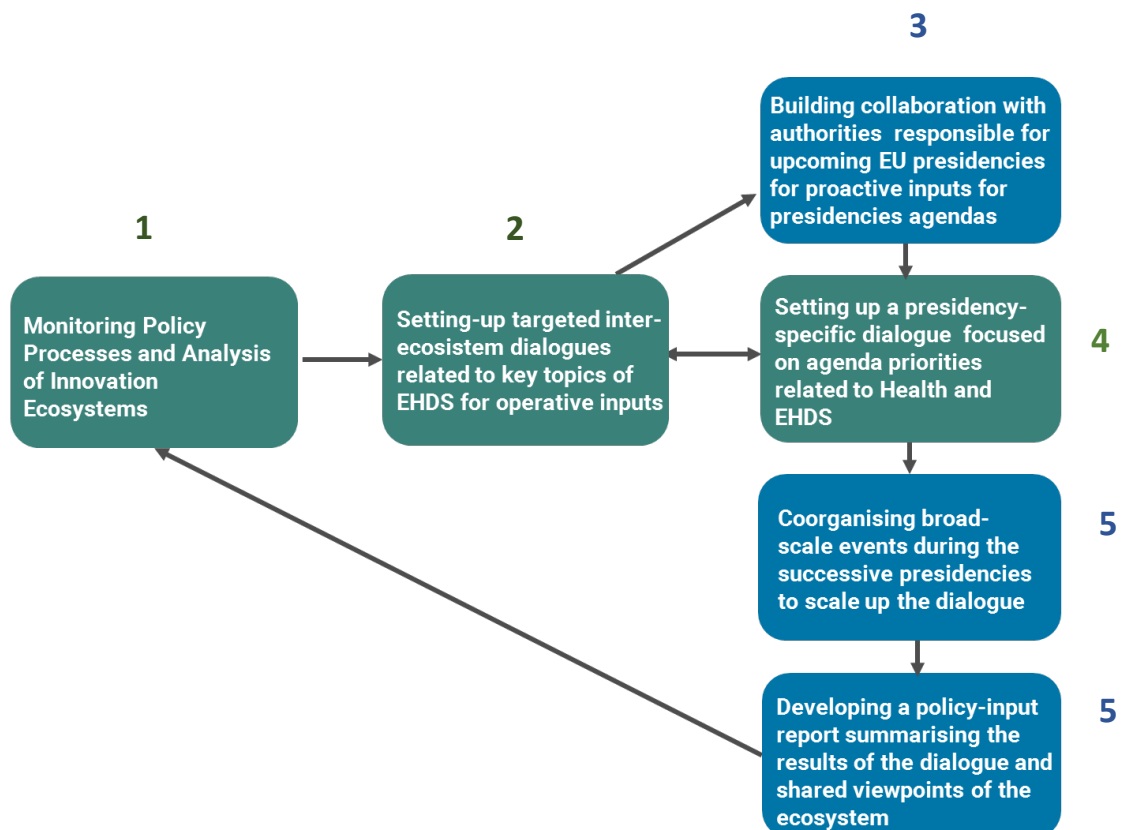


Figure 1: Workflow of the EDAH project: step 1 is the analysis of Innovation Ecosystems

List of consortium partners and beneficiary numbers

Beneficiary #	Name	Acronym	Country
1	BIOCAT LA FUNDACIO BIOREGIO DE CATALUNYA	Biocat	ES
2	HEALTH CLUSTER PORTUGAL	HCP	PT
3	SCANBALT	ScanBalt	EE
4	COUNCIL OF EUROPEAN BIOREGIONS	CEBR	BE

Work Package 2 – Analysis of ecosystems and innovation agendas

Objectives

- Monitoring and analysing strategic EU-level processes related to the development of the European Health Data Space;
- Getting in-depth understanding of seven key innovation ecosystems, namely in Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria;
- Based on the above, identifying good practices, potential for synergies and complementarities in innovation agendas and with ongoing initiatives/processes to advance the development of EHDS as a joint effort of EU interconnected innovation ecosystems.

Task 2.1 Scanning strategic developments regarding European Health Data Space

The consortium will continuously track advancements in various important EU-level policy processes, monitor progress related to initiatives such as TEHDAS and GAIA-X (e.g., key milestones achieved), relevant new studies and analyses, etc. This information will be processed and analysed to identify potential synergies, needs for action and inputs by EDAH to support important developments in line with the idea of more dynamic, inclusive, gender diverse, and connected innovation ecosystems for the joint development of the European Health Data Space, fostering innovation in industry and the public sector.

The work under this task will materialise into monthly Strategic Progress Updates (SPUs) prepared for the monthly EDAH Coordination Working Group meetings. The SPUs will cover the key developments as well as suggestions for related response and actions in the context of the EDAH project.

Task 2.2 Carrying out case studies

Case studies on seven key EU clusters/networks/ecosystems will be carried out in order to 1) facilitate learning from various good practices of strong EU clusters/networks in advancing digital health and related innovation in their regions/ countries as well as good practices related to quadruple helix collaboration; 2) reach a better understanding of the ecosystems and innovation agendas of these clusters/networks; 3) five case studies will additionally focus on the possibilities of advancing specific topics related to the EHDS in the context of the upcoming EU presidency in the clusters'/networks' country of origin. The clusters/networks selected for case studies represent Czech Republic, Sweden, Spain, Hungary, Belgium (five countries holding the EU presidency during the lifespan of the project), Portugal (partner of EDAH) and Bulgaria (as an example of Emerging Innovator, to get insights about key needs for development in terms of digital health and related ecosystem in such context).

1 – Spanish Ecosystem Overview

1.1 – Country Overview

Situated in the South-West of Europe, Spain shares borders with Portugal, France, and Andorra. It has an area of 505,990 km² making it the 6th largest country in Europe, with a population of around 47.3 million⁸. Spain possesses an economy that exhibits a per capita GDP of approximately €50,506.64.⁹

The political form of the Spanish State is a parliamentary monarchy. The Government is composed of the President, the Vice Presidents, if applicable, and the Ministers. The exercise of the legislative authority of the State belongs to the General Courts (Cortes Generales), which represent the Spanish people and oversee the actions of the Government. They are composed of two Chambers: The Congress of Deputies and the Senate. The Spanish State is territorially organized into municipalities, provinces, and 17 autonomous communities, with autonomy for the management of their respective interests.¹⁰

1.2 - National Health System

The **Spanish National Health System (SNS)** is a decentralized structure (General Health Law of 1986¹¹), with two main actors: the **Ministry of Health** and the **Departments of Health in the 17 Autonomous Communities (ACs)**, in line with the territorial organization of the State. Related to that is relevant to highlight the multiplicity of providers of health services.



Figure 1: Autonomous Communities in Spain depicted in colors according to the public resource usage as an analysis of the efficiency of the Health Systems. Source: <https://www.sciencedirect.com/science/article/abs/pii/S0033350616000949>

⁸ <https://data.oecd.org/spain.htm#profile-health>

⁹ <https://data.oecd.org/spain.htm#profile-health>

¹⁰ <https://www.lamoncloa.gob.es/espana/organizacionestado/Paginas/index.aspx>

¹¹ <https://www.boe.es/buscar/act.php?id=BOE-A-1986-10499>

During the 1980s and 1990s, the process of health decentralization took place with the transfer of competencies to the Autonomous Communities in matters of health (Royal Decrees). Additionally to the significant degree of self-governance of the 17 Autonomous Communities (ACs), the Institute for Health Care Management (INGESA) is responsible for the organisation and management of public health care services in the territorial scope of the Cities of Ceuta and Melilla. Since 2013, INGESA has been tasked with organizing centralized procurement and public auctions for specific goods and services, including certain medicines. This is done on behalf of the Autonomous Cities that have formally agreed to participate in this shared service.

The system is **financed** as per an agreement where the Spanish Government allocates taxes and establishes levelling subsidies based on formulas related to the population's needs, according to the Finance Framework laws of 2001 and 2009. Operating under statutory regulations, it offers nearly universal coverage, primarily funded through taxes, and delivers care predominantly through the public sector. Services are provided free of charge at the point of delivery, except for certain outpatient pharmaceutical prescriptions and specific orthoses and orthopaedic prostheses.

The **Spanish Ministry of Health** does not deliver healthcare services but takes on the role of supervision and coordination, with support from the **Interterritorial Council for the SNS** (Consejo Interterritorial del Sistema Nacional de Salud, CISNS). The CISNS is a governing body composed of representatives from the 17 regional Ministries of Health, along with the highest-ranking officials from the National Ministry of Health, namely the Health Minister of Spain and the Health Regional Ministers, also known as counsellors. Its purpose is to promote the cohesion of the National Health System through the effective guarantee of the rights of citizens throughout the territory of the State.

Within the Ministry of Health, the **General Secretariat of Digital Health, Information and Innovation of the National Health System** is the governing body responsible for addressing projects for the modernization, innovation, improvement and transformation of the National Health System, particularly those related to digital health and information systems.

Additionally, four specialized bodies assist the Ministry:

- [The Spanish Agency for Medicines and Health Products](#) (AEMPS)
- [The National Institute of Health Management](#) (INGESA)
- [The National Transplant Organization](#) (ONT)
- [The Foundation for Health, Childhood and Social Welfare](#) (CSAI)

Other interested ministries have specific roles related to the health system (innovation and digitalisation):

- The **Ministry of Science and Innovation**, with its [Institute for Health Carlos III](#) (Instituto de Salud Carlos III, ISCIII). The ISCIII combines health technology assessment, research centres, public health services, and the coordination and financing of biomedical research.
- The **Ministry of Economic Affairs and Digital Transformation**, with the State Secretariat of Digitalisation and Artificial Intelligence, responsible for the Spanish Health Data Lake.

Health indicators

Spain's health spending has increased in recent years but remains below the EU average. In 2022, the per capita public health expenditure in Spain was 2,061 euros per inhabitant, accounting for 7.37% of GDP.¹² Conversely, Spain's out-of-pocket payment levels are above the EU average (6,4% higher in expenditure in 2019), due mainly to co-payments for drugs, medical devices outside hospitals and dental care.

The public health indicators in the country show that women in Spain have a life expectancy of 86.6 years, while men have a life expectancy of 80.9 years at birth.¹³

In recent years, the main causes of death in Spain have been ischemic heart disease, stroke, and lung cancer. These health challenges are further compounded by significant public health concerns related to smoking, alcohol consumption, and obesity.

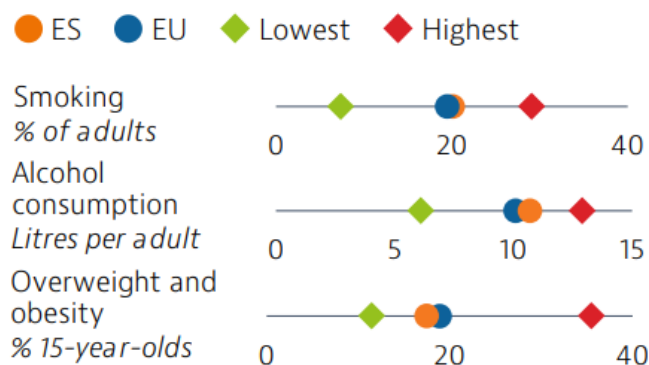


Figure 2: Risk factors for health in Spain. Source: Country Health Profile Spain 2021

Before the pandemic, the Spanish health system was considered by Bloomberg (2018) to be the most efficient in Europe and the third most efficient in the world after Hong Kong and Singapore¹⁴. Although the COVID had a huge impact on the Spanish Health system, it's worth mentioning that the vaccination campaign exhibited rates significantly higher than the EU average.

In recent years, there has been an increase in the numbers of doctors and nurses in Spain, although temporary contracts have also risen. The number of doctors per 1,000 inhabitants is slightly above the EU average, while the proportion of nurses (excluding nursing assistants) is still notably lower at 5.9 per 1,000 inhabitants compared to the EU average of 8.4. Additionally, the utilization of temporary contracts within the SNS has grown over time, with 41.9% of all employees being on temporary employment contracts in 2020, up from 28.5% in 2012.¹⁵

Spain has a network of 800 public and private hospitals. Fourteen of them were named in 2022 among the 250 best in the world¹⁶. The number of hospital beds in SNS hospitals has remained

¹² <https://datosmacro.expansion.com/estado/gasto/salud/espana>

¹³ https://www.sanidad.gob.es/estadEstudios/estadisticas/sisInfSanSNS/tablasEstadisticas/InfAnualSNS2020_21/Inf_anual_2020_21_Res_Ejecutivo.pdf

¹⁴ The Bloomberg Report measures the efficiency of health systems by life expectancy, per capita spending on health and the percentage of GDP spent on health

<https://www.bloomberg.com/news/articles/2019-02-24/spain-tops-italy-as-world-s-healthiest-nation-while-u-s-slips>

¹⁵ INE 2021

¹⁶ <https://www.newsweek.com/worlds-best-hospitals-2022>

low, with only 3 beds per 1,000 population, in contrast to the EU average of 5.3 beds. However, there has been a notable increase in the number of long-term care beds, rising from 19.2 beds per 1,000 population aged 65 and over in 2005 to 43.7 beds in 2018.

Being accessibility to healthcare one of the primary focus for the health systems transformation, the country profile 2021 published by the European Observatory on Health Systems and Policies for the OECD stated that (in 2019) the percentage of the population in Spain reporting unmet medical care needs due to cost, distance, or waiting times was very low, with only 0.2%, well below the EU average of 1.7%, and minimal disparity is found between individuals in the highest and lowest income quintiles.¹⁷ The situation differed concerning dental care, as most people were not covered for dental services. In 2019, 5% of the population reported forgoing dental care due to financial reasons, distance, or long waiting times. Notably, this rate was much higher among those in the lowest income quintile (12%) compared to those in the highest (approximately 1%). It's important to acknowledge that the data from the Eurofound survey and the EU-SILC survey may not be directly comparable due to differences in methodologies.

As main subject of this case study it's also worth mentioning is in this overview the level of digitalization of the Spanish National health system. The Smart Health Systems International comparison of digital strategies¹⁸ ranks Spain fifth, behind Estonia, Canada, Denmark and Israel. The report points at the nationwide implementation of identification systems, digital medical records and prescriptions, patient portals and electronic appointments as main causes of this strong position.

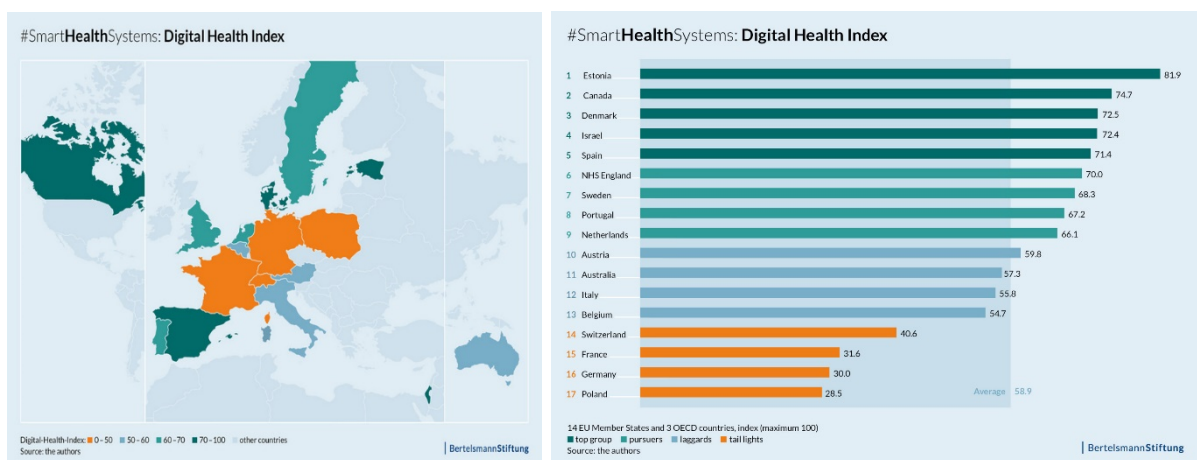


Figure 3: Map and ranking of 14 EU member states and 3 OECD countries according to their level of digitalization, provided by the 2018 Empirica report. Source: [https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der digitale Patient/VV_SHS-Studie_EN.pdf](https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der_digitale_Patient/VV_SHS-Studie_EN.pdf)

¹⁷ https://health.ec.europa.eu/system/files/2021-12/2021_chp_es_english.pdf

¹⁸ <https://www.bertelsmann-stiftung.de/en/our-projects/the-digital-patient/project-news/smarthealthsystems/>

eRecords and ePrescriptions

As gathered the report by Empirica and Bertelsmann Stiftung,¹⁹ the decentralized structure of Spain's healthcare system requires that any initiative must be agreed by the central government and the regions through above mentioned Interterritorial Council of the Spanish National Health Service. The need for a minimum electronic dataset of health-related data to be used and exchanged throughout the regions was recognized as early as 2002. However, this idea was only decided upon in 2010, and even then, it was non-binding.

At the Ministry of Health's website, there's specific information about the Digital Health Records of the National Health System (HCDSNS)²⁰, a system that allows the Autonomous Communities to share relevant clinical information on their citizens so that it is available electronically in any regional SNS service at the request of citizens. The entry point for each Autonomous Community It allows citizens and professionals to access clinical information regardless of where it was generated, guaranteeing the privacy of the clinical information, restricting their consultation to the professionals authorized and allowing the patient to know the accesses that have taken place. The key agents in this system are i) the Autonomous Communities responsible for implementing the technical and functional requirements that allow the communication of content and facilitating interoperability from their information systems, and ii) the Ministry of Health as coordinator and facilitator, by the Law on Cohesion and Quality and Law 41/2002 on Patient Autonomy.



Figure 4: Current situation of the clinical records in the different Autonomous Communities of Spain. The interactive [map](#) allows to see which kind of reports from the table in the right are available. The documents are: HCR (Summarised Clinical Record), ICAP (Clinical report of primary care), ICU (clinical report from emergency care), ICA (clinical discharge report), ICCE (external consultation report), IRPL (clinical report of laboratory tests), IRPI (clinical report of imaging tests), ICE (nursing care reports), IROPD (report of results from other diagnostic tests), EUPS (summary of EU patient), CP (population coverage).

Some Autonomous Communities have also implemented the Patient Summary (European Union Patient Summary), a document that collects the most relevant and essential clinical information

¹⁹ https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der_digitale_Patient/VV_SHS-Studie_EN.pdf

²⁰ <https://www.sanidad.gob.es/areas/saludDigital/historiaClinicaSNS/home.htm> (in Spanish)

from the patients' Electronic Medical Records so that professionals from other EU countries can provide care to any citizen who requests unscheduled healthcare outside their country.

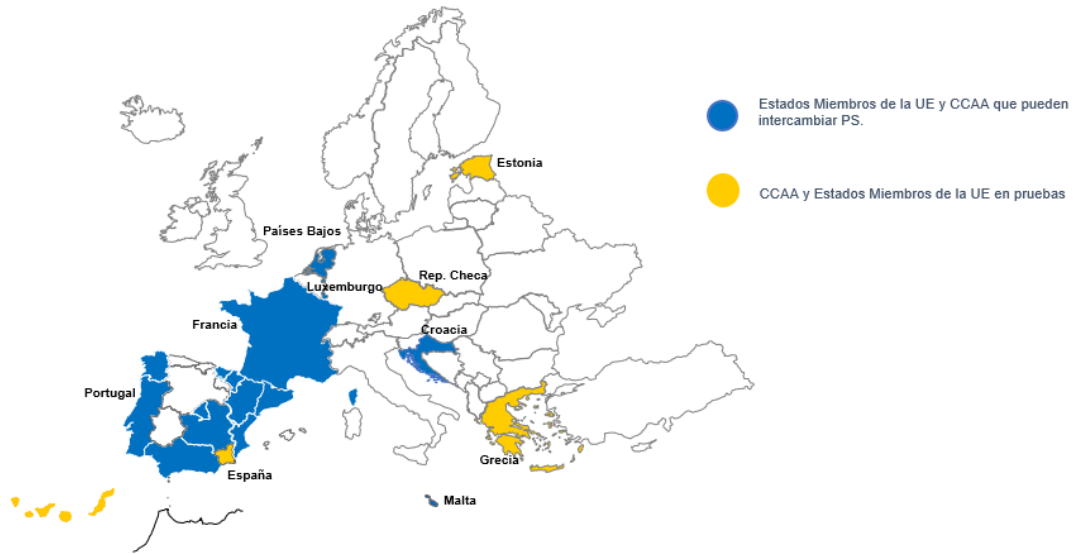


Figure 5: Blue: Autonomous Communities of Spain that can communicate EUPS reports and EU Member States with which they can operate. Yellow, Autonomous Communities and Member States with testing in progress. Source: Ministry of Health Spain June 2023.

As per ePrescriptions, the interoperable electronic prescription service of the National Health System (RESNS) allows the dispensation from any pharmacy, by electronic means, of the medication prescribed in another autonomous community. It is only necessary to present the individual health card. Spain participates in the MyHealth@UE project, under which a medicine prescribed electronically by a health professional in a patient's country of origin can be dispensed at any pharmacy in another country of the European Union. The Spanish electronic prescription interoperability project with the EU is coordinated by the Ministry of Health.

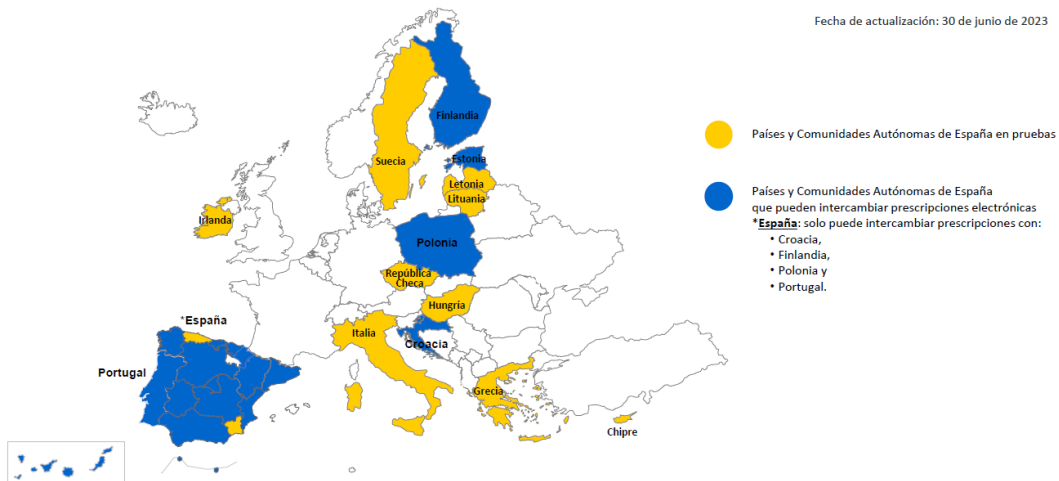


Figure 6: Blue: Countries and Autonomous communities that can interchange ePrescriptions. Yellow, Autonomous Communities and Member States with testing in progress. Source: Ministry of Health Spain June 2023.

1.3 - Life sciences and healthcare ecosystem

Spain has a dynamic healthcare industry, with a market size of over 1,000 companies, 500 of them manufacturers, and over 29,000 people work in the industry, according to Invest in Spain²¹

Industry associations



AseBio is the Spanish Bioindustry Association. The AseBio Report, published every year by the Spanish Bioindustry Association since 2003, is the benchmark publication for the Spanish biotechnology sector. It also provides information on production (pipelines) and technology transfer (patents) for Spanish biotechnology companies and on investment in the sector.



The **Spanish Federation of Healthcare Technology Companies, FENIN**, operates as an umbrella organization for Spanish companies in this sector. Fenin has developed the 'Index of Digital Maturity in Health', with the participation of the IT managers of the Health Services of the 17 Autonomous Communities. The index focuses on digital services for patients, for professionals, digital health IT infrastructure and analytical systems.



Farmaindustria is the National Trade Association of the Spanish based pharmaceutical industry. It gathers most of the R&D based pharmaceutical companies established in our country, representing nearly 100% of prescription medicine sales in Spain.



Ametic represents the digital industry in Spain. The size and nature of the organizations that are part of AMETIC are very varied, from SMEs to large global companies in the fields of Information Technology, Telecommunications, Electronic Industry, Digital Services and Content, Digital Transformation, Enabling Technologies, Banking, Energy, Sustainability, etc.

Patients

The effective participation of patients in the Health System and its transformation is ensured by the multiple patients' associations, many of them represented by the Platform of Patients Organisations.



The **Platform of Patient Organizations (POP)** is a non-profit organization that brings together state-level patient organizations, in order to unite their voices and exercise effective representation of the rights and health and socio-health needs shared by people with chronic diseases or chronic symptoms, before the main agents of the health sector in Spain. It gathers up to 1.796 associations.

²¹ <https://www.investinspain.org/en/industries/life-sciences>

Cluster organisations and networks

Health cluster organizations and associations of companies play a crucial role in the Spanish Health Ecosystem fostering collaboration, innovation, and growth within the sector. These entities bring together various stakeholders, such as healthcare providers, research institutions, biotech companies, medical device manufacturers, startups, and government bodies, to form a unified ecosystem dedicated to advancing the field of healthcare. Some of those umbrella organisations are indicated below, representing many more at regional, local and national level boosting innovation in the Healthcare sector.



AraHealth promotes innovation and competitiveness of the health sector in Aragón.



The **ARABIOTECH Cluster** is a networking organization that links the biotechnology companies in the region of Aragón.



The **Basque Health Cluster** is the association for the bioscience and health sector of the Basque Country.



BIOVAL is the Association of Companies and Entities in the BIO sector and which constitute the cluster of the Valencian Community



Biocat is a strategic stakeholder and catalyst for building, promoting and projecting the Catalan life sciences and healthcare ecosystem.



The mission of the **Barcelona Health Hub** association is to promote innovation in digital health and its transfer to the sector, linking startups, health organizations, companies and investors



TechBarcelona launched the Health Pier initiative to align stakeholders within the life sciences ecosystem. Located at Pier07 in downtown Barcelona, there's a health space to align innovation and business.



Bioga is a non-profit business association that supports the value chain of the biotechnology sector with activity in Galicia.



CataloniaBio&HealthTech is the entity that represents companies in the biomedicine and health sector in Catalonia.



The **Cluster de la Salud** is an intermediate, private and non-profit organization that houses companies from the social and health sector of Extremadura with the aim of improving their competitiveness through inter-company cooperation.



The **Cluster Saúde de Galicia** is a non-profit public-private professional collaboration platform that encompasses industries and institutions related to the Galician health field in a broad sense



The **Digital Cluster of Catalonia** is a private association that includes companies and entities in the Catalan ICT sector



BioMad is the bioregion of health and well-being, at the initiative of the Department of Health of the Community of Madrid, which will facilitate the coordination and ordering of the processes of management and execution of health research projects of a strategic nature in the Community of Madrid.



The Cluster **MAD e-Health** brings together all the stakeholders of the healthcare sector that primarily carry out their activities in the Madrid area.



The **Cluster Saúde de Galicia** is a non-profit public-private professional collaboration platform that encompasses industries and institutions related to the Galician health field in a broad sense



The **Cluster SIVI**, based in Castilla y León, brings together organizations of innovative technological solutions in the fields of active and healthy aging, mental health and independent life.



Ticbiomed is an association specialized in digital health. Its mission is to drive the Digital Transformation of European Healthcare



The **Xartec Salut** network, led by CREB UPC, is made up of 81 research groups of 23 different institutions. It aims to be a catalyst for R+D+I in the field of HealthTech



The Association **Digital Health Spain** puts in contact professionals are innovating in the field of Technology and Health, to share projects and experiences and collaborate with the private health sector for a progressive digitization of the services provided and define business models that help the sustainability of the health system.

Academia

Universities

The Spanish University System (SUE) consist of 84 universities with activity, 50 of which are public and 34 are private, carrying out R&D activities.²²

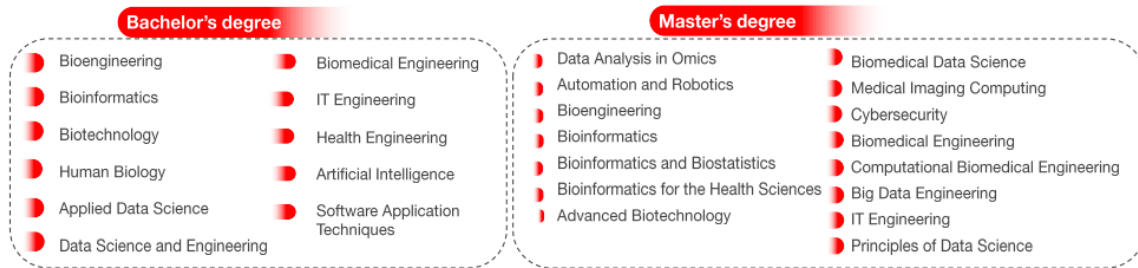


Figure 7: bachelor's and master's degree offered in Catalonia whose knowledge is applicable to digital health. Source: Digital health in Catalonia Technology Report. November 2022

Research Centres

The Institute of Health Carlos III (ISCIII) promotes the certification of health research institutes across the Spanish territories. The accredited Health Research Institutes are oriented towards individual health needs and from the perspective of society. They have effective governance, to guarantee the necessary resources and capacities, to fulfil the mission of generating scientific knowledge, the translation of which produces an impact for the improvement of the individual and society. All this, within the framework of Responsible Research and Innovation and Open Science, in compliance with the recommendations of the European Union. Currently 35 IIS are accredited by the ISCIII, in 13 Autonomous Communities, with more than 24,000 affiliated researchers.

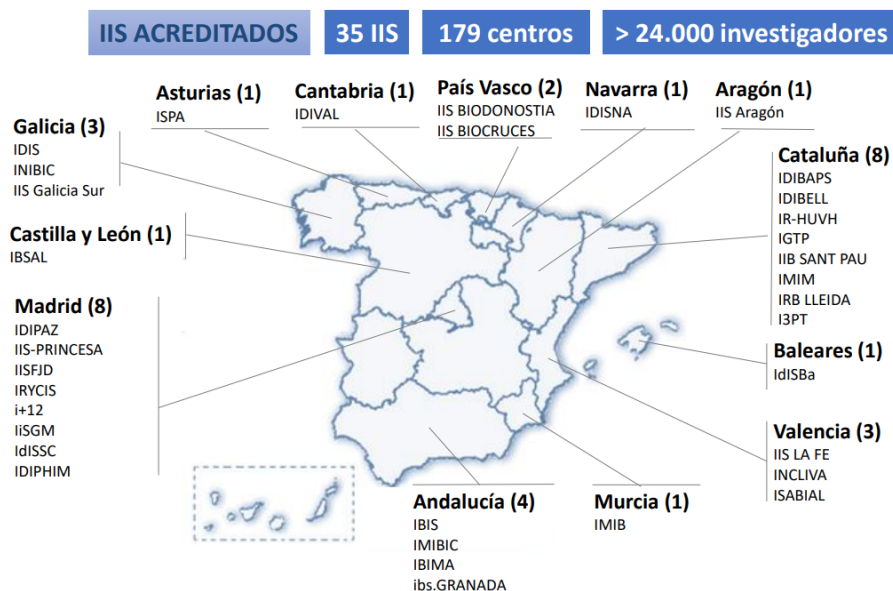


Figure 8: Geographic distribution of Health Research Institutes per Autonomous Community. Source: ISCIII²³

²² https://www.universidades.gob.es/wp-content/uploads/2022/11/Datos_y_Cifras_2021_22.pdf

²³ <https://www.isciii.es/QueHacemos/Financiacion/IIS/PublishingImages/Paginas/IIS-Acreditados/MAPA%20IIS.pdf> (in Spanish)

R&D centres

In addition, Spain is home to a network of 147 technological centres, fostering cutting-edge advancements across various industries, including healthcare. The country hosts 78 Science or Technology parks, serving as hubs for collaboration, innovation, and the commercialization of scientific and technological endeavours.²⁴

Hospitals

In Spain, the healthcare system is comprised of both public and private hospitals, collectively forming a robust network of about 900 medical facilities across the country (40% public and 60% private) and 300,000 professionals. While the majority of these hospitals fall under the public sector, there is a notable presence of private hospitals as well.

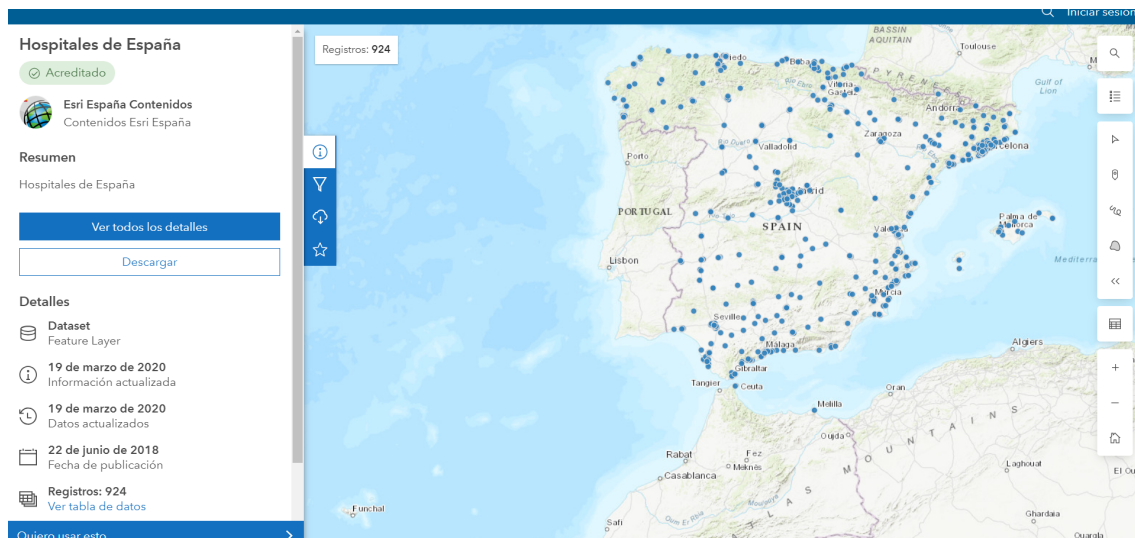


Figure 9: Open dataset of hospitals in Spain, licensed to the Ministry of Health and last updated on March 2020.²⁵

Healthcare levels

The National Health System is organized into two environments or levels of care: Primary Care and Specialized Care. Spontaneous access by citizens and technological complexity are inversely related.

The Primary Care is characterized by its accessibility and ability to comprehensively address the most frequent health problems. Health promotion, education, prevention, maintenance and recovery, rehabilitation and social work are concentrated in Primary care. In 2018, the number of SNS health centers and Primary Care clinics was 13,000 (3,000 health centers, 10,000 clinics and 2,000 extra-hospital emergency care points).

The Specialized Care includes assistance, diagnostic, therapeutic and rehabilitation and care activities. It has the diagnostic and/or therapeutic means of greater complexity and cost within the system and they are accessed by indication of the Primary Care physicians.

Specialized care is provided in specialized centers and hospitals, on an outpatient basis or on an admission basis. In 2018 there were 457 hospitals, with 110,000 beds, 4,000,000 million hospital admissions with a global average stay of 7.8 days. Specialized Care also has Reference Centers,

²⁴ <https://www.ciencia.gob.es/Estrategias-y-Planes/Sistema-de-Informacion-sobre-Ciencia--Tecnologia-e-Innovacion--SICTI-/Datos-globales-del-sistema/Red-Espanola-de-Centros-de-I-D-I--RECIDI-.html>

²⁵ <https://opendata.esri.es/datasets/68745a7fb7a348b6b0d722c8517790af/explore>

Services and Units (CSUR) for the care of complex pathologies that are not very prevalent or that require a high level of technological and professional specialization. In 2018, there were 281 reference centers, services and units for the treatment of 63 pathologies.

Companies

Spain boasts a diverse landscape of 512 health & tech corporates encompassing various types of technologies. 25 of them are large companies specifically dedicated to digital health.²⁶ In total, according to the National Institute of Statistics, the number of companies that focus their activity on the health sector increased by 3.7% in 2021, with 6,296 more companies, reaching 175,471 companies.

The subsector dedicated to health activities was the one that grouped the most companies, concentrating a total of 163,997 companies as of January 1, 2022. These data represent an increase of 3.8% compared to the data from the previous year. The subsector of companies manufacturing pharmaceutical products went from 369 companies in 2020 to 379 companies, which represents a year-on-year increase of 2.7%.

Relevant SMEs

Catalonia is one of the most mature regions in digital health, with 212 companies established in 2022, a number that has been increasing since 2010.

The following are some of the most relevant companies in Spain



Aimentia HealthTech develops disruptive solutions with Artificial Intelligence to enhance professionals' capacity and efficiency, promoting their work and vocation at the forefront of mental health



Amelia Virtual Care makes the advantages of immersive technologies accessible for mental health



Cuideo is a platform that helps families hire and manage home care for elderly individuals



Devicare is a specialty biotech company dedicated to developing pathbreaking medical treatments in Urology combining the most recent scientific advances in nutritional therapy with digital technologies.



Human IT Care is an AI-based solution that gathers insightful data and generates smart alarms for healthcare professionals or caregivers in real time based on the tailored needs of the patient's chronic condition

²⁶ Dealroom



Inbrain Neuroelectronics produces high density and high resolution graphene intelligent neural systems for central and peripheral Neuroelectronic applications



iSalud digitalises medical insurance companies with innovative solutions for HR and employees.



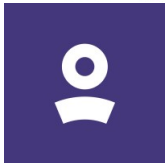
Koa Health is a company of mental health therapies



Mediktor has developed an AI algorithm which detects symptoms using language recognition



Mediquo is an integrative platform of telemedicine addressed to professionals and patients



Oliva is an employee mental wellbeing platform



PromoFarma by DocMorris is an e-commerce company that connects consumers directly with pharmacies and beauty and personal care product providers



Sequentia Biotech analyses genomic data to develop and improve diagnostic and therapeutic solutions



Therpychat is a psychotherapy and coaching online platform



Top Doctors, platform to find and contact with medical specialists of private health.

Over the past years, Spain has shown significant activity in the field of e-mental health, witnessing a thriving of solutions throughout the country.



Figure 10: Solutions e-mental health in Spain. Source: <https://www.digitalhealthconnector.com/post/mental-health-startups-in-spain>

Investment

Private investment is increasingly interested in Life Sciences. Up to 11% of private equity + venture capital investment accounts for Life Sciences companies. The Biotech sector ranks 2nd and the Healthcare sector ranks 3rd in number of venture capital transactions.

Table 1: Investment in technological research and innovation in the healthcare sector in Spain (M€) in 2021. Source: Cambra de Barcelona from INE

Investment in technological research and innovation in the healthcare sector in Spain (M€)	
Private companies	1.607
Public Administration	999
Universities	794
Non-profit organisations	33
TOTAL	3.433

2 – Existing legal framework²⁷

2.1 - Processing health data for the primary use of providing health and social care²⁸

2.1.1 - Legislation on processing health data for normal healthcare provision purposes within the context of a patient - healthcare professional relationship

According to Additional Disposition 17 of the Organic Law 3/2018, dated 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights, the processing of health and genetic data is governed by several laws. These laws fall under the implementing provisions, specifically letters (g), (h), (i), and (j) of Article 9(2) of the GDPR. The relevant laws include:

- Law 14/1986, General Healthcare Law, which establishes the general framework for individual health protection rights.
- Law 31/1995, on the Prevention of Occupational Risks, which deals with data processing for promoting workplace health.

Additionally, the following laws are significant in relation to health data processing:

- Law 41/2002, Basic Regulation of Patient Autonomy, Rights, and Obligations Regarding Clinical Information and Documentation. This law governs duties and rights concerning clinical records and other clinical documents. It is a fundamental law developed by Autonomous Communities with competence in health matters, and its essential content remains consistent across regions concerning clinical documentation rights and duties.
- Law 16/2003, on the Cohesion and Quality of the National Health System. This law ensures access to clinical records to provide healthcare services to patients nationwide.
- Law 14/2007, on Biomedical Research. Despite its title, it regulates clinical genetic analysis in its Title V and contains specific provisions regarding the processing of health data in general.
- Law 14/2006, on Assisted Human Reproduction Techniques. This law regulates the processing of data related to donors and users when assisted reproduction techniques are utilized.

It's important to note that the Spanish law that develops health data processing does not reference Article 6 of the GDPR but specifically refers to Article 9(g), (h), (i), and (j).

2.1.2 - Legislation that regulates the way in which healthcare providers or professionals are allowed to share health data with another healthcare provider or healthcare professional for healthcare provision purposes

According to Article 16(1) of the Basic Regulation of Patient Autonomy and of Rights and Obligations Regarding Clinical Information and Documentation, the medical record serves as a primary tool to ensure proper patient care. Healthcare professionals at the center responsible for diagnosing or treating the patient have access to the patient's clinical history, which is essential for providing appropriate care.

Furthermore, Article 56 of the Law on the Cohesion and Quality of the National Health System governs the exchange of health information among different bodies, centers, and services within the National Health System. The Ministry of Health and Consumer Affairs coordinates

²⁷ <https://www.aepd.es/es/areas-de-actuacion/salud>

²⁸ https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_annex_en_0.pdf

mechanisms for the electronic exchange of clinical and individual health information in agreement with the Autonomous Communities. This facilitates access to the patient's clinical record by both the individual concerned and the healthcare professionals involved in the patient's care, ensuring the quality of the care provided while safeguarding the confidentiality and integrity of the information, irrespective of the administering authority.

2.1.3 - Specific law addressing the processing of health data for providing digital health services

Spain has no specific legislation on this topic. Regions (namely Autonomous Communities) hold the competencies on health care provision, including for providing any digital health services, therefore the regions are the competent governance level to regulate this issue.

2.1.4 - Specific legislation on genetic testing

Spain has specific regulations governing genetic testing, particularly in articles 46 to 57 of the Law on Biomedical Research. Article 56 emphasizes the importance of quality requirements in the process of genetic counselling and analysis for health purposes. It stipulates that such procedures must be conducted by qualified personnel in accredited centres that comply with the quality standards established by the relevant regulations.

Furthermore, Article 57 specifies that the competent regional or state authority is responsible for accrediting both public and private centres authorized to perform genetic analyses.

2.2 - Processing health data for the secondary use of planning, management and improvement of the healthcare system

2.2.1 - Specific legislation addressing the processing of health data for planning, management, administration and improvement of the health and care systems entities such as health authorities

Article 16.5 of the Basic Regulation of Patient Autonomy and of Rights and Obligations Regarding Clinical Information and Documentation specifies that duly accredited health personnel with inspection, evaluation, accreditation, and planning functions have access to clinical records to fulfil their duties in checking the quality of care, respecting patient rights, and meeting any other obligations of the centre related to patients, users, or the health administration.

The General Health Law (Article 18) assigns Public Administrations, through their Health Services and competent bodies, the responsibility of controlling and improving healthcare quality at all levels. Additionally, the General Healthcare Law (Article 69.2 and 69.3) mandates that the evaluation of care quality is an ongoing process that informs the activities of health personnel and services in the National Health System. Centres are required to establish care quality evaluation systems, and qualified professionals should participate in evaluation bodies. Furthermore, the Law on the Cohesion and Quality of the National Health System makes it obligatory for Public Administrations to develop quality accreditation systems.

2.2.2 - Specific legislation addressing the processing of health data that was originally collected for the purpose of providing care to allow it to be used for monitoring of medical device safety and/or pharmacovigilance

Law 29/2006, on Guarantees and Rational Use of Drugs and Health Products, provides assurances for monitoring the risk-benefit ratio of drugs and establishes the Spanish Pharmacovigilance System. The Royal Decree 577/2013 further develops these provisions, outlining the responsibilities of various institutions involved in pharmacovigilance, including

Autonomous Communities, the Spanish Drug Agency, health professionals, and drug authorization holders. The regulation also covers post-authorization studies, which complement pre-authorization clinical data. Royal Decree 957/2020, effective since 2021, regulates observational studies with medicines for human use. Consent from subjects is usually required, except in cases where the Ethics committee determines significant social value and a waiver is necessary for feasibility and minimal risks to participants, or when other legal bases apply.

2.3 - Secondary use for scientific or historical research by both public and private sector organisations

In Spain, the legislation treats not-for-profit researchers and for-profit researchers equally when it comes to accessing medical records for research purposes. The relevant legislations that apply in this context include:

Law 41/2002 modified by OL 3/2018 Article 16(3)	Sixth transitional provision of OL 3/2018	Law 14/2007 on Biomedical Research	Other laws
<ul style="list-style-type: none"> • Access to medical records for research purposes is governed by data protection legislation and Law 14/1986 • It must ensure anonymity by separating identificative data from clinical data unless the patient has consented otherwise • Exceptions are made for research cases specified in Additional Provision 17^a of OL 3/2018. 	<ul style="list-style-type: none"> • States that the re-use of data collected before the law's entry into force for health research will be considered lawful under certain circumstances. These include using the data for the specific purpose for which the patient gave consent or using the data for research in the medical specialty related to the initial study for which consent was obtained. 	<ul style="list-style-type: none"> • Outlines the procedure for obtaining approval from an Ethical Review Board/ERB, which applies to all types of research bodies. 	<ul style="list-style-type: none"> • Law 14/1986, the General Healthcare Law: Article 9 (Duty of communication) and Article 50 (Promotion of research in public health) are relevant in the context of accessing medical records for research purposes. • Additional Provision 17a.2: This provision covers the re-use of personal data for biomedical research purposes and the use of pseudonymized personal data in biomedical research.

The data controllers provide direct access to health data for research upon proof of agreement of a research ethics committee or DPA.

2.4 - Rights related to health data²⁹

2.4.1 - General regime of health data (article 9 GDPR)

Data relating to health is considered sensitive data, and its processing is prohibited unless one of the following circumstances occurs:

- Explicit consent of the data subject.
- Necessary for the fulfillment of obligations and the exercise of specific rights of the data controller or the data subject in the field of labor law and social security and protection.
- Necessary to protect the vital interests of the data subject.
- Carried out, within the scope of their legitimate activities and with appropriate safeguards, by a foundation, association, or any other nonprofit organization with a political, philosophical, religious, or trade union purpose.
- Relates to personal data that the data subject has manifestly made public.

²⁹ <https://www.aepd.es/es/areas-de-actuacion/salud/tus-derechos-en-relacion-con-tus-datos-de-salud>

- Necessary for the establishment, exercise, or defence of legal claims or when courts are acting in the exercise of their judicial function.
- Necessary for reasons of vital public interest.
- Necessary for the purposes of preventive or occupational medicine, assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment, or the management of health and social care systems and services, based on the obligation of professional secrecy or under the responsibility of a professional subject to the obligation of professional secrecy.
- Necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border health threats or ensuring high standards of quality and safety of healthcare and medicinal products or medical devices.
- Necessary for archival purposes in the public interest, scientific or historical research purposes, or statistical purposes.

2.4.2 - Right of access to the medical record

Article 18 of Law 41/2002³⁰, of November 14, which regulates the basic autonomy of the patient and the rights and obligations regarding clinical information and documentation, is the regulation that, due to its subject matter and specificity, recognizes the right of access to the medical record in the following terms:

The patient has the right to access, subject to the reservations indicated in section 3 of this article, the documentation of the medical record and to obtain a copy of the data contained therein. Healthcare centres shall establish the procedure to ensure compliance with these rights.

Exercise of the right of access

In accordance with this, users or patients have the right to address the data controller (i.e., doctors, healthcare centres, both public and private) requesting access to the documentation that constitutes their medical record. Access includes both electronic and paper documentation.

The data subject shall have the right to obtain from the data controller confirmation as to whether or not personal data concerning them are being processed, and, if so, the right to access the personal data and the following information:

- Copy of the personal data undergoing processing (if multiple copies are requested, a fee may be charged for the additional copies);
- The purposes of the processing;
- The categories of personal data concerned;
- The recipients or categories of recipients to whom the personal data have been or will be disclosed, in particular recipients in third countries or international organizations;
- Where possible, the envisaged period for which the personal data will be stored, or, if not possible, the criteria used to determine that period;
- The existence of the right to request from the controller rectification or erasure of personal data or restriction of processing of personal data concerning the data subject, or to object to such processing;
- The right to lodge a complaint with a supervisory authority;
- Where the personal data are not collected from the data subject, any available information as to their source;

³⁰ <https://www.boe.es/eli/es/l/2002/11/14/41/con#a18>

- The existence of automated decision-making, including profiling, and meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.
- Where personal data are transferred to a third country or to an international organization, the data subject shall have the right to be informed of the appropriate safeguards relating to the transfer.

The patient's right of access to the documentation of the medical record cannot be exercised to the detriment of the rights of third parties to the confidentiality of the data collected therein for the therapeutic benefit of the patient, nor to the detriment of the rights of the professionals involved in its preparation, who may invoke the reservation of their subjective annotations against the right of access. Unless expressly permitted by law, the right of access does not include the identification of healthcare professionals who access the medical record.

It is also worth mentioning that healthcare centres and individual practitioners shall only grant access to the medical record of deceased patients to persons related to them, for family or factual reasons, unless the deceased expressly prohibited it and such prohibition is duly proven. In any case, third-party access to the medical record motivated by a risk to their health shall be limited to relevant data. Information that affects the privacy of the deceased or the subjective annotations of the professionals, or that harms third parties, shall not be provided.

Therefore, with the aforementioned exceptions, the right of access to the data in the medical record can be exercised by addressing the data controller. They must provide it within one month, although this period may be extended.

2.5 - Guidelines, reports from the Legal Office, and inquiries from Data Protection Delegates on health-related matters³¹

Based on the Guidelines for patients and healthcare users Report developed by the Spanish Agency of Data protection³²:

It is not necessary for the doctor or healthcare centre to request consent from patients for the collection and use of personal and health data if they are to be used for the purposes of preventive or occupational medicine, assessment of the worker's labour capacity, medical diagnosis, provision of healthcare or social assistance or treatment, or management of healthcare and social assistance systems and services.

It is also not necessary if the data processing is carried out for reasons of public interest in the field of public health, such as protecting against serious cross-border health threats, or to guarantee high levels of quality and safety of healthcare and medicinal products or medical devices, or the inspection of citizens' complaints.

However, patients have the right to be informed about various aspects related to the processing of their health data. The responsible party, contact information, and data protection officer details (if applicable) must be provided. The purposes and legal basis of data processing, as well as the recipients of the data, should be disclosed. Patients should be informed if data will be transferred to third countries or international organizations. The duration of data retention and the right to access, rectify, erase, limit processing, and data portability must be communicated.

³¹ <https://www.aepd.es/es/areas-de-actuacion/salud/guias-informes-del-gabinete-juridico-y-consultas-de-delegados-de-pd-sobre-salud>

³² <https://www.aepd.es/es/documento/guia-pacientes-usuarios-sanidad.pdf>

Patients can withdraw consent at any time, and they have the right to lodge a complaint with the relevant data protection authority. They must also be informed if providing data is a legal or contractual requirement and of the consequences of not providing the data.

2.6 – Current situation in Spain

2.6.1 – Primary use of health data

In Spain, significant progress has been made in the digitalization of healthcare-related documents and processes, benefiting both patients and healthcare providers. The country has embraced various digital solutions to improve the efficiency, accessibility, and accuracy of medical information, such as patient summaries, electronic prescriptions and dispensations, discharge reports and laboratory results.

While substantial progress has been made, the ongoing digital transformation of healthcare in Spain continues to evolve. Efforts are underway to integrate these digital systems further, enhance interoperability, and explore the potential of emerging technologies such as artificial intelligence and telemedicine.

Within the Digitalisation Strategy of the Health System, there are several lines of action to digitalise and improve the interoperability of medical images and reports between the Autonomous Communities.

2.6.2 - Secondary use of health data

Both the GDPR and the LOPDGDD offer more extensive possibilities for processing health research data compared to previous regulations. For instance:

- Researchers can now obtain "broad consent" from individuals for using their data in health research, which allows for more flexible and broad applications beyond specific projects.
- In the realm of public health, health authorities and institutions with public health surveillance responsibilities can conduct scientific studies without requiring individuals' consent in exceptional situations of high relevance and gravity for public health. The ongoing COVID-19 situation falls under this exception due to its urgent and significant impact on public health.
- Personal data collected with consent for a specific research project can be utilized in related areas, enabling more efficient and interconnected research efforts.
- Moreover, under specific requirements and safeguards outlined in additional provision 17 of LOPDGDD, health research can be conducted using pseudonymized data, providing an added layer of privacy protection.

These regulatory advancements provide researchers and health institutions with increased flexibility and opportunities for conducting impactful health research while still upholding individuals' data privacy rights. As a result, medical knowledge can advance more effectively, contributing to improved public health outcomes.

The LOPDGDD permits the reuse of personal data for health research in related areas to the initial study, as long as consent has been obtained initially for conducting research with the data. However, direct reuse of data from medical records for health research is not allowed without obtaining consent. Alternatively, health research can be conducted with pseudonymized data, adhering to additional guarantees outlined in the LOPDGDD.

In addition, certain healthcare systems, like the Catalan (PADRIS program) and Aragonese (BIGAN platform) systems³³, have implemented programs to reuse health information generated within their systems. They make anonymized data available for research, evaluation, planning, and management purposes within their respective healthcare systems. These initiatives promote more extensive use of health data for various applications while ensuring data privacy and consent compliance.³⁴

3 – Innovation agenda in the field

3.1. Digital Spain 2026³⁵

The Government launched the Spain Digital agenda in July 2020, also linked with the previous strategy but encompasses a broader scope, conceived as the roadmap to drive the country's digital transformation process. This agenda was designed as a strategic pillar for recovering from the crisis caused by the pandemic and as a driver of medium-term modernization and prosperity, acting across three dimensions: (i) infrastructure and technology, (ii) economy, and (iii) people.

During 2021 and 2022, significant impulse has been given to investments from the Recovery Plan in the digital field. With the European Next Generation EU funds, the main investment programs managed at the national level have been activated, ranging from connectivity to R&D, including the digitalization of the administration and small and medium-sized enterprises (SMEs). Alongside the digitalization programs, all the strategic projects for economic recovery and transformation (PERTE) incorporate this dimension, and a specific program has been launched to promote networks of technology innovation projects led by the Autonomous Communities (RETECH). The "España Digital 2026. Execution Report" includes all the latest updates regarding the progress of agenda implementation, capturing information until February 2023.³⁶

Digital health is considered one of the key sectors for ensuring the success of digital transformation. This is not only due to its significance in the Spanish economy but also because of two fundamental elements: the potential of data as a valuable strategic asset and the existing synergies between public health and the private, research, pharmaceutical, and university sectors, among others.

A significant portion of the PERTE funding, amounting to 1.650 million euros, was allocated towards digital personalized care, research and development in health, and the training of healthcare professionals. Within this framework, on November 30th, 2021, the Council of Ministers approved an investment of 982 million euros to incorporate personalized precision technologies and medications into the national healthcare system.

The following points outline the main focal axis in relation to health:

³³ Both explained in Section 5 – Transferable Good Practices

³⁴ <https://www.uv.es/catedra-pagoda/es/actualidad/reutilizacion-uso-secundario-datos-salud-interes-general-belen-andreu-1286053802801/Novetat.html?id=1286162435657>

³⁵ https://portal.mineco.gob.es/RecursosArticulo/mineco/ministerio/ficheros/EspanaDigital_2026.pdf

³⁶ https://portal.mineco.gob.es/RecursosNoticia/mineco/prensa/noticias/2023/Informe_ejecucion_V7.pdf

3.1.1. Axis 1 – Digital connectivity

Under the Spain Digital 2026 Strategy, the **UNICO Demanda Programme ACs Public Services** will provide financing for the development of wideband infrastructure, offering speeds of 1 Gbps, in essential reference centres like hospitals and healthcare facilities.

3.1.2. Axis 4 – Data economy and AI

The **National Artificial Intelligence Strategy (ENIA)** is a strategic asset for the deployment of AI in Spain. For this reason, the Recovery Plan incorporates it in its component 16 and expands the scope of the measures proposed in Spain Digital 2025. Its implementation has allowed progress in the implementation of multiple initiatives during the period 2020-2021:

- **To establish a regulatory and ethical framework for the deployment of AI**, the Digital Rights Charter has been published, the AI Advisory Council has been launched, and significant efforts are being made to raise awareness nationally and internationally about the ethical deployment of these technologies. To strengthen this commitment to the humanistic deployment of artificial intelligence, the Chair of Artificial Intelligence and Democracy has also been created in collaboration with the European University Institute.
- **The governance of the data economy**, which fuels the deployment of AI, is ensured through the creation of the Data Office and the role of the Chief Data Officer.
- **The promotion of R&D and talent attraction in AI has been fostered** by calling for grants worth 50 million euros for five R&D missions in three sectors aimed at developing AI solutions. The objective is to use these solutions to address sector-specific, industrial, and socio-economic challenges. Progress has also been made in fostering research networks in AI, with the publication of an expression of interest for the creation of an innovation ecosystem in neurotechnology in Spain (Spain Neurotech initiative).
- **Data and technological infrastructures that support AI are being promoted.** Progress has been made in fostering strategic supercomputing capabilities by financing the first phase of the "Quantum Spain" initiative with 22 million euros. Additionally, the first Spanish hub of the GAIA-X initiative has been established, initiating its activities to develop national sector-specific data spaces and lead the creation of standards and secure data management systems in the tourism sector.

3.1.3. Axis 8 - Sectorial digital and sustainable transformation

Significant advancements have been achieved in implementing the initiatives initially proposed in Spain Digital 2025, specifically in the area of digital health. Moreover, notable progress has been made in executing the initiatives outlined in both Spain Digital and in the overall Recovery Plan, particularly those pertaining to the field of healthcare:

- **In digital health, the Digital Health Strategy was approved by the Interterritorial Council of the National Health System (CISNS)**, and the Digital Health Commission was established. In 2021, a total of 220 million euros was distributed to the Autonomous Communities from the Farmaindustria fund to support initiatives aimed at improving the efficiency and sustainability of the National Health System (SNS) in areas such as pharmaceutical provision management, data analytics, digital capacity enhancement of healthcare centers, and the development of integrated systems for medical image management and analysis.
- **Additionally, in November 2021, the Cutting-Edge Health (Salud de Vanguardia) PERTE was approved**, incorporating actions for the digital transformation of primary and community care.

These actions include the implementation of smart healthcare centers, personalized care, and digital transformation of processes, with a maximum funding of 230 million euros. Furthermore, 40% of the funds from Component 11, Investment 2, allocated to the digital transformation of the General State Administration in the healthcare sector, have been executed.

3.1.3.1. Measures in Digital and cutting-edge digital health

Within the framework of the Cutting-Edge Health PERTE (Strategic Projects for Recovery and Economic Transformation), approved by the Council of Ministers on November 30, 2021, as well as Component 11 of the Recovery Plan, various actions will be implemented to promote an advanced digital healthcare ecosystem.

Sanitary data lake

A collaborative effort with the Autonomous Communities will establish a data lake specifically for healthcare. This repository will gather information from different existing information systems, enabling large-scale data processing and analysis. As a result, real-time response capabilities will be achieved, facilitating the identification and enhancement of diagnosis and treatment, identification of risk factors, trend analysis, pattern identification, prediction of health risk situations, and resource allocation for their management.

Precision personalized healthcare

To promote equitable implementation of precision personalized medicine and foster the growth of competitive companies, several initiatives will be introduced. A notable endeavour is the launch of a flagship project focused on precision personalized healthcare. The aim is to enhance the health of the Spanish population by leveraging scientific knowledge and innovation. This project includes the implementation of a Data Science Plan for Health, which seeks to utilize health data, particularly genomic and molecular data, in a standardized, effective, and secure manner within the National Health System (NHS). By integrating these data with other pertinent health information, significant benefits can be realized for the overall well-being of citizens.

Enhancing response capabilities to health crises: digitalization

As part of the investments under the Recovery Plan, component 18, investment 3, digital tools will be developed for the National Transplant Organization and the Spanish Agency of Medicines. In addition, suitable digital tools will be made available to public health services to ensure improved surveillance of public health. This serves as the foundation for prevention plans and decision-making during crisis and emergency situations affecting population health. These tools involve all stakeholders within the healthcare system, including Primary Care, Hospital Care, and Public Health, across their respective components

3.2 - Digital Health Strategy

As part of the Modernization of Public Administrations initiative, the [Digital Health Strategy](#)³⁷ outlines the digital transformation of NHS services across three key areas: the development of digital and intelligent services, the interoperability of health information, and the promotion of data analytics. These efforts aim to enhance business intelligence within the NHS, drive innovation in health information analysis, advance digital health and electronic interoperability of clinical and health data at both national and international levels, and ensure cybersecurity. The strategy also involves equipping the NHS with the necessary information systems for efficient management of healthcare services, protection of public health, and coordination with

³⁷ https://www.sanidad.gob.es/ciudadanos/pdf/Estrategia_de_Salud_Digital_del_SNS.pdf

the Autonomous Communities to address health challenges arising from the COVID-19 pandemic.

To develop the **Digital Health Strategy**, the Spanish government has deemed it necessary to align the approach and objectives of this Strategy with the actions established in the **Spain Digital Strategy 2025** plan from the Ministry of Economic Affairs and Artificial Intelligence, as well as with the **National Artificial Intelligence Strategy**, the **Industrial Policy Strategy for Spain 2030** (being developed by the Ministry of Industry, Trade, and Tourism), and the **Personalized Medicine Strategy** (being developed by the Ministry of Science and Innovation).

Additionally, the Digital Health Strategy aims to leverage synergies that may arise from national research plans within the framework of the new **Spanish Strategy for Science, Technology, and Innovation, 2021-2027**, as well as from the aforementioned European programs such as **Digital Europe, Europe-4-Health, and Horizon Europe**.

The goal of the **Digital Health Strategy** within the National Health System is to actively contribute to the well-being of the Spanish population and enhance the public healthcare system by harnessing the transformative power of digital technologies, focusing on individuals, healthcare professionals, healthcare service providers, and other relevant stakeholders. The Strategy establishes the reference framework for the implementation of diverse initiatives and actions by the relevant health authorities, promoting a harmonious and coordinated digital transformation within the Spanish National Health System.

Strategic objectives:

1. Empower and involve individuals in the care of their health and facilitate their relationship with the system.
2. Improve the performance of the National Health System by supporting the work of healthcare professionals and generating value processes.
3. Improve decision-making: interoperable information and National Data Space.
4. Support the progress of the NHS through Innovation policies oriented towards 5P medicine.

Lines of action:

1. Development of digital health services oriented towards individuals, organizations, and the processes that integrate the health protection system, with an equity-focused approach.
2. Generalization of interoperability of health information.
3. Promotion of data analytics related to health, its determinants, and the healthcare system.

Areas of intervention:

1. Surveillance of health risks and threats.
2. Health promotion and disease prevention
3. Healthcare: accessibility, quality, resolution capacity, personalization, continuity of care, and patient safety. Digital medical records and imaging for diagnosis, prognosis, and treatment.
4. Management processes that support the fulfillment of healthcare functions and their efficient use.
5. Interoperability of information at a national and international level.
6. Strengthening of digital services in the National Health System (SNS).
7. Development of the SNS service portfolio based on scientific evidence and cost-effectiveness.
8. Professional organization, specialized healthcare training, and postgraduate education.
9. Creation of a National Health Data Space for its massive processing and analysis, along with the establishment of enabling conditions and facilitating resources for knowledge generation and extraction.
10. Health information system for the evaluation of activity, quality, effectiveness, efficiency, and equity in the SNS.

4 – SWOT Analysis on digital health innovation

SWOT analysis of the health system situation in terms of supporting digital health (data sharing) innovation.

Strengths

Spain has a very high degree of digitization of the Health System, at the level of the most advanced countries in Europe, such as Estonia, Denmark, Finland and Sweden. Some of the Autonomous Communities are leaders in Europe (Catalonia, Basque Country, Andalusia).

It is a strength the commitment of the Government with Health Innovation, Health system excellence and Digital Health in particular, as reflected by the approved “Digital Health Strategy for the national Health System”.

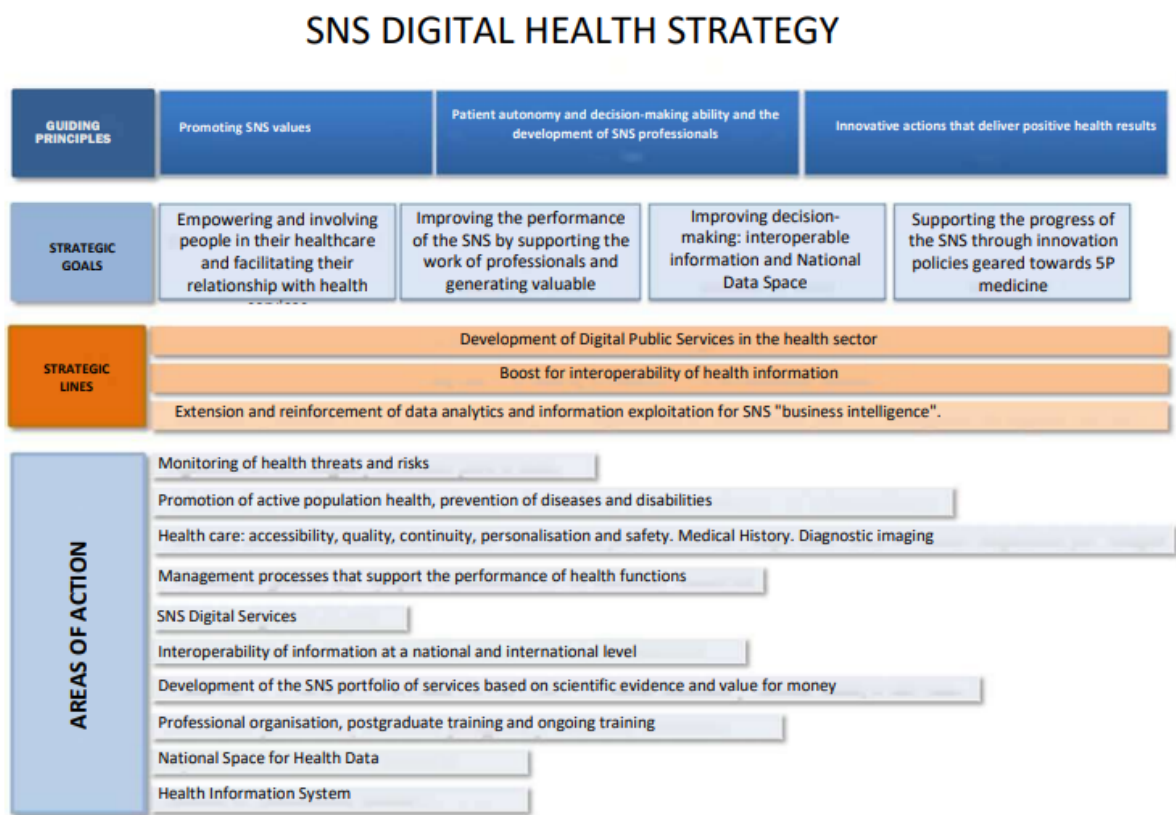


Figure 11: As a strength of the Spanish SNS, the 3 strategic lines are devised to facilitate the EHDS adoption. Source: Ministry of Health.³⁸

³⁸ https://www.sanidad.gob.es/ciudadanos/pdf/Digital_Health_Strategy.pdf

Weaknesses

Low level of interoperability of medical records between the different levels of health care (primary care, hospitals, specialized centres...) and the almost non-existent level with the socio-sanitary level, home care and community pharmacy.

The central government does not boast the same level of digitalisation as the Communities. The interoperability of data between the autonomous communities is very limited, and this affects the mobility of data, and therefore the quality of health services for citizens, who may have difficulties with their data being accessible in other autonomous communities."

As a weakness of the system, a report by Computer World gathering the SEIS Index, points out at the lack of qualified ICT talent as the great brake on the digital transformation of the health sector. The study reveals the number of ICT professionals belonging to the National Health System, which amounts to 2,962 people (between civil servants/statutory and labour), a figure insufficient to serve the Spanish public health sector, with a total of 3,055 health centres, 10,067 primary care clinics and 450 hospitals, where more than 665,000 healthcare professionals work.³⁹

Is also a weakness the reduced number of notified bodies for the certificate of medical devices, as pointed out by the Spanish Federation of Health Technology Companies (Fenin), which believe that an enhanced structure is necessary to expedite the delayed appointments and absorb the heavy workload that currently exists.

Opportunities

The Spanish Presidency is clearly an opportunity for Spain and for Europe. The programme is explicit in priorities related to health data and digital transformation of health systems. The third priority, "Promote greater social and economic justice" includes as a line of action "Complete the European Health Union, creating a European Health Data Space and strengthening EU action on caregiving and mental health".⁴⁰

The European Commissioner highlighted that "the Spanish Presidency comes at a crucial moment that will allow us to deliver tangible results to citizens and empower patients throughout the European Union. The Commission commits to work hand in hand with Minister Miñones to fulfil important priorities in the field of health, including the digitalization of healthcare systems through the European Health Data Space."^{41 42}

Another opportunity comes from Spain having joined the IPCEI, the Important Project of Common European Interest (IPCEI) on Health. The three main objectives are: i) provide an important contribution to the European Health Union, the New Industrial Strategy for Europe and its update, and their respective objectives; ii) contribute to the first industrial deployment of fundamentally innovative production processes, in particular sustainable ones, and iii) foster

³⁹ <https://www.computerworld.es/tendencias/la-inversion-tic-en-el-sistema-nacional-de-salud-roza-el-17-en-2021>

⁴⁰ <https://spanish-presidency.consilium.europa.eu/media/e4ujaagg/the-spanish-presidency-programme.pdf>

⁴¹ <https://www.boehringer-ingelheim.com/es/prensa/notas-de-prensa/expertos-debaten-sobre-la-futura-presidencia-espanola-del-consejo-de-la-union-europea>

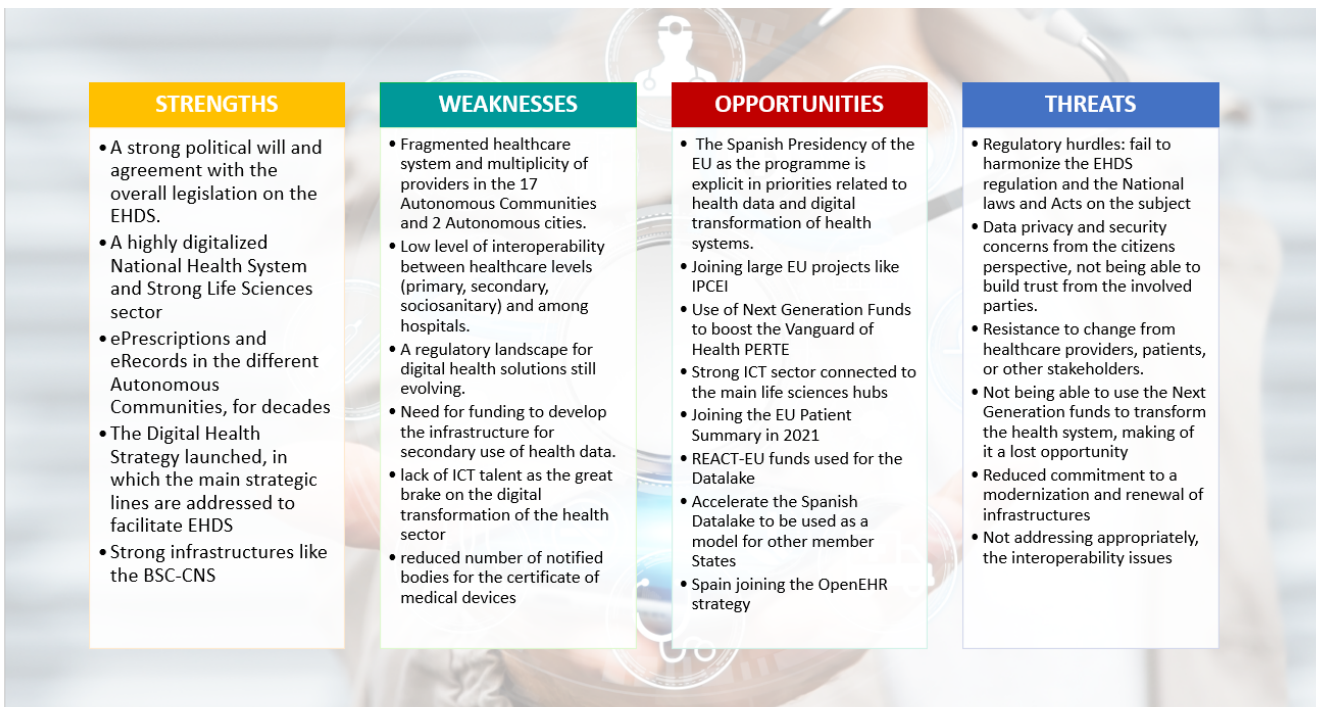
⁴² <https://www.lamoncloa.gob.es/serviciosdeprensa/notasprensa/sanidad14/Paginas/2023/280423-minones-union-europea-salud.aspx>

state-of-the-art, quality, and accessible healthcare through the development of new products and services with a high research and innovation content. The second wave of IPCEI is an opportunity as it would address digital health, MedTech and medical devices.

Threats

Regulatory hurdles: fail to harmonize the EHDS regulation and the National laws and Acts on the subject. Also, concerns about data privacy and security will need to put special efforts in building trust.

It is important also that the Next Generation funds are used to transform the health system, not losing the opportunity for modernization and facilitating the adoption of EHDS. Reduced commitment to a modernization and renewal of infrastructures is a threat, as is not addressing appropriately the interoperability issues.



5 – Transferable Good practices

1. [PADRIS program](#)

The Agency for Health Quality and Assessment of Catalonia (AQuAS) coordinates the PADRIS program, which was born in 2017 as a program promoted by the Catalan Health Department. Its mission is to facilitate the reuse of healthcare-related data of the Catalan Health System. Members of the catalan public health system and public universities or research centers can request data through this program. PADRIS has access to the following data sources or types:

- ✓ Catalan Central Registry of Insured Individuals
- ✓ Hospitals and primary care EMR
- ✓ Pharmacy prescription and dispensing
- ✓ Laboratory tests
- ✓ Mortality, biobank, and health surveys data
- ✓ Specific registries and
- ✓ Medical images

PADRIS has achieved several significant milestones in recent years. Notable accomplishments include the deployment of the COVID-19 response and request prioritization system in 2020, followed by the implementation of changes in the data access system (TREs) in 2021. Additionally, the program is participating in the AI in Health Program since 2022.

Since its inception in 2017, the program has handled a total of 453 data request projects. However, along the journey, the program has encountered certain challenges, primarily revolving around data integration, curation, and quality.

Looking ahead, the program is gearing towards a paradigm shift, transitioning from merely providing data to facilitating access to data. This shift needs the development of new infrastructures and changes in our operational approach. Moreover, the program is actively involved in the Program of Artificial Intelligence in the Catalan Health System. Within this initiative, AQuAS and PADRIS play crucial roles in platform development, data preparation, offering guidance, and evaluating the presented solutions.

2. [BIGAN](#)

BIGAN is the Big Data project initiated by the Department of Health of the Government of Aragon, with the purpose of leveraging data routinely collected within the Aragonese public healthcare system to improve healthcare services. The development of this project has been assigned to the Aragonese Institute of Health Sciences (IACS).

The main objective of the project is to consolidate all the data collected within the healthcare system into a single technological platform. This platform will allow healthcare professionals, administrators, educators, and health researchers to analyze the data comprehensively. The ultimate aim is to enhance the healthcare system and improve the well-being of the people in Aragon through careful observation. For this purpose, it is essential to gather, analyze, and share information collaboratively among all the parties involved.

BIGAN Research is the service offered by the BIGAN platform, providing access to the data contained within it for researchers interested in conducting biomedical research projects using health data for secondary purposes.

The data access service for research is overseen by the Aragonese Institute of Health Sciences and requires prior approval of the research protocol from the Aragon Research Ethics Committee (CEICA).

3. [Únicas Network](#)

The Únicas Network is a project that aims to create an ecosystem of alliances for the improvement of patients with complex minority diseases. SJD Barcelona Children's Hospital is the promoter of the project, which aims to weave a network of hospitals in Catalonia, Spain and Europe, and synergies with companies and research centres. The main purpose of Únicas is to change the care model and sectors involved in the present and future care of rare diseases.

Some of the Únicas Network programmes:

4P diagnostic program (precision, personalised, early and predictive)

The objective is to support the network's centres through the application and development of new genomic diagnostic techniques (developed in the framework and in coordination with the ISCIII's IMPaCT project), radiomics, metabolomics, molecular genetics of cancer and precision neurophysiological diagnosis.

"Discovery" program for innovative therapies

This focuses on developing new treatments in collaboration with universities, research centres, hospitals, the pharmaceutical industry, and health technology companies.

Share4Rare (S4R), data intelligence software

Creation of a federated data ecosystem in which each associated centre has its own information and shares the information needed to generate knowledge. Share4Rare aims to move towards personalised prediction and prevention models while researching rare diseases available to patients and families.

Cortex telemedicine program

Advanced telemedicine platform to support synchronous, urgent and scheduled care will offer a service within reach of the network's centres. The Cortex, or hospital control centre, provides real-time access to and evaluation of large volumes of data to improve care and hospital management.

4. [H2O Project – Health Outcomes Observatory](#)

H2O represents a strategic collaboration between the public and private sectors, aiming to establish a strong data governance and infrastructure model. In Spain, the Vall d'Hebron University Hospital and Takeda Spain join forces and expertise to develop an observatory that will gather health outcomes reported by patients at a national level. Its main objective is to collect and integrate patient outcomes on a large scale, enhancing healthcare decision-making at both individual and population levels. The unique H2O approach empowers patients with full control over their health data, ensuring that only they can exercise this authority.

As and when patients provide consent, this health data can be analysed in multiple ways and allow:

- Patients and their physicians to communicate better.
- Health authorities to make more informed decisions.

- Researchers to advance knowledge and science in health care.

The Observatories created by H2O are an ethically and legally appropriate and efficient system of using data in a way that:

- Measures outcomes more effectively
- Facilitates personalised treatments.
- Enhances health research prospects and
- Promotes value-based approaches in health care systems.

H2O brings together 24 partners (13 Academic institutions and SMEs and 14 EFPIA companies) to:

- Establish Observatories as legal entities and running services in each of the four participating countries (Austria, Germany, Netherlands and Spain) and in three disease areas (diabetes, IBD, Cancer).
- Collect data and share evidence information on patient reported outcomes.
- Empower patients with the digital tools data to better manage their health, report their health outcomes, and remain in control of their data.
- Extend the H2O concept to additional data sources and other settings.

6 - Good practices related to gender diversity and inclusiveness

Biocat elaborated a report on behalf of the Department of Equality and Feminism, Government of Catalonia including a participatory process between stakeholders on gender impacts in the industry, keys to reduce the gender gap in the sector, and good practices from different countries. The subsectors analysed were biotechnology, pharmaceutical, medical technology, and digital health.⁴³ The report proposes ten measures that could be implemented in the sector by 2025. Among the observations, mainly focussed in Catalonia but also benchmarked with Europe and globally, it's worth highlighting that in the last 5 years, 32% of health startups in Catalonia are led by women (in senior management positions or "C-Suite Level"). Biopharma stands out here (at 37%), followed by the MedTech environment (at 35%) and digital health (at 28%). Catalonia is the second region in the European Union with the highest presence of women in founding teams of startups (or with women on their founding or executive teams).

WomenTech Network

It is a non-profit international organization with the mission to break the gender gap and encourage women's access to the technology sector. It promotes the empowerment of girls and women worldwide, focusing on Sustainable Development Goal 5b: leveraging technology.

GenderDataLab.org

GenderDataLab.org is a collaborative open repository where community members can build and use gender and sex disaggregated datasets to tackle the Gender Data Gap. Their website includes guides on how to generate and share these datasets, and they also organize educational workshops and master classes to teach GenderData.

⁴³ <https://www.biocat.cat/en/current-news/blog/10-recommendations-closing-gender-gap-life-sciences-and-healthcare-sector>

[Prioritisation of open data relating to gender inequality for the Government of Catalonia](#)

The Government of Catalonia has also included gender equality in its Government Plan. In the report "Prioritisation of open data relating to gender inequality for the Government of Catalonia," they compile literature and local and international experiences that can serve as inspiration for both publishing and using this type of datasets. The report also proposes a series of indicators to consider and details some datasets whose opening is necessary and it makes a specific mention to the health sector.

"Data on health is one area particularly susceptible to this problem; men are more likely to be subjects of health analyses than women and, therefore, universalised symptoms and treatments are often tailored to males. This makes women invisible and complicates their 11 treatments. The fact that there are metabolic differences between the sexes creates a bias around how diseases affecting women should be treated. It is essential to have accurate and robust data so that governments and public policies can be held accountable for reducing discrimination and promoting equality." "Prioritisation of open data relating to gender inequality for the Government of Catalonia".

Stakeholders Map



Figure 12: Map / visual representation of the different pro-equality groups invited to address the issue of gender equality in the health sector at the discovery sessions. Source: Prioritisation of open data relating to gender inequality for the Government of Catalonia Technical Report

[Women's Health Observatory](#)

The Ministry of Health coordinates the Health Observatory (OSM) which aims to promote the reduction of health inequalities based on gender. It acts in a participatory and collaborative manner to generate and disseminate knowledge that allows for analysis and promotes the inclusion of a gender perspective and equity in health policies and systems. On the website, you can find documents, links, the SNS Quality Plan, and a list of events related to health and gender.

[Guide from the Spanish government on how to address the gender gap through data](#)

Datos.gob.es published a post for Women's Day analysing the importance of data in the fight for equality and providing guides on how to address the gender gap through data, compiling the most significant bibliography on this topic. They also discussed the options to contribute to reducing the data gap.

7 - Potential synergies with other EU regions

Spain is present and takes part in most of the international, and particularly pan-European, initiatives related to innovation in the digital health field.

openEHR

Spain joins experiences, challenges and opportunities in the public health systems of countries like Netherlands, Norway, Finland and Sweden, also with Scotland and Autonomous communities like Catalonia.

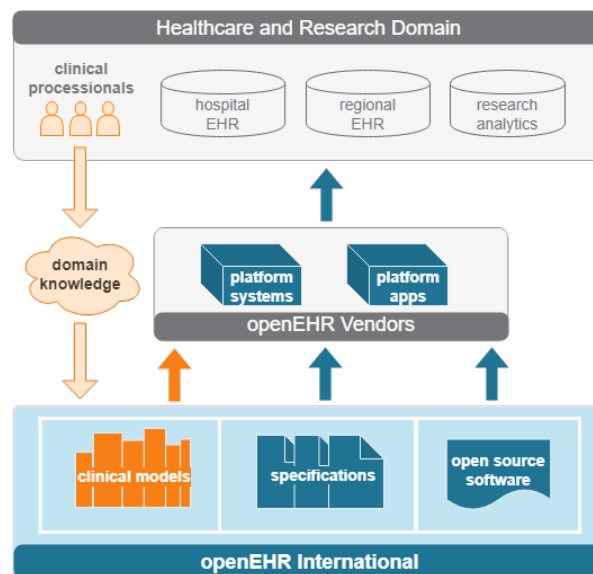


Figure 13: The principal architectural concepts include the lifelong, patient-centric shared health record, future-proof data and clinical process support.

ICPerMed

The Institute of Health Carlos III, with 2 more Autonomous Communities (Basque Country and Navarra) are partners in ICPerMed, the International Consortium of Personalised Medicine.

Era PERMED

ERA PerMed is a new ERA-Net Cofund, supported by 32 partners from 23 countries and cofunded by the European Commission. To align national research strategies, promote excellence, reinforce the competitiveness of European players in PM, and enhance the European collaboration with non-EU countries, national funding organisations have agreed to launch Joint Transnational Calls for collaborative innovative research projects in Personalised Medicine (PM). The Spanish Government and some Autonomous Communities are partners in the project.

TEHDAS

Spain, through the Institute for Health Sciences in Aragon, led Package 7 (Connecting the dots), analysing options for the technical interoperability of the secondary use of health data in the European Health Data Space and encouraging participation of future users of the European Health Data Space, such as researchers and policymakers, and of the technical implementers, such as companies and institutions, in co-designing the services.

Regional Innovation Valleys

Spain, and Catalonia, see an opportunity in connecting with the New European Innovation Agenda through the Regional Innovation Valleys (RIVs), in support of key EU priorities regarding EHDS.

EuroHPC

Spain has been one of six European countries selected by the European Union (EU) supercomputing consortium, the European High Performance Computing Joint Undertaking (EuroHPC JU), to host and operate the first EuroHPC quantum computers. The new infrastructure will be installed at the Barcelona Supercomputing Centre - Centro Nacional de Supercomputación (BSC-CNS) and will be integrated into the MareNostrum 5 supercomputer, the most powerful in Spain and among the most advanced in Europe, in collaboration with the Institut de Física de Altes Energies (IFAE), and the International Iberian Nanotechnology Laboratory (INL), in Portugal.

EIT Health

EIT Health Spanish node is part of a pan-European initiative promoted by the EIT Health Think Tank in which similar roundtables will be held in 10 European countries, the conclusions of which will provide input for local reports and a European report to be presented at the end of 2023 in Brussels.

GAIA-X

Spain is part of this project, of secure and federated data infrastructure that stands for European values, digital sovereignty of the data owners, interoperability of different platform and open source. Within this ecosystem, it will be possible to provide, share, and use data within a trustworthy environment. Thus, spurring innovation and creating added value for the data economy to all who share data.

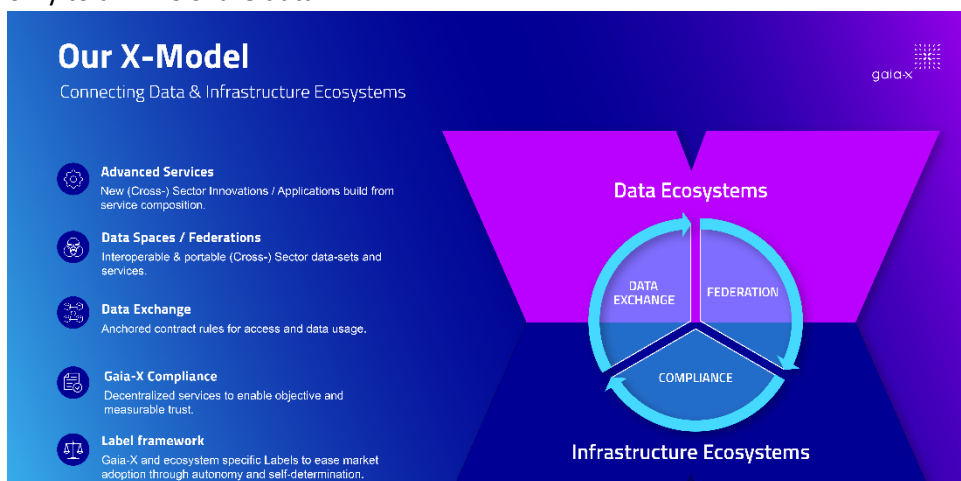


Figure 14: Gaia-X Framework, which builds upon the evolution of the X-Model and enables the transition from disjoint data & infrastructure ecosystems, to composable, interoperable & portable cross-sector data sets and services.

NOTE ON REFERENCES AND SOURCES

This report has been elaborated with inputs from available public sources published on the Internet and from interviews with main stakeholders from the quadruple helix.

All the main sources used for information or assessment are mentioned in the text or listed as foot notes or as links to the text.