



DIGITAL HEALTH STRATEGY

NATIONAL HEALTH SYSTEM

*General Secretariat for Digital Health,
Information and Innovation for the SNS*



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1 Executive summary

The National Health System's Digital Health Strategy aims to contribute to maintaining the Spanish population in good health and to strengthen the public health system through the transformation capacity of digital technologies aimed at people, health professionals, health service provider organisations and other related agents.

The Strategy constitutes the reference framework for the development of the different initiatives and actions of the corresponding health administrations, promoting the National Health System to address its digital transformation in a standardised and coordinated manner. This approach arises both from its very nature (a system or set of interrelated elements) and from the fact that such a transformation pursues objectives that are common to all its components.

The Strategy focuses primarily on four **strategic objectives**:

1. Empowering and involving **people** in their healthcare and disease control and facilitating their relationship with health services by promoting their participation at all levels and encouraging their joint responsibility.
2. Maximising the value of **processes** for better performance and efficiency of the public health system, supporting the work of professionals and facilitating communication between them in a way that ensures continuity of care and strengthens the governance of organisations.
3. Adopting **data** management and governance policies that allow for interoperable and quality information and create a National Space for Health Data to generate scientific knowledge and the assessment of services.
4. Adapting the evolution of the SNS to the demands of today's society, applying **innovation** policies oriented towards 5P medicine (Population, Preventive, Predictive, Personalised and Participatory).

The Strategy is structured around three main **lines of action** that serve as the pillars for articulating the contents and initiatives associated with it:

1. Development of **digital health services** oriented towards **individuals, organisations** and the **processes** that make up the health protection system, with a focus on equity.
2. Generalisation of the **interoperability** of health information.
3. Boosting **data analytics** related to health, the determining factors and the health system.

Ten areas of intervention are identified in which the digital transformation is expected to have a significant positive impact:

1. Monitoring of health threats and risks
2. Promotion of health and prevention of disease and disability, with community participation and a focus on equity
3. Healthcare: accessibility of services, responsiveness, personalisation, continuity of care and patient safety. Digital health records and the empowerment of health imaging for diagnosis, prognosis and treatment.

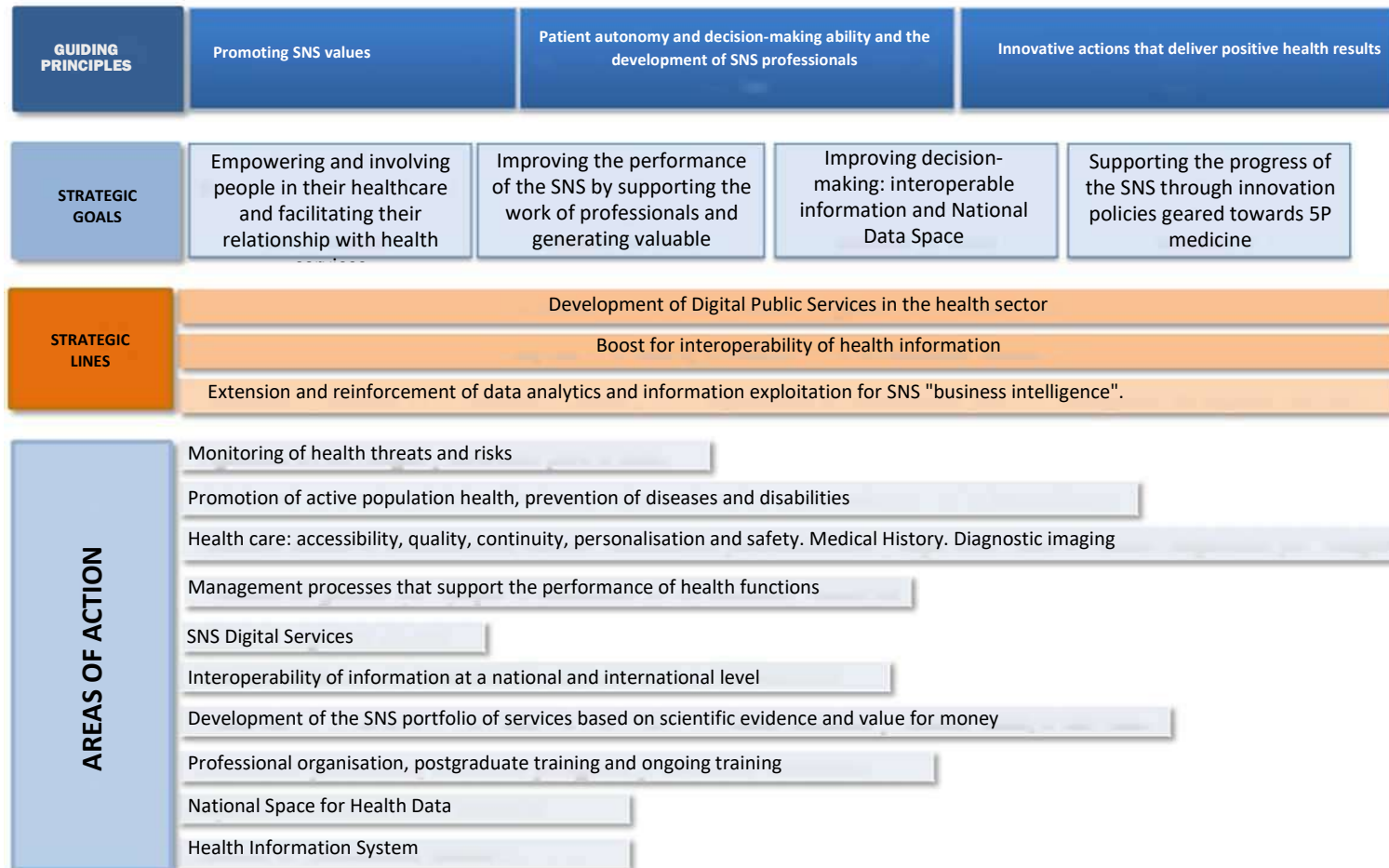
4. Management processes that support the performance of health functions and their efficient use.
5. Interoperability of information at a national and international level
6. Strengthening the SNS' digital services
7. Development of the SNS' portfolio of services based on scientific evidence and value for money.
8. Professional organisation, specialist health training and postgraduate training.
9. Creation of a National Space for Health Data for mass processing and analysis and establishing enabling conditions and facilitating resources for the generation and extraction of knowledge.
10. Health information system for the assessment of the activity, quality, effectiveness, efficiency and equity of the SNS.

The Strategy sets out the common space in which the digital health transformation initiatives associated with the public sector, developed by the different administrations responsible for health matters and public bodies linked to the field of innovation and research in health and other entities involved, must be developed.

It describes the mechanisms for its governance and monitoring, which are necessarily placed within the framework of the Interterritorial Council of the SNS. The strategic planning of projects and their financial programming will be entrusted to the Strategy's governing bodies, along with their monitoring and assessment.

The Digital Health Strategy will be developed between 2021 and 2026, fundamentally linked to the implementation of the funds associated with the "Recovery Assistance for Cohesion and the Territories of Europe (REACT-EU)" and the "Recovery and Resilience Mechanism". Coordination and possible participation in other EU programmes, such as Horizon Europe, Digital Europe and Europe4Health, is also worth note.

SNS DIGITAL HEALTH STRATEGY



2 Introduction

Twenty-first century society faces demographic, social, political and economic challenges of great significance, with a high impact on health systems around the world.

Although EU countries have a more favourable starting position in terms of their health systems compared to other regions of the world, they still face specific challenges and Spain, within the European context, also faces specific problems in relation to its population structure, its territorial distribution, its economic and industrial performance and its organisational model.

The universal and redistributive nature of its health protection system through a National Health System is a pillar of the Spanish welfare state and one of its main features; therefore, its maintenance and extension are citizen demands that require a clear commitment to the most appropriate policies and measures to reinforce this and ensure its long-term sustainability.

In turn, the global crisis caused by the COVID-19 pandemic has dramatically highlighted the need for, on the one hand, resources capable of providing health care and personal care in changing circumstances and, on the other hand, the importance of having accurate, comprehensive and reliable information, almost immediately, in order to make decisions of major significance to the lives of individuals and the functioning of society as a whole.

Advanced digital technologies such as big data, artificial intelligence or the Internet of Things (IoT) have the potential to transform different aspects of the healthcare system, both in terms of the daily activities of healthcare professionals and their relationship with patients, increasingly supported by the use of data and communication, and in terms of anticipating risks, greater precision in medical treatments and the development of research, without overlooking the overall management of the system and its resources. In other words, what the WHO means by digital health: the field of knowledge and practices related to the development and use of digital technologies to improve health.

Against the current backdrop, the penetration of different mobile health devices is facilitating the involvement of individuals in their health care, which represents another opportunity to support its evolution from a reactive approach to health care to a proactive approach to integrated health, with the consequent impact on the welfare of society as a whole and on the sustainability of the health system. Similarly, the diversification of access and communication channels *with* the system and *within* the health system should benefit users and improve professional performance.

However, the introduction of digital technologies in healthcare also presents many complex issues in relation to patients' rights, access to technologies, risk transfer in decision-making, unnecessary medicalisation or secondary uses and ownership of data, to name just the most obvious issues, which must be taken into account.

Therefore, we must not lose sight of the fact that the digital transformation of healthcare must be, above all, at the service of people and serve both to involve each individual in their healthcare and to strengthen the professional-patient and professional-professional relationship as central elements in the processes of health promotion, disease and disability prevention and healthcare.

The Strategy aims to focus on this statement and have an impact on both surveillance and health promotion, disease prevention, clinical practice, health planning and management and research, facilitating the necessary cultural change, identifying and preventing associated risks and generating the greatest possible value for individuals, professionals and society as a whole.

Finally, the Digital Health Strategy must provide greater transparency in relation to the public health system, both in terms of the actions undertaken and their impact on the health situation, in addition to making innovation the driving force behind its transformation.

3 Development context

3.1 International Context

3.1.1 United Nations: Sustainable Development Goals (SDGs)

The Sustainable Development Goals (SDGs), adopted in 2015 by the United Nations as part of the **2030 Agenda** for Sustainable Development, define 17 major milestones to be achieved within that time horizon as defining elements of fair, sustainable and inclusive global progress, focused on ending poverty, protecting the planet and improving the lives and prospects of people around the world.

Goal 3, "Good health and well-being" is understood as **"To ensure healthy lives and promote well-being for all at all ages"** and, in view of the specific targets of this goal, there is a growing consensus that the strategic and innovative use of digital and cutting-edge information and communications technologies will be key factors in its achievement.

On the other hand, **Goal 9, "Build resilient infrastructure, promote inclusive and sustainable industrialization, and foster innovation"**, recognises the importance of digital technologies and communications infrastructure in development and growth, particularly for SMEs in the least developed countries, as well as their impact on research and innovation.

In the other 17 SDGs and 169 targets, digitalisation and the incorporation of information and communication technologies appear as essential means for the advancement of society from a social, economic and environmental perspective.

As part of this framework, SDG 8 is worth particular mention in relation to economic growth, especially taking into account the importance and dynamism of the health sector in Spain, SDG 9 on innovation and its importance in improving treatment and SDG 10 on reducing inequalities, bearing in mind that the digital divide can pose very significant risks in the field of health.

The perspective of the SDGs and their associated targets will be part of the definition and monitoring of the projects that make up the Strategy, as a means of harmoniously advancing the progress and well-being of all people, in an increasingly open, inclusive, fair and caring society.

3.1.2 World Health Organisation

The World Health Organisation (WHO)¹, which defined *eHealth* in 2012 as "the use of information and communications technologies in support of health and health-related fields", adopted at its General Assembly in May 2018, resolution WHA71.7 on Digital Health, "to develop, within existing resources, and in close consultation with Member States and with inputs from relevant stakeholders as appropriate, a global strategy on digital health, identifying priority areas including where WHO should focus its efforts".

In relation to digital health, the WHO includes digital consumers, with smart and connected devices, and encompasses different uses of health technologies, such as the Internet of Things, machine learning, artificial intelligence, advanced computing, big data analytics and robotics.

WHO considers Digital Health as a catalyst of the Sustainable Development Goals (SDGs)², identifying these technologies as essential enablers to ensure that 1 billion more people benefit from universal health coverage, 1 billion more people are better protected from health emergencies and 1 billion more people enjoy better health and well-being (WHO's three billion targets included in its 13th General Programme of Work, 2019-2023).

On 5 July 2020³, the WHO published a general proposal for the provision of Digital Health services that each country could use and adapt to its specific circumstances. The proposal identifies three levels of action that extends to: public policy developers as being responsible for the ethical, safe and sustainable use of technology applied to health; professionals, who use technologies to provide effective healthcare services to the population; and the population itself, as beneficiaries of Digital Health to improve their health and well-being. Its strategic objectives include but are not limited to:

- Promoting global collaboration and making progress with the transfer of knowledge on Digital Health.
- Advocating digitally enabled, people-centred health systems.
- Advancing the national implementation of Digital Health strategies.
- Strengthening governance for digital health at global, national and regional levels.
- Establishing national interoperable digital health ecosystems, as well as strengthening coordinated collaboration, promoting the use of big data and Artificial Intelligence under appropriate ethical principles and a review of regulations.

¹ WHA71.

² <https://www.agenda2030.gob.es/>

³ Draft global strategy on digital health, https://www.who.int/docs/default-source/documents/gd4hdhaa2a9f352b0445bafbc79ca799dce4d.pdf?sfvrsn=f112ede5_48

3.1.3 The experience of other countries

The *Smart Health Systems International comparison of digital strategies*⁴, a systematic and extensive international comparison of health systems with a particular focus on digital transformation, shows that the context and challenges of health systems in Europe and in developed countries are quite similar.

Comparing the digital strategies of health systems in 17 countries (Australia, Belgium, Denmark, Estonia, France, Germany, Israel, Italy, Canada, the United Kingdom, the Netherlands, Austria, Poland, Portugal, Sweden, Switzerland and Spain) applying a series of indicators to generate a 'digital health index'.

This study ranks Spain fifth, behind Estonia, Canada, Denmark and Israel, suggesting it occupies a strong position thanks to the nationwide implementation of identification systems, digital medical records and prescriptions, patient portals and electronic appointments. It also reflects the solid development of security and privacy practices in data processing, as well as the broad application of standards in data terminology and coding.

However, it places an emphasis on the loss of joint efficiency attributable to the fact that there is no **shared Digital Health strategy** that: includes semantics, standardisation and interoperability strategies; designs capacities for access, exchange and massive analysis of data; plans the incorporation of digital technologies in all healthcare areas; establishes how to increase the capacity and autonomy of patients with respect to their own information; identifies how to improve the work of professionals; develops and promotes models of cooperation with the private sector; and, ensures the availability of information for decision-making, from an operational to a strategic level.

Several countries already have Digital Health Strategies in place and a brief description of a number of these is provided in ANNEX I.

In short, all these initiatives share a number of elements, from which it is possible to highlight **three**: the **capacity** that technologies offer **people**, giving rise to much more informed and much more demanding patients; **the impact of these technologies** on the way in which **the service** is provided; and, finally, the **possibilities associated** with the collection, exchange and mass analysis of the **data** collected in all processes (with the possible participation of the private sector to the extent that the applicable legislation allows).

The combination of these three vectors determines the overall transformation of the health sector.

⁴ <https://www.bertelsmann-stiftung.de/en/our-projects/the-digital-patient/project-news/smarthealthsystems/>

3.1.4 Context of the European Union

Some time ago, the European Union identified digital technologies as one of the key factors for the development of the Union, not only in economic terms but also in terms of cohesion, equity and protection of European values, from the first benchmarking studies of public e-services and broadband services in the early 2000s to more recent sectoral initiatives, whether in the field of health, mobility, environmental protection or energy.

Thus, the *European Parliament resolution on enabling the digital transformation of health and care in the **Digital Single Market**, empowering citizens and creating a healthier society*⁵, considers that health and care systems face significant challenges in the context of an ageing society, longer life expectancy and steadily declining birth rates that raise concerns about the sustainability of healthcare provision in the future.

In this context, there is a need for a paradigm shift towards responsive and proactive health systems, in which the maintenance of good health is the primary objective.

The **European Commission (EC)** expects **Digital Health** to promote people's participation in managing their own health, with an emphasis on lifestyles and prevention, connecting the various stakeholders in the health and social care sectors, improving emergency preparedness and response to epidemics, improving procedures, reducing inefficiencies and supporting outcome-oriented healthcare through the analysis of digital health data.

Through various standards and working documents^{6,7} the EC establishes that models that include, in a common space, healthcare data (medical records, electronic prescriptions, pathological anatomy, results of diagnostic tests or clinical procedures), telemedicine and other digital technologies such as applications resulting from 4G/5G mobile communications, artificial intelligence and supercomputing, are a model of significant value in the generation of knowledge.

Thus, the European Data Strategy calls for the creation of a European health data space⁸, an idea that is also present in the **Communication "Shaping Europe digital future"** advocating that digitised health records, collected in a European health data space, can lead to better treatment of major chronic diseases, such as cancer and rare diseases, but also to equal access to high quality health services for all people⁹.

Finally, the Commission considers that the evidence-based assessment of innovative health technologies is essential to reorient the approach to modern medicine and to make progress with the new perspectives of personalised medicine.

These proposals are reflected in the **New European Agenda 2019-2024**¹⁰ which, the second priority of which is "Developing our economic base: the European model for the future", assuming that the digital transformation will continue to accelerate and have far-reaching

⁵ 2019/2804(RSP)

⁶ COM (2018) 233 final

⁷ SWD (2018) 126 final

⁸ COM (2020) 66 final

⁹ Communication-shaping-europes-digital-future-feb2020_en_4.pdf

¹⁰ <https://www.consilium.europa.eu/media/39964/a-new-strategic-agenda-2019-2024-es.pdf>

impacts. This new Agenda seeks to ensure that Europe is digitally sovereign and obtains its fair share of the benefits of this evolution, always within the framework of European values.

To do so, the EU must work on all aspects of the digital revolution and artificial intelligence: infrastructure, connectivity, services, data, regulation and investment. This means fostering inclusive and multidisciplinary initiatives to maximise the benefits of digital transformation in the context of European values, promoting inclusion, empowerment, prosperity and sustainability.

It is therefore consistent that decisions taken throughout 2020 in the EU, in the overlapping scenario of the COVID-19 pandemic, reinforce the importance of digitisation as a pillar of recovery in the EU. Indeed, this is stated both in the 2021-2027 Recovery and Budget Package and in the recent conclusions adopted by the European Council on the Single Market and Digital Transformation¹¹.

Along these lines, Article 3 of the proposed European Council Regulation on the Resilience and Recovery Mechanism, on the "Scope of Application", expressly includes but is not limited to, in terms of the areas of action, those related to the digital transition and health¹².

The development of these priorities will take the form of a series of European plans and programmes to support the digital transformation of health in the coming years. These include **EU4Health 2021-2027** - "A vision for a healthier European Union", through which the EU will provide funding to EU countries¹³ and the **Digital Europe Programme**, also with its own budget, focusing on building the EU's strategic digital capabilities and facilitating the extensive deployment of digital technologies also within the multi-annual budgetary framework.

Other EU programmes, such as the proposed **Horizon Europe** programme for research and innovation, as well as the **Connecting Europe Facility** for digital infrastructure, make up the EU's portfolio of mechanisms in this area.

Specifically, the **Digital Europe** programme, which seeks to boost Europe's leadership in this sector, is structured around five main objectives ("High Performance Computing", "Cloud, Data and Artificial Intelligence", "Cybersecurity", "Advanced Digital Capabilities" and "Accelerating the best uses of technology") and proposes initiatives specifically aimed at healthcare, both from a public and private sector perspective, in four of them.

All these European programmes and initiatives provide a key framework and financial support for the development of the **SNS Digital Health Strategy**.

However, in recognition of the enormous possibilities offered by the use of the most advanced technologies in healthcare, this process can only be undertaken from an integrative perspective, focused on the benefits for all stakeholders in the system: patients, professionals, managers, the health economic sector and society in general, and with a view to guaranteeing an ethical, equitable and inclusive use of all the possibilities offered by these technologies.

¹¹ COM(2020) 408 final

¹² <https://www.consilium.europa.eu/media/45932/021020-euco-final-conclusions-es.pdf>

¹³ <https://ec.europa.eu/health/funding/eu4health>

It is also a process that raises a number of issues related to cultural change¹⁴, organisational transformation, participation and governance which, if not taken into consideration from the outset, will lead to failure¹⁵.

For this reason, the aspects associated with the governance of the process, the management of change, the empowerment and participation of people and the values of the SNS have been expressly considered in the development of the Strategy.

3.2 National Context

3.2.1 Digital transformation in the public sector

Developing a **Digital Health Strategy** requires a prior review of the digital transformation framework of the public administration as a whole and of the sectoral digitalisation initiatives promoted by the other ministerial departments.

The approach and objectives of this Strategy must be aligned with the lines of action set out in the plan **Digital Spain 2025 Strategy**¹⁶, developed by the Ministry of Economic Affairs and Artificial Intelligence, as well as with the **National Artificial Intelligence Strategy**¹⁷, the **Industrial Policy Strategy for Spain 2030** (being developed by the Ministry of Industry, Trade and Tourism) and with the **Personalised Medicine Strategy**, being developed by the Ministry of Science and Innovation.

The **Digital Health Strategy** should also take advantage of the synergies that can be derived from national research plans, within the framework of the new **Spanish Science, Technology and Innovation Strategy, 2021-2027**¹⁸, as well as from the European programmes already mentioned, such as **Digital Europe, Europe-4-Health and Horizon Europe**.

The importance of strengthening the National Health System is also part of the "Spain 2050" strategy, in particular "Challenge 9: Expanding the foundations of our future well-being" and in this sense the Digital Health Strategy aims to support other strategies developed by the Ministry of Health, including the Primary Care Action Plan, currently under development, the Mental Health Plan and the Strategic Plan on Antimicrobial Resistance.

The most relevant elements of the Strategies with the greatest impact on the Digital Health Strategy are summarised below.

¹⁴ Meskó B, Drobni Z, Bényei É, Gergely B, Gyórfy Z. Digital health is a cultural transformation of traditional healthcare. *mHealth* 2017;3:38. doi: 10.21037/mhealth.2017.08.07

¹⁵ McKinsey "Promoting an overdue digital transformation in healthcare", 2019

¹⁶ https://www.lamoncloa.gob.es/presidente/actividades/Documents/2020/230720-Espa%C3%B1aDigital_2025.pdf

¹⁷ <https://www.lamoncloa.gob.es/presidente/actividades/Documents/2020/021220-ENIA.pdf>

¹⁸ <https://www.ciencia.gob.es/stfls/MICINN/Ministerio/FICHEROS/EECTI-2021-2027.pdf>

3.2.2 Digital Spain 2025

The Digital Spain 2025 Strategy is structured around 10 axes, each of which incorporates a series of specific measures to achieve a series of goals: Ensuring 100% of the population has internet access of over 100Mbps, 80% of people with basic digital skills, 20,000 cybersecurity, AI and data specialists, 50% of public services available via apps and 25% of companies using AI and big data.

The field of health is directly present in the area of Cybersecurity (services for the SNS) and Digital Competences (training of health professionals) and, indirectly, will benefit from measures to boost digital connectivity and 5G technology.

In addition, pillar number 7, which aims to "accelerate the digitalisation of the production model", specifically identifies Digital Health as one of the areas with the capacity to generate projects that serve as a driving force and promote a sectoral transformation with structural effects.

Specifically, it envisages a project for driving the digital transformation of the health sector through innovation, research, care and patient empowerment, with the ultimate aim of increasing the population's quality of life.

This transformation of the SNS is seen as the result of a coordinated, interoperable, integrated and multidimensional development that generates applications for the entire bio-health ecosystem: public health and epidemiology, clinical practice, health management, universities, research centres and a thriving sector of innovative start-ups around health and healthy lifestyles, with clear synergies between them all. In addition, it establishes that it will work with all ministerial departments and with the different levels of public administrations in the gradual exploration, launch and promotion of other strategic opportunities for the digitalisation of public services.

3.2.3 Recovery, Transformation and Resilience Plan

Along the same lines, the **Recovery, Transformation and Resilience Plan**¹⁹, in its **Objective VI "Science and Innovation Pact. Strengthening the capacities of the SNS"** also includes the need to adopt measures to address the problems of the health system that the COVID-19 crisis has brought to light, establishing new bases for a system that requires the systematic incorporation of new digital technologies in all aspects of health promotion, disease and disability prevention, clinical practice, planning, management and decision-making.

One of the projects set out in this Plan is the "Renewal and expansion of the capabilities of the SNS", establishing the need to redesign the SNS to respond to the needs of citizens and anticipate future challenges, by reinforcing the strategic capabilities of analysis and prevention; preserving and promoting professional talent, improving joint governance, cohesion and efficiency; technological modernisation, equipment renewal and digital transformation; the strategic reserve of healthcare and pharmaceutical products; digitalisation and accessibility for patients to their own medical data; and the promotion of an industrial sector in line with healthcare needs.

3.2.4 Spanish Science, Technology and Innovation Strategy

In turn, the *Spanish Science, Technology and Innovation Strategy 2021-2027*²⁰ defines health as one of the strategic lines of R&D&I, and addresses precision medicine, tackling emerging and re-emerging infectious diseases, new diagnostic and therapeutic techniques and the approach to cancer and geroscience.

Therefore, it will be necessary to align and coordinate the main actions of both Strategies, so as to create the appropriate synergies to achieve the objectives of both, in which the identification and prioritisation of the actions to be developed, as well as R&D&I and training, are of particular importance.

3.2.5 Spanish Artificial Intelligence Strategy

The Artificial Intelligence (AI) Strategy establishes seven strategic objectives or results to be achieved with its application: scientific excellence and innovation in Artificial Intelligence, the projection of the Spanish language, the creation of qualified employment, the transformation of the productive fabric, the creation of confidence in the use of AI, the incorporation of humanist values into AI and the development of inclusive and sustainable AI.

One of the aims of strategic pillar 3 of the Strategy, "Developing data platforms and technological infrastructures that support AI", in line with European initiatives, is to ensure the development of the regulatory framework for Open Data (of particular relevance for the secondary use of health data) and the promotion of the National Language Technology Plan, which is widely used in the exchange of health information.

¹⁹ https://www.lamocloa.gob.es/presidente/actividades/Documents/2020/07102020_PlanRecuperacion.pdf

²⁰ Ministry of Science and Innovation

In addition, line 5 on "Promoting the use of AI in the Public Administration and in national strategic missions" envisages the creation of strategic missions in the area of health, with which some of the projects of this Digital Health Strategy will be integrated.

Finally, in pillar 7 "Establishing an ethical and regulatory framework that reinforces the protection of individual and collective rights, in order to ensure social inclusion and well-being", the need for close and continuous collaboration throughout the implementation of both strategies is evident.

3.2.6 Personalised Medicine Strategy

The Personalised Medicine Strategy, currently being drawn up by the Ministry of Science and Innovation, will define the priorities for research and development of the so-called "-omics" sciences; therefore, the prospects for the application and incorporation of new solutions into the SNS, including the use of biomarkers, as well as the data needs for this public and private research.

The incorporation of proven effective advanced therapies should form part of initiatives to promote personalised assistance solutions that increase the effectiveness of treatments and the quality of life of individuals.

Moreover, in this area, the promotion of public-private partnerships should accelerate the availability of proven, safe and accessible solutions for everybody.

4 The protection of health in Spain: National Health System

Article 43 of the Spanish Constitution recognises the right of all persons to health protection. Its implementing regulations specify this right from a comprehensive perspective that includes surveillance, health promotion and maintenance, preventive, diagnostic, therapeutic and rehabilitative activities, all of which form part of the portfolio of services offered by the National Health System (SNS).

The SNS coordinates the different public structures and services for the protection of health across Spain, offering universal access to its services, which are financed through the collection of taxes. Healthcare is organised in a first primary care setting where professional teams, mainly dedicated to medicine and nursing, are responsible for an area's population, encouraging the promotion and preservation of their health, treating their prevailing problems and ensuring continuous follow-up. This reinforces equality in access to services, minimising geographical and personal autonomy barriers.

At the same time, this equality is maintained when it comes to accessing more complex and costly resources, placing the technical decision to intervene in the second area of care in the hands of professionals in the fields of family medicine and paediatrics, simultaneously contributing to the efficiency of the system.

Public health surveillance is developed through a series of activities aimed at collecting, analysing, interpreting and disseminating information related to the population's health condition and the factors responsible for this, with the aim of justifying the actions of the health authorities in the face of health risks and threats.

Powers for health matters have been largely transferred to the autonomous regions of Spain, except for those reserved exclusively to the State (bases and general coordination of health, foreign health and legislation on pharmaceutical products), and the Ministry of Health is responsible for exercising these powers, as well as for proposing and executing the Government's policy on health, planning and health care. The public health system operates mainly through its own resources, there is management control by the public authorities and there is competition from the private sector in some subsidised activities.

The Digital Health Strategy is therefore aimed at a public health system based on the right to health protection recognised in the Spanish Constitution and on the responsibility of the public administrations. It is a system that is deeply rooted in society, which has developed by incorporating essential values of universality, equity and solidarity.

4.1 Health indicators

Within the context of the European Union,²¹ Spain's indicators are strong, among other aspects, for life expectancy, both in absolute terms and in relation to health spending, healthy life years at birth and aged 65, mortality from cancer or cardiovascular diseases, the percentage of the population reporting unsatisfied healthcare needs, perception of personal health, vaccination coverage and transplants.

However, it is still among the countries with the highest population of smokers, obesity is on the rise, only 40% of people consume fruit and vegetables every day and 36% of the population do not engage in any form of physical exercise.

4.2 How the system works

The SNS portfolio of services is one of the broadest in the EU and is free at the time of use, except for prescription pharmaceuticals which may involve an income-related co-payment. The flaws of the portfolio include access to dental care being limited to a series of basic services and there is a general consensus that access to mental healthcare needs to be expanded²², with the ratio of professionals in this field lower than in other neighbouring countries.

It should be noted, however, that the SNS portfolio of services is a dynamic instrument that reviews and updates its benefits and progressively incorporates new techniques and technologies with proven scientific evidence into healthcare.

Each autonomous region assumes operational and economic responsibility for protecting the health of its inhabitants, although this responsibility transcends its geographical limits since, on the one hand, protection must be maintained when necessary at any time and place in the SNS and, on the other, there are services which, by their nature, must be concentrated and shared. To this end, the health authorities have a sectoral conference, the Interterritorial Council of the SNS, where cohesion, reciprocity and compensation of services, where appropriate, within the public health system are organised and supervised.

Individuals have a single personal identification code that is used throughout the SNS, linked to their personal health card, providing access to health centres and services throughout the system under the terms established in the regulations.

Similarly, health centres, services and establishments have a common coding system in the SNS, using standardised classifications of diseases and diagnostic and therapeutic procedures and with classifications for nursing diagnoses and interventions also increasingly used. Similarly, coding is also applied to medicines and progress is being made in the standardisation of medical devices.

²¹ "Health systems in the countries of the European Union". Health characteristics and indicators 2019. <http://www.sanidad-ue.es/es/index>
²² ENSE

All of this constitutes the structure that supports and enables the flow of data and information and interoperability services in relation to medical records or electronic prescriptions between autonomous regions.

4.3 Resources and activity

The SNS has a total of 3,055 health centres and 10,067 primary care clinics. It has a network of 468 hospitals, both owned and subsidised, 321 of which are acute hospitals and 147 are long-stay hospitals. There are 665,985 professionals working at these facilities, a rate of 14.3 per 1,000 inhabitants.

There are 3.2 medical professionals and 4 nursing professionals per 1,000 inhabitants²³. The overall ratio in Spain (public and private sector) is respectively 4/1,000h (average for OECD countries) and 5.8/1,000h (below the OECD average²⁴).

Primary care handles 365 million regular consultations, 13 million home visits and 31 million emergencies²⁵. Similarly, hospitals handle 83 million outpatient consultations, 24 million emergencies and 4 million admissions.

The ratio of Computerised Axial Tomography (CAT) and Magnetic Resonance Imaging (MRI) equipment (in hospitals and outpatient care) is 1.9 and 1.7 per 100,000 inhabitants, respectively, which places Spain 13th/26th and 7th/25th among the EU-28 countries.

Spending on health accounts for 9% of GDP, compared to 9.8% on average for EU countries, having increased in line with GDP since 2010, from \$2,736 per capita per year in 2010 to \$3,616 in 2019²⁶.

70.5% of spending on health is in the public sector and 29.5% is privately financed²⁷, in the case of the latter, with a significant weight of direct payments made by households going on the purchase of medical devices and products (glasses, contact lenses or hearing aids), the purchase of medicines (including pharmaceutical co-payments) and outpatient dental care.

Across the SNS, 13.9% of expenditure was on primary care in 2018 (14.2% in 2002) and 62.8% on all forms of hospital care (53.6% in 2002).

As regards Information and Communication Technologies (ICT), according to the SEIS 2020 Index²⁸, the overall budget of the autonomous regions combined for ICT in healthcare in 2020 came to 783,553 thousand euros, a 10.77% change compared to 2019, when healthcare spending on technologies dropped by 2.95% year on year. Based on these figures, the ICT budget as a percentage of the overall health budget came to 1.20% in 2020, up by 6%

²³<https://www.mscbs.gob.es/estadEstudios/estadisticas/sisInfSanSNS/tablasEstadisticas/InfAnualSNS.htm> (2019 data)

²⁴ The figures for this group should be treated with caution as there are variations in the professional profiles that each country includes in its calculation.

²⁵ Includes all out-of-hospital emergencies <https://www.mscbs.gob.es/estadEstudios/estadisticas/estadisticas/estMinisterio/SIAP/Estadisticas.htm>

²⁶ <https://stats.oecd.org/Index.aspx?DataSetCode=SHA>

²⁷ <https://www.mscbs.gob.es/estadEstudios/estadisticas/sisInfSanSNS/pdf/SCSprincipalesResultados.pdf>

²⁸ Spanish Society of Health IT: SEIS 2020 Index.

compared to 2019. These figures contrast with the European average for investment in ICT in healthcare, which stands at 5%²⁹.

In terms of human resources, the SEIS Index demonstrates that the number of staff dedicated exclusively to the use of ICTs in the regional health systems increased by 5% in 2020 compared to 2019 and stands at around 0.8% in the SNS.

4.4 Citizen perception

The degree of satisfaction with the care received is generally positive³⁰; primary care is the best rated service (7.3 out of 10) with hospital admissions coming in at 6.9 out of 10 and emergencies scoring worst (6.1 out of 10).

The SNS is clearly perceived as being equal as regards individual care: 86.7% of the people surveyed in the Health Barometer stated that gender had no influence on the provision of care, 70.8% that benefits did not depend on age, 69.6% that social status did not affect the care received and 58.6% that care was independent of nationality. However, in terms of region, only 37.7% of the people interviewed consider that the provision of public health services is equal regardless of the autonomous region you live in, and 43.4% that it is equal regardless of whether you live in a rural or urban area. Waiting lists and the overcrowding of emergency departments are the most frequently mentioned problems in opinion surveys³¹.

The COVID-19 crisis does not seem to have reduced the public's assessment of the level of care received³² from the health system, although it has led 84% of those surveyed to think that it is now urgent to increase economic resources, the number of professionals in the system, coordination between the autonomous communities and the facilities and resources for the prevention of pandemics.

On the other hand, 22% of those consulted in primary care, 27% of those visiting a hospital specialist and 32% of those admitted to hospital replied that they had not been able to participate as much as they would have liked in the decisions that doctors made about their health.

Finally, data obtained from the Health Barometer, before the pandemic, showed that the population's assessment of some digital services, such as online appointments (8.4 out of 10), access to clinical reports (7.9), electronic prescriptions (8.8) and telephone consultations with doctors (8.1), was very positive.

4.5 The challenges facing the SNS

The Spanish healthcare system cannot escape the **continuous growth in demand for healthcare** as its population is living longer and ageing overall. Living longer is evidently desirable, especially if the quality of that life is appropriate for a dignified and just existence:

²⁹ FENIN Index of Digital Maturity in Healthcare

³⁰ https://www.msbs.gob.es/estadEstudios/estadisticas/BarometroSanitario/home_BS.htm

³¹ https://www.msbs.gob.es/estadEstudios/estadisticas/BarometroSanitario/home_BS.htm

³² CIS September Barometer http://www.cis.es/cis/export/sites/default/-Archivos/Marginales/3280_3299/3292/Es3292mar.pdf

responsible and developed societies seek to extend the life expectancy of their members in good health or free from disability.

In this context, the goods sector dedicated to healthcare, with a growing supply of effective services and solutions, is economically very active and capable of inducing demand, which should be viewed positively from the perspective of scientific and economic development. In the case of a national healthcare system, this vision has to be brought in line with an appropriate cost/effectiveness balance in the use of resources, while taking into account the opportunity cost in health policy decisions. Public healthcare is a powerful mechanism for redistributing income and welfare among individuals, based on solidarity, which distinguishes it from the mere provision of services and the law of supply and demand: the bottom line is measured in terms of health gains, equity and the appropriate and efficient use of diagnostic and therapeutic resources.

The differences between the rates of growth in health spending and the limited budget allocations have led to a continuous imbalance in the public health system, which has not been resolved by the various restructuring operations, extraordinary appropriations or agreements of the sectoral conference responsible for tax and financial matters that have been implemented successively.

The pursuit of this **balance between demand/supply** - and vice versa - that allows an effective response to health needs through different organisational and financial models has undoubtedly influenced Spain's decision to opt for a model that places a series of structured resources in a community position, taking charge of the general healthcare of an assigned population, in such a way that Primary Care coordinates and plays an agency role in relation to the rest of the health system. As mentioned above, the aim is not only to ensure equality by reaching all people, the quality of services by attending to processes in a timely manner through expert decisions, but also the efficiency of the system by modulating the discretionary nature of demand for more complex and costly health services, through responses proportionate to the nature of health problems.

The tools on which the SNS has been relying to develop this model are not proving to be as effective as they should be in achieving their objectives. For example, the **organisation of care processes** involving different professionals, units and areas is not, in general, part of a multidisciplinary working culture with an effective and dynamic division of roles. One of the main weaknesses of the healthcare system has been the **lack of communication mechanisms between professionals and functional units**: the fact that individuals traditionally work in watertight compartments has hindered the necessary relationship between professionals from different care areas treating the same patient, and even within the same area, which, to the detriment of quality, often leads to an inadequate use of resources and causes a reduction in the efficiency of the system and patient safety.

Similarly, there are structural and organisational deficits in terms of **delays in care**. Waiting lists³³, both for scheduled surgery and for consultations and diagnostic tests, are a cause for concern to citizens and managers; therefore, for example, despite the fact that surgical activity

³³ <https://stats.oecd.org/Index.aspx?ThemeTreeId=9>

in the SNS is highly dynamic (3.7 million surgeries per year, six times higher than the number of people on the waiting list at any given time), average waiting times in recent semesters have been around 120 days, which has only increased during the pandemic ³⁴.

Hospital consultations also show average delays of 81 days in terms of an initial consultations³⁵. In primary care, while half of those who request an appointment for the same day or the next day obtain one, others, on average, have to wait 5.8 days³⁶.

Electronic health record systems have made clear progress in terms of their availability and accessibility from the different patient care devices, although they are still not perceived as an essential asset for relations between professionals and between professionals and users. The **decision-making support systems** that have been adopted up until now consist mainly of generic aids with little development of tools based on massive data management.

The diversification of **relationship channels**, which can facilitate patients' access to services and the organisation of professionals' agendas, had in general been timid until the outbreak of the pandemic, with face-to-face appointments predominant, which on many occasions may have more agile alternatives that are more appropriate to the nature of the specific intervention required. There is also room for improvement in the **provision of information to patients and their carers** on their process: quality health care requires that this information be provided in a timely manner, taking advantage of the various communication options now widely available.

In turn, the introduction of **portable digital devices** for disease management and control, especially in the case of chronic diseases, provides patients with greater autonomy and quality of life and allows them to interact with the health services. Their use needs to be strongly encouraged, always supported by systematic evaluation and monitoring, so that their incorporation into clinical practice is based on a correct cost-effectiveness ratio.

It is also necessary to **review the status of the SNS Health Information System**, defined in Chapter V of Law 16/2003, of 28 May, on the cohesion and quality of the SNS, which must guarantee standardisation, comparability, transparency and accessibility within the legal framework of personal data protection.

The SNS has large databases that allow for numerous indicators to be generated that provide information on health status, determining factors, system resources, activity, results and the opinions and expectations of the population and patients³⁷. This information system, which is one of the backbones of the cohesion of the SNS, is based on specific registers and statistics, which exist at both national and regional levels and are highly standardised.

However, there are still underdeveloped aspects such as those related to the socio-economic, cultural and environmental determinants of health, or the physical, social or family environment that play a relevant role in the population's health status, as well as progress in

³⁴ https://www.mscbs.gob.es/estadEstudios/estadisticas/inforRecopilaciones/docs/LISTAS_PUBLICACION_jun2020.pdf

³⁵ <https://www.mscbs.gob.es/gabinete/notasPrensa.do?id=5139>

³⁶ https://www.mscbs.gob.es/estadEstudios/estadisticas/BarometroSanitario/home_BS.htm

³⁷ <https://www.mscbs.gob.es/estadEstudios/sanidadDatos/home.htm>

the analysis of health outcomes, information that would enrich the knowledge of health and, as a consequence, facilitate the prioritisation of health policies.

In turn, as a result of the COVID-19 health crisis, the need for shared information in real time in the SNS has become even more evident, both for **epidemiological surveillance and control** and for the care and assistance response to the population. In this way, the systems for surveying and controlling the evolution of the pandemic have been reinforced and systems for recording and exploiting information on the disease and its approach have been set up to enable the monitoring and control of healthcare capacity and the effective allocation of available resources, which must be integrated with the other sources that supply the Health Information System.

Information systems should support all SNS activity, from health surveillance that allows early detection of risks and rapid response to threats to the population to personalised medicine seeking the best option for each patient.

Finally, and along the same lines, one of the fundamental challenges facing the healthcare system and related institutions is the massive storage of data for advanced data analysis. A **National Space for Health Data** must be set up, comprising both those available in the SNS and in other repositories of the health administrations and their bodies, from other public administration sources, from academia or from the Internet of Things (IoT), on which to apply digital methodologies and technologies such as big data analysis or Artificial Intelligence tools, machine learning (ML) or natural-language processing (NLP).

In short, the challenges currently facing the SNS require, on the one hand, increasing and improving **people's** capacity to take action in relation to their own health, and on the other, strengthening the mechanisms for **protecting the health of the population** and transforming **the processes of health promotion, disease and disability prevention, as well as care**, based on the integration of actions based on the patient.

This should translate into a higher **quality** of services, increased **responsiveness**, greater patient and professional **satisfaction** and an appropriate cost/effectiveness ratio in the management of resources that contributes to the **financial balance** of the SNS.

All of this is ultimately related to the **management of data and the knowledge** they are capable of generating, which should act as a driving force for innovation in both sectoral and multisectoral health policies and actions.

The incorporation of all digital technologies also presents specific challenges related to the establishment of new organisational and regulatory frameworks, the digital empowerment of healthcare professionals and individuals, ethics, privacy protection and the humanisation of care.

5 National Health System Digital Health Strategy

The objective of the SNS Digital Health Strategy (ESD-SNS) is to contribute to maintaining the Spanish population in good health and to strengthen the SNS through the transformation capacity of digital technologies aimed at people, health professionals, health service provider organisations and other related agents.

The Digital Health Strategy has been developed as part of a participatory and iterative multi-stage process, taking the preparation of the strategic objectives as its starting point, arising in turn from the challenges identified in the analysis of the status of the SNS.

As agreed by the Digital Health Commission on 18 October 2021 and approved by the Interterritorial Council of the SNS at its plenary meeting on 2 December, it includes the working framework of all the administrations and organisations that make up the SNS for the transformation of its functioning through the planned and systematic incorporation of digital technologies in all areas of activity (surveillance, health promotion, prevention of illness and disability, care, research, planning and management) as well as in all the relationships between the stakeholders in the system.

The Strategy should be seen as a living and dynamic working instrument, which will be reviewed periodically by the Digital Health Commission and, where appropriate, the Interterritorial Council of the SNS.

It therefore aims to serve as a guide that allows the SNS to jointly obtain the greatest possible benefit from digital technologies, increasing coordination between the functions that make up the comprehensive framework of health protection: promotion, prevention, care and rehabilitation, in addition to including aspects of teaching and research.

Similarly, it must facilitate the participation and involvement of the different stakeholders, bearing in mind that the demand from citizens to play an active and informed role in their own health is growing every day. Therefore, it must take patients, health and non-health professionals, managers and policy makers into account, as well as the health-related business sector.

People's well-being and health are the result of a series of elements that are intrinsic and extrinsic to the health system, such as food, environment, social habits, education, culture and values, which determine, to a large extent, the fortunes of the members of a given society. Therefore, the ESD-SNS also aims to integrate with other public and private, national and international sectors, that have the capacity to contribute to the achievement of this well-being, for society as a whole and for each of its components.

The Strategy's approach follows the following hierarchy:

- Guiding principles
- Strategic objectives
- Strategic lines

- Areas of intervention
- Action plan
- Governance system
- Development framework
- Risk analysis

5.1 Guiding principles of the Digital Health Strategy

The guiding principles are fundamentally those set out in Article 43 of the Spanish Constitution, which recognises the right of all persons to health protection and its implementing regulations, the most relevant of which are Law 14/1986, on General Health, Law 16/2003 on the cohesion and quality of the SNS and Law 33/2011, on General Public Health.

- The Digital Health Strategy aims to promote the **values of the SNS**: equity, cohesion, participation, integration of actions, sustainability, transparency and accountability.
- It aims to increase the **autonomy and decision-making capacity of patients** and the **development of SNS professionals**, based on the recognition that health protection is a shared task that requires communication between the different stakeholders, sectors, levels and professional profiles.
- It seeks to **prioritise innovative actions** that provide the most evidence of **positive health outcomes**. Within this framework, the initiatives that comprise it must be aligned with the circumstances, proposals and needs of the autonomous regions, in order to ensure the systemic development of the digital transformation.

5.2 Strategic objectives

The objectives are directly linked to the challenges identified for the SNS and are structured across **four components: people, processes, data and innovation in health sciences**. These four components should reinforce one another, increasing the efficiency of the system as a whole.

5.2.1 People and Health

Empowering and involving people in their healthcare and facilitating their relationship with health services by promoting their participation at all levels and encouraging their joint responsibility.

People must be the focus of the digital transformation of healthcare, meaning that policies are centred on them and on their active participation in healthcare, increasing the culture and tools for both health promotion and prevention and/or good disease control.

In turn, the aim is to ensure that they have easy access to the SNS, diversified and organised in the different health services, so that they are attended to in the most clinically appropriate way, at appropriate times and without any gaps in care processes, guaranteeing equity and taking into account diversity in access to digital technology.

5.2.2 Value Processes

Promoting the performance of the public health system by means of instruments to support the work of professionals and the generation of value processes, understood as those that take into account health outcomes, together with costs and the opinion and preference of patients.

They are aimed at supporting **professional performance** through flexible technologies for both patient relations and multidisciplinary work and digital tools that support the activity, decision-making in terms of the promotion of health, disease and disability prevention and clinical care, as well as the development of competences. It is also about facilitating the work of those who manage and administer health resources and facilities.

The redesign of processes, reinforcing the logic in each case (health promotion, disease and disability prevention or clinical care), simplifying and automating tasks, facilitating decisions, avoiding the lack of coordination and redundant or unnecessary actions, and ensuring the continuum of care and the sustainability of the system, are the desired outcomes of the implementation of the Strategy.

Digital capabilities of the SNS

It is essential to strengthen physical and expert knowledge infrastructures in order to meet the needs of the digital transformation and, in particular, of the actions resulting from the strategy.

The ICT infrastructure is essential for organisations, professionals and users to access online digital services, as well as to enable the implementation and deployment of applications in such a way that is not constrained by response times, communication and processing capabilities. The recruitment of human resources with training in ICT for health across all levels of the SNS is necessary to ensure the realisation of the Strategy.

5.2.3 Interoperable and quality information

Improve decision-making in the SNS, providing it with interoperable and quality information, and a Data Space that allows its secondary use for the generation of scientific knowledge and for the assessment of services.

Digital transformation must ensure that all data generated in and by the SNS can be transformed into interoperable information between the various stakeholders in the system and for the generation of knowledge. The principle of FAIR (*findable, accessible, interoperable and reusable*) data generated by research, together with the adequate protection of personal data and the development and application of ethical standards in their processing, should underpin the development of digital health services.

The aim is, on the one hand, to strengthen public health surveillance systems in such a way to ensure that they are equipped with a greater capacity for coordination, immediacy and prediction in order to anticipate risks and support decision-making by health authorities.

On the other hand, those involved (professionals and patients) must be assured of the availability of the information required for better and safer health promotion, disease and disability prevention and healthcare, including teaching and research factors.

In the same way, it promotes healthcare oriented towards the best results, through the advanced analysis of data that should provide knowledge returns to professionals and enhance the work of researchers for scientific development in the field of health and in particular to increase the strength of scientific evidence for decision-making in terms of public health.

To facilitate the construction of the Data Space, the definition and standardisation of the concepts of surveillance, prevention, care and management should be extended and an omnichannel approach must be ensured, i.e. the health data of individuals must be common and cross cutting, regardless of the point of collection or access and pursuant to the provisions of the current regulatory framework for the protection of personal data.

5.2.4 Innovation and 5P healthcare

Adapting the progress of the healthcare system to the demands of today's society, through innovation policies oriented towards 5P healthcare (Population, Preventive, Predictive, Personalised and Participatory).

The incorporation of digital technologies into the SNS must catalyse its transformation towards this new paradigm and translate into new and better services in line with the needs of the population, which are more adapted to each person, with more autonomy and decision-making capacity for patients and compatibility with the sustainability of the system.

Innovation must demonstrate evidence of the benefits it offers and the proportionality and efficiency of healthcare efforts, to which end ,the sharing of experiences between different

autonomous regions will be promoted, making it possible to take advantage of the results of innovation in similar scenarios in terms of new digital services.

5.3 Strategic lines

These constitute the main pillars that support the objectives and activities of the Digital Health Strategy. The strategic lines are cross-cutting in nature and should be mutually reinforcing as part of the specific projects that the objectives are broken down into.

1. Development of **Digital Public Services** in the health sector.

This line should have a direct impact on strategies for promotion and prevention, health care delivery, rehabilitation and social reintegration after illness.

The possibilities that digital technologies offer in terms of increasing accessibility, capacity and diagnostic and therapeutic precision must be applied in such a way that their use does not generate new inequalities. To this end, it is essential to bear in mind, as part of all these initiatives, the aspects of change management, usability, accessibility and digital training, both for citizens and for health professionals as a whole. Special attention should be paid to the needs of vulnerable groups, with chronic health problems, living in poorly communicated areas or that experience functional difficulties.

2. Promoting the **interoperability of health information**, nationwide and internationally, to the service of both health surveillance and health interventions of any kind, facilitating decision-making by health authorities, managers and professionals. In turn, the availability of interoperable data for secondary uses that generate knowledge adds extraordinary value to health-related information.

This line is key to facilitating the work of professionals in all areas of healthcare, strengthening the quality of care and patient safety. It also aims to increase the cohesion of the SNS and improve inter-administrative cooperation mechanisms, both nationally and internationally, the importance of which has been emphasised during the COVID-19 crisis.

In this sense, the ability to articulate responses and services at both a national and international level in "VUCA" scenarios (i.e. characterised by their variability, uncertainty, complexity and ambiguity) depends very much on the ability to have and exchange accurate and homogeneous information at the required time.

3. Extension and reinforcement of **data analytics and information exploitation** for SNS "business intelligence".

This line of action will contribute both to optimising clinical decision-making and the capacity to plan and anticipate risk, enhancing the effectiveness of surveillance services and promoting basic and applied research.

The re-use of clinical information, linked to other big data sources, represents a major opportunity for quality improvement in health promotion, disease and disability prevention, healthcare, research, education and epidemiological surveillance.

The goal is to create a data space and associated services, in line with the action area of the DEP (Digital Europe Programme) in health, European Health Data Space, in which the different existing solutions in the field of the SNS are integrated, making it possible to work with shared data models for advanced analysis, simulation, prediction and personalisation.

The physical architecture will be distributed across the 17 autonomous regions and a central organisation, facilitating access to shared services. This can take assume control over the infrastructure should one of the autonomous regions so require.

5.4 Areas of intervention

Ten major healthcare and health system areas have been identified where the application of digital solutions can have a significant positive impact:

1. Monitoring of health threats and risks
2. Promotion of health and prevention of disease and disability, with community participation and a focus on equity
3. Healthcare: accessibility of services, responsiveness, personalisation, continuity of care and patient safety. Digital health records and the empowerment of health imaging for diagnosis, prognosis and treatment.
4. Management processes that support the performance of health functions and their efficient use.
5. Interoperability of information at a national and international level
6. Strengthening the SNS' digital services
7. Development of the SNS' portfolio of services based on scientific evidence and value for money.
8. Professional organisation, specialist health training and postgraduate training.
9. Creation of a National Space for Health Data for mass processing and analysis and establishing enabling conditions and facilitating resources for the generation and extraction of knowledge.
10. Health information system for the assessment of the activity, quality, effectiveness, efficiency and equity of the SNS, with a wide range of easily accessible public information, under appropriate conditions of security and protection of personal data.

Intervention in these areas implies, in all cases, cooperation between the Ministry of Health and the autonomous regions, as well as with other ministerial departments and the European Union, as part of actions that can reinforce and complement one another.

5.5 Action plan

The Action Plan encompasses the areas of intervention and associated activities, characterising them depending on whether the Ministry of Health is responsible for them with the participation of the autonomous regions or whether the autonomous regions are responsible for them on a collaborative basis, in which case the Ministry of Health acts as a coordinator to facilitate the adoption of agreements and standards that can be extended to the entire National Health System. In turn, epidemiological surveillance must be developed and managed in an integrated manner so that the responsibilities of health authorities can be effectively exercised.

The Ministry of Health is responsible for liaising with the European Union in relation to projects financed with European funds. The Ministry of Health will act as the single point of contact for the management of these funds as part of these projects.

The definition of the areas of action for collaboration between the autonomous regions has been based on the information provided by them, identifying and grouping together common initiatives that facilitate the development of shared projects, which can be applied in all the regions that wish to do so. In all cases, the aim is to generate scalable, nationwide projects in which the participation of at least two autonomous regions allows the introduction of interoperability criteria from the outset, the exchange of information and the aggregation or federation of data for analytical and research purposes. Consideration shall be given to the experience of similar programmes previously run, such as the BIFAP Programme financed and managed by the Spanish Agency of Medicines, in which nine autonomous communities are already collaborating.

As regards digital health transformation projects with European funding, this model of shared leadership among the autonomous communities, with the coordination of the Ministry of Health, should serve to obtain the maximum benefit for the SNS and, in short, society as a whole.

5.5.1 Areas of execution of the Ministry of Health with the participation of the autonomous regions

a) Boosting interoperability

General description

Expansion and improvement of the SNS interoperability services that enable the movement of people and clinical information, both in their functional scope and in their technical support, improving their usability.

Actions

- Promote the adoption of standards and best practices for the operation of the Digital Health Record and the interoperable SNS e-Prescription.
- Make progress with the full interoperability of clinical information between health services and the integration of the essential data of each person in the SNS as a whole, preferably adopting clinical data models with open standards.

- Strengthen the Protected Population information system, which provides each person with a unique identity across the entire SNS, and establishes access to it from all health centres.
- Promote and support the digital identification resources required for professional and patient access to the different digital services offered by the SNS.
- Achieve full integration in the European interoperability projects of the abridged medical record and the e-Prescription.
- Implement an information system for population-based screening programmes that includes the programmes in the SNS' common portfolio, for their assessment and monitoring, helping to improve their coverage and the times for their clinical consideration.
- Promote inter-administrative cooperation, especially with social services for the coordinated care of people considered vulnerable in terms of health and social situations.

b) Expansion, integration and improvement of the National Health Information System.

General description

Review and expansion of the information systems that make up the SNS, with the reinforcement and extension of their analytical and predictive capacities for analysis, assessment and support for decision-making in health policies.

Actions

- Strengthen the adoption of models, standards, procedures and best practices by all SNS stakeholders to facilitate the exchange of data and information. Likewise, digital technologies should be used to promote collaboration between the different autonomous regions in the development of their own digital services and to exchange the results of these, for potentially scaling up in other environments.
- Increase the aggregation and consolidation of information nationally and strengthen international exchanges and collaboration.
- Incorporate new data sources, integrating them and incorporating new tools for the analysis and presentation of information through the improvement of the SNS Information Portal.
- Develop mechanisms to facilitate access to potential stakeholders, consultation and re-use of information, applying the conditions of use determined by the applicable legislation in each case.
- Establishment of homogeneous performance measurement indicators with universal indicators.

c) Strengthening the SNS' digital services

General description

Expansion of the capacities and benefits of the SNS managed by the Ministry of Health with the launch of the Technical Office for the Digitalisation of the SNS.

Actions

- Define and implement an information systems and technology service management model for the autonomous regions in the SNS.
- Improve the technological infrastructure of the Public Digital Services of the SNS
- Implement a vaccination registry, which makes it possible to monitor COVID-19 vaccination schedules and for other diseases and the analysis of vaccination coverage and population groups.
- Implement collaborative tools to facilitate the coordination of SNS agents.
- Improve population risk stratification systems to address chronicity.

d) Development of the Portfolio of Services

General description

Actions to support the development of the National Health System's Portfolio of Services through the availability of adequate and timely information that reinforces its basis in scientific evidence and cost-effectiveness analysis, incorporating the opinion of patients.

Actions

- Technological support for pharmaceutical invoicing and financial compensation for services provided across regions and countries.
- Facilitate the application of effectiveness criteria by means of objective and quantifiable parameters to obtain detailed information available when negotiating prices with suppliers and to favour the financial sustainability of the SNS.
- To support the assessment of health technologies, as well as the definition of new services and pricing, facilitating the traceability and control of fraud involving these types of products.

- Standardise the implementation of molecular diagnostics and biomarkers in the SNS Portfolio of Services with the diagnosis of pathologies and the financing of the medicines that require them.
- Evaluate the incorporation of the European environment into the service portfolio.

e) Organisation of health professions and their incorporation into the SNS

General description

Technological support for the identification of needs, planning and coordination of SNS human resources policies through robust, transparent and flexible technological solutions.

The effective, homogeneous and permanent implementation of the SNS' Register of Health Professionals is a key element to which the necessary resources must be devoted, so that its joint and coordinated operation and use can be guaranteed.

Actions

- Make progress with the analysis of the needs of health professionals, as well as with the incorporation of new key profiles for the development and implementation of the ESD-SNS.
- Improve the planning and coordination of the SNS' human resources policies to enable the training and recruitment of new professionals with maximum speed and quality.
- Facilitate the exchange and interoperability of information on professionals' CVs.

f) National Space for Health Data

General description

The objective is to provide the SNS with a platform of data and associated services aligned with the DEP (Digital Europe Programme) action area in health, European Health Data Space, "Building a common European data space for the adoption of AI technologies".

This will provide the entire SNS (Ministry of Health, health departments, health centres, health agencies, research institutes, scientific societies, professionals and other interested parties) with a technological platform for storage, massive archiving (*data lake/ big data*), processing and analysis with advanced digital capabilities for data from the SNS information systems and other sources, whether clinical, management, epidemiological or health-related statistical operations.

This cloud data platform must be designed bearing in mind interoperability, growth capacity, quality, data protection, security, traceability and auditing by SNS and external agents (AEPD, CCN, etc.), as well as segmentation, so that it allows the autonomous regions and associated bodies to have their own data stores if they so wish, and the SNS as a whole to have aggregated and consolidated data.

Based on the data repository and advanced digital tools for analysis, simulation and prediction, the platform will provide specific services for the information systems of the SNS, the autonomous regions, state agencies, health centres and researchers, and patients themselves. It should also provide information for the monitoring and assessment of the SNS Health Strategies.

The platform will also support interoperability with EU projects such as the European Health Data Space and other more specific projects including but not limited to Genomics (1+ Million Genomes initiative), Medical Imaging of Cancer, HSD/HCE (Digital Health Record/Electronic Health Record), taking into account the need for compliance with repository reliability standards, as well as interoperability with other health data repository projects, such as the ISCIII's precision medicine research infrastructure and others that may be developed in different health-related domains and institutions.

Finally, scenarios for public-private cooperation may be defined to undertake initiatives of particular interest to the National Health System with the participation of business organisations.

Actions

- Design and implement a cloud platform for the storage, advanced processing and **massive analysis of data from the SNS** and related organisations to be applied to the public health surveillance, clinical practice, assessment of services and research. The platform will have segmented spaces for the autonomous communities and will be prepared to interact with the other nodes of the *European Health Data Space*. The platform should also support the use of structured and unstructured data, including "real world data".
- The Ministry of Health will set up a Technical Office for the Standardisation and Quality of Health Data, which will be solely responsible (with the participation of the autonomous regions) for the definition, review and updating of standards and regulations to ensure data management, interoperability throughout the SNS and with interested third parties, as well as the correct pseudonymisation or anonymisation of data and their cases of application.
- Establish the enabling conditions and facilitating resources that allow for the generation and extraction of knowledge applicable to prevention, diagnosis and treatment, as well as to the management of the health system, and that define an appropriate framework for technological innovation in collaboration with the private sector, providing regular information to the public on the functioning of the system as a whole.
- Provide the whole system with analysis and simulation tools (AI, ML, NLP, etc.) that facilitate health risk surveillance and control activities, monitoring and control of healthcare quality levels, as well as planning, shared decision-making and assessment of public policies based on data, increasing the transparency of the system.
- Implementing operational tools and services provided by the platform will contribute to improving the skills of healthcare professionals in advanced digital technologies, as well as boosting public-private collaboration in the healthcare sector.

5.5.2 Areas of action for collaboration between the autonomous regions

a) Promotion of health and prevention of disease and disability, with community participation and a focus on equity

General description

Development of initiatives that promote healthy habits and lifestyles, through digital content and technologies, with the active participation of citizens and health professionals, as well as other educational and social agents, etc. Adoption of solutions that promote health and prevent illness, injury and disability. Incorporation of the digital empowerment of citizens and professionals as an element of active health. Training and dissemination of new digital solutions, models and tools to both professionals and patients is essential in ensuring maximum efficiency and employability.

Actions

Digitalisation should contribute to the population's knowledge and experience of "positive health". Consequently, to **reduce consumerism, medicalisation and reliance on the health system** by aligning with the objectives set out in the Promotion of Health and Prevention of Disease Strategy of the SNS, adapting them to the different stages of life (children, young people, adults and the elderly) and in the different environments in which they interact (family, education, social and work):

- Provide relevant and quality information and support to citizens to help them to adopt and maintain a healthy lifestyle.
- Provide digital tools that help with the adoption and maintenance of healthy lifestyles.
- Establish a system for assessing the impact of the use of digital tools on the reliance on the health system.
- Enable synergies with activities in other sectors with an influence on the health of citizens, facilitating the identification and invigoration of community assets for health, intersectoral collaboration and impact assessment.
- Help to improve the environments where we live and work to enable healthier lifestyles.
- Facilitate early detection and address frailty in older people through multifactorial care and preventive intervention plans and individualised follow-up, with particular attention to unwanted loneliness.
- Support adherence to treatment and evidence-based pharmacological description, where necessary.
- Develop training actions and dissemination campaigns

b) Healthcare

General description

The aim is to **strengthen the capacities** of health centres and hospitals, **improving the quality of services** for patients and facilitating the **work of professionals**.

The aim is to expand and improve services inside and outside healthcare facilities, transcending the *centre-based* approach to healthcare and facilitating the delivery of certain services through a virtual and intelligent care network that is patient-centred and integrated into the health continuum.

Digitisation must be conceived with an approach that integrates all the functions of the healthcare system, facilitating the specific performance of each level of care and a joint approach to patient treatment. It must be adapted to the circumstances of each of the stakeholders and to the changing demands of society.

The aim is, on the one hand, to take advantage of the possibilities that technology provides in terms of information management and, on the other hand, diversify the means of communication with patients and between the different professionals. Digital health centres will help to facilitate the online relationship with patients in activities that do not require face-to-face actions, to organise the schedules of professionals on the basis of the new forms of relationship and to streamline communication between care areas.

At the same time, the digital transformation must promote the availability of models, standards, procedures and good practices available to all SNS professionals. Specifically, consideration must be given to the standardised integration of professional medical devices deployed at care centres into the corresponding information systems.

Similarly, it should contribute to the adaptability of the system in situations of risk such as the current pandemic, to ensure the level and quality of healthcare provisions in circumstances of limited physical contact or reduced availability of healthcare personnel. To this end, training in the use and indications of advanced digital technologies should be imparted to healthcare professionals.

The adoption of collaborative environments, both between centres and outside centres, should also be encouraged, to facilitate support and strengthen interdisciplinary monographic units, always bearing in mind that not all patients can use online resources, that there are processes or situations that cannot be dealt with in this way, and bearing the digital divide in mind.

This project has an obvious relationship with the Digital Transformation of Healthcare Management project, insofar as it affects the processes that support the healthcare activity indicated below, meaning that the design, interfaces and information exchanges between the two must be coordinated.

In this area, the provision of digital clinical decision support tools according to "evidence-based medicine" should be promoted through the availability of clinical practice guidelines and computational clinical pathways.

Likewise, in this area the molecular, environmental and social information required for a true adoption of personalised medicine must be incorporated.

b.1 Digital Health Centre

Actions

- To facilitate people's access to the primary care area through digital communication tools, applicable at certain times of clinical processes and especially relevant for chronic patients, remote areas or people who experience difficulty travelling to primary care centres, including access from home and residential centres and taking into account both digital skills and people's functional diversities.
- Incorporate tools to improve the **time management** of professionals, through the planning of their activities, an adequate distribution of tasks among the different professionals, ergonomics in data recording and bureaucratisation, agility in accessing clinical information, and the possibility of diversifying the way of relating with patients through non-face-to-face systems.
- Provide professionals with the relevant clinical and diagnostic information and decision support systems that encourage the proper **provision of services** and improve decision-making capacity, ensuring access from the home or residential centres where appropriate.
- Implementation of effective relationship tools between professionals and care settings, including those working in health and social care centres, to promote **continuity of care**, patient safety and operational efficiency.
- Initiatives that can be combined with the strategies for tackling **chronicity**, both for patient management and for stratifying the population and adapting the population assigned to professionals in line with the burden of disease and social vulnerability.
- Incorporate tools to easily capture up-to-date electronic Product Information (eP) for medical professionals and patients, e.g., package leaflet, package leaflet and labelling.

b.2 Digital Hospital

Actions

- Implementation of digital tools that ensure integrated responses and well organised processes for patients, improving the **accessibility** of people referred by the primary care area, the **association of actions** and **inter-area communication**, as well as the possibility of diversifying the way of interacting with patients through non-face-to-face systems.
- **Management of clinical activity**, through digital technologies that facilitate the planning and execution of clinical activity, electronic systems for recording, integration and retrieval of data, interconnection of equipment and other digital initiatives that promote the quality of clinical practice.
- Improve **departmental information systems**, introducing standardisation elements that enable their interoperability and their integration into the clinical

history, reviewing the functional content in areas such as clinical analysis laboratories, ICUs and hospital pharmacies, among others.

- Implementation of technological solutions that improve **information** to patients and their relatives and **communication** between them, helping to maintain contact between the person admitted and their environment and to inform authorised relatives about their progress. These solutions have proven to be very useful in a situation of restricted access to healthcare facilities and can also contribute to the general streamlining of visitor traffic in hospitalisation processes.
- Adoption of systems that facilitate collaborative work between centres, promoting the appropriate use of the best resource for each situation, maximising effectiveness and efficiency, as well as relations with Reference Centres, Services and Units (CSUR).

b.3 Digital Health Record

General description

Development of the current electronic health record systems towards a Digital Health Record (HSD) within the framework of the new 5P healthcare approach (Population, Preventive, Predictive, Personalised and Participatory), which is fully digital, interoperable nationally and internationally and focussed on the person/patient (information follows the patient), with a view to ensuring both the quality of their healthcare and the efficiency and equality of SNS actions.

Actions

- Renew, expand and standardise the current HCE (Electronic Health Record) by reorienting it towards a new integrated, technologically advanced and nationally shared HSD (Digital Health Record) model, which is the central element of a person-centred digital health system.

This HSD must be intelligent, going beyond the mere recording of the activities carried out, making patient interaction and control over the use of their data compatible with the incorporation of new technological capabilities and new data sources - for example, IoT devices - that facilitate the activity of professionals, increasing their abilities in terms of prevention, diagnosis and treatment.

This new HSD will be the focal point of the new Digital Health Services in the SNS, as well as the axis of an active and preventive approach to the well-being of citizens, while contributing to the improvement of health surveillance systems.

b.4 Medical Imaging

General description

Digital Transformation of Diagnostic Medical Imaging Processes (radiodiagnosis, ultrasound, CT, MRI, nuclear medicine, as well as images from other specialisations

such as anatomical pathology, laboratory medicine, ophthalmology, dermatology, etc.) to make resources (data, images) and results (reports, interpretation) arising from the use of diagnostic imaging techniques available to healthcare professionals in a timely manner and regardless of their location, while facilitating their use and access to the best specialists, increasing the efficiency of the system.

It is all about providing:

- Access to data, reports and objects of imaging techniques in a transparent manner for health professionals, regardless of location.
- Secure and interoperable storage and processing of data and results
- Data analysis using technologies such as AI/ML, NLP, speech-to-text conversion and others.
- Access and clinical guidelines and therapeutic drug protocols for guidance.
- Templates for standardised reporting

In other words, "functional clinical imaging units in health" available to the entire health system in a virtual manner for the application of imaging to diagnostics, prognostic evaluation and personalised treatment selection.

This project is closely related to the Data Space project, since the latter would house the repository and analytical services using which the operation of these "functional imaging units" is achieved, also benefiting the entire system by sharing and aggregating data.

Actions

- Obtain remote access to Integrated Diagnostic Imaging Services throughout the entire network of services or units that use imaging in the SNS, facilitating the knowledge of the best specialists per pathology to be shared and optimised, ensuring accessibility and equity in the use of these techniques.
- Support the resolution capacity of both primary care and secondary care, through effective access to diagnostic imaging tests.
- Incorporate new data analysis technologies to improve the quality and outcomes of the SNS, both in diagnosis and in early disease detection programmes.
- Serve as a Driver Project in terms of AI/ML with the advancement of Assisted Diagnosis solutions, based on algorithms developed by professionals themselves, preserving and improving knowledge in the organisation.

b.5 Personalised Assistance

General description

The aim is to design, develop and operationally deploy, within the portfolio of public health services, a comprehensive model for the provision of face-to-face, remote and virtual services specifically designed for groups of patients who require personalised, continuous and systematic assistance, due to their health or other personal circumstances, within the general context of the Digital Transformation of healthcare.

By incorporating technologies such as IoT (internet of things) or blockchain, the aim is to ensure adequate levels of care, quality and safety for people in these circumstances, in addition to assessing the extension of certain services to wider groups to improve the capacity for prevention and anticipation through the use, for example, of wearable devices.

This project also includes initiatives for the incorporation of Virtual, Augmented and Mixed Reality, as well as additive printing laboratories for the prototyping and short series of customised innovative healthcare devices and even remotely operated robotic devices.

The project will also generate valuable data for further analysis from both clinical and research perspectives, which will require the establishment of appropriate public-private collaboration frameworks.

Actions

- Personalise the portfolio of care services (digital and/or face-to-face) for groups that require them by incorporating technologies and smart devices to improve the quality and proximity of care, promoting the integration of clinical, genomic and other types of data for the development of new treatments that improve the SNS.
- Educate patients in situations in which their health requires special assistance and care in prevention and prediction of possible processes that may aggravate their condition.
- Manage with quality, humanity and efficiency the care of groups such as chronic patients who require personal assistance given their health or people in situations of isolation or limited mobility, extending the capabilities of professionals and services with new technological tools and assisting them with clinical decision support systems in order to obtain better health results.
- Establish mechanisms for liaison with social services, so as to facilitate coordinated attention to health and to people's vulnerability and lack of autonomy.
- Develop guidelines and models, as well as update processes and care, to establish standardised procedures for the use of new solutions and modalities that ensure and promote the comprehensiveness of the personalised, continuous and systematic assistance model.

c) Digital transformation of healthcare support services

General description

The project aims to define and implement the necessary information systems so that the **management of the health services** have the broadest possible digital support that guarantees the availability of all the information, the singularity of the data and the integration between all of them.

These non-clinical information systems will interact with care information systems, integrating with them where appropriate through the HCD, and will provide

aggregated information to management structures on the performance of services and improve their planning and use.

Health centres and hospitals develop a series of non-care processes, such as patient management, monitoring the activity and occupancy of the different services, financial and personnel management, contracting, equipment and physical infrastructure management, which, on the one hand, are essential to support care activities and, on the other, have a direct impact on the overall efficiency of the system and its quality.

Achieving the digital transformation of these processes, integrating them with each other and with care systems, and generating aggregated information for decision-making is essential as regards the sustainability of the public health system.

Actions

The aim of the project is to achieve a digital and integrated environment for the planning, management and analysis of resources (human, economic, health equipment and products, infrastructures, etc.) used in the health services and to provide an integrated digital support for the non-health care activity of the health centres that improves the quality of care, facilitates the work of professionals and increases the resolution capacity of the health system.

The project also aims to improve the administrative management systems used at centres to facilitate the organisation of demand for care and the networking of the different related structures (health centres, hospital centres and services, centre and area management, medical inspections, emergency services and others).

Initiatives in this area should also contribute to making the relationship between the patient and the SNS easier and more flexible, by simplifying organisational or bureaucratic procedures that do not require a healthcare professional.

5.5.3 Areas of action of shared execution between the Ministry and the Autonomous Regions

a) Epidemiological Surveillance

General description

The aim is to have advanced information systems in place in the autonomous regions that make it possible to generate a single integrated epidemiological surveillance information system in near-real time. The connection between information and action is the factor that determines the value and usefulness of surveillance.

Actions

- Ensure the availability of a system with homogeneous data and standardised measurement and collection processes, providing efficient and reliable epidemiological information on the health status, determining factors and health

problems of the population, in real-time where appropriate, oriented towards decision-making.

- Establish elements of effective coordination between surveillance units and health care centres, with primary care as the focal point of care.
- Integrate the Electronic Health Record (HCE) of the autonomous regions into the epidemiological surveillance systems, both as a source of data and as an instrument for the management of individual cases.
- Incorporate interactive analysis, simulation, prediction and representation tools, with geo-referencing capabilities and standardised alert systems that are interoperable with other components of health information systems that can be used for the purposes of health surveillance.

6 Governance of the Digital Health Strategy in the SNS

The SNS Digital Health Strategy requires a governance model that facilitates the coordinated and collaborative efforts of each public administration and the bodies involved with a view to maximising the results for people in general and for SNS' users and professionals in particular.

The governance model should be an extension and reinforcement of the existing model for the SNS, articulated through the Interterritorial Council of the SNS (CISNS).

The following sections develop on the elements that make up this governance model, from the perspective of the governing bodies and the organisational model.

6.1 Governing bodies

The governance of the Digital Health Strategy will be developed through the Digital Health Commission of the Interterritorial Council of the SNS and its two subcommittees, the Subcommittee on Information Systems and Technologies for Digital Health and the Subcommittee on Health Information, so that the Commission and its two subcommittees can streamline decision-making, improve the effectiveness of their projects, promote synergies and collaboration between all the actors of the SNS and guarantee the sustainability of the initiatives that make up the Strategy over time.

Likewise, the Committee and the two subcommittees will be responsible for monitoring and controlling the implementation of the Strategy, periodically providing the CISNS with information on its progress and results.

The Subcommittee on Health Information will be responsible for the definition and validation of the functional aspects in general and, in particular, those related to standardisation, data models, and operation guidelines, coordinating for this purpose the collaboration between the autonomous regions and European and international institutions.

The Subcommittee on Information Systems and Technologies for Digital Health will be responsible for the definition, coordination and monitoring of the technological components of the projects, as well as for the verification of the investments and outcomes of the projects associated with European funds managed by the Ministry of Health.

The two subcommittees will set up joint working groups to define cross-cutting issues, especially those in relation to interoperability, the regulatory framework and the re-use of data.

Furthermore, the Committee on Digital Health may set up committees associated with specific initiatives or projects, which may include experts from the world of academia, representatives of mutual insurance companies, scientific societies, universities, professional or business associations or the health and digital technology sectors, as necessary.

6.2 Working model

The Digital Health Strategy aims to secure the transformation of the entire health system, from health promotion and protection to care and clinical practice, the working environment of professionals and the use of both health and management information.

Consequently, all the projects that make up the different lines of the Strategy involve functional aspects, associated with the field of health, together with technological aspects, associated with digital technologies, and both parts are inseparable.

Therefore, the aim is to work in such a way that all projects have teams in which, in addition to the participation of all the autonomous regions with different degrees of involvement depending on their priorities and resources, specialists from both environments are also present, always seeking the formation of multidisciplinary teams of professionals.

The involvement of SNS healthcare professionals in the processes for defining and selecting tools and information systems is a critical element of the change management involved in digital transformation.

These teams will report periodically to both sub-committees on the progress of their projects, so that common or related factors shared between the different projects can be identified and maximised, maintaining an integrated vision of the Strategy and its degree of implementation.

The subcommittees will also report to the Committee on Digital Health for the purpose of taking any corrective decisions that may be required to ensure the success of the Strategy.

Finally, the Committee on Digital Health will in turn regularly report to the CNIS on progress with the Strategy and the degree to which its objectives have been achieved.

6.3 Project selection model

The Subcommittees will analyse the project proposals from the autonomous regions and the Ministry of Health and will establish an objective and transparent assessment system to select the most appropriate projects based on

- Direct relationship with the objectives of this Strategy;
- Alignment with the strategic lines of work defined;
- Suitability as regards the fields of action (macro-project);
- Participating autonomous regions and distribution of the project;
- Project resources, planning, deliverables and indicators; indicators should be measurable, indicating baseline and target values linked to the success of the project;
- Project risk management plan;
- Training plan (for the project and for its subsequent operation);
- Contribution of the project to the SNS as a whole in terms of reuse, interoperability, sharing of results, exploitation of data and, in general, to the results that the Digital Health Strategy aims to achieve.

To review the projects in line with the assessment criteria defined, the Subcommittees may appoint a group of experts (with the participation of professional, scientific or patient associations) that will prepare the project proposal, to be reviewed by both subcommittees and forwarded to the Committee for Digital Health for approval.

The implementation of the projects will be carried out by the Ministry of Health or the autonomous regions with their own resources or by contracting external resources, in line with their corresponding needs and competences, and consideration may be given to other mechanisms such as innovative public procurement or aggregate purchasing systems.

6.4 Project monitoring model

The subcommittees shall monitor the progress of the projects on the basis of the plans submitted for approval, at the frequency deemed most appropriate, which shall be no less than once every six months for projects financed by European funds and coordinated by the Ministry of Health.

Both subcommittees will establish working models that not only facilitate the coordination of the two subcommittees' work, but also information sharing and agile decision-making.

As regards projects financed using European funds and coordinated by the Ministry of Health or using the department's own funds, a favourable report from both subcommittees will be essential for the justification of the funds.

Furthermore, the Committee on Digital Health will prepare, at least twice a year, a monitoring report on the Digital Health Strategy, based on the progress of the projects and the indicators for each project.

This monitoring report will be submitted to the Interterritorial Council of the National Health System, which will periodically approve the publication of progress reports that provide information on the progress of the established indicators, in addition to the investments made.

Furthermore, the Committee on Digital Health may propose that the Interterritorial Council of the SNS adopt recommendations or resolutions to strengthen the implementation of the projects, with the involvement of patients, professionals, professional organisations and other agents involved and paying special attention to information and training.

6.5 Continuous assessment model

The subcommittees will perform an assessment of all projects, upon completion and at least once per year after their implementation, with a view to assessing the results and incorporate lessons learned into subsequent projects.

Furthermore, once a year, the Committee on Digital Health will draw up a balance sheet of the projects completed during the year or that have been in operation for one year, which will be submitted to the Interterritorial Council of the SNS.

7 Development framework of the Digital Health Strategy

The implementation of the Digital Health Strategy requires a framework of enabling conditions and resources to make it possible. In terms of the enabling conditions, the most relevant are the rules and standards that make up the regulatory framework, as well as training.

As for the resources that make this possible, in addition to the governance framework described in section 7, this section describes the time and financial framework, as well as communication and stakeholder involvement.

7.1 Regulatory framework

This section refers to the series of rules and standards whose development is a key element in terms of the implementation of the Strategy.

7.1.1 Regulations

The main regulatory provisions that provide the framework for the development of the Strategy, together with the application of ethical principles and standards, should ensure the protection of individual and collective digital rights.

- Law 41/2002 governing the autonomy and rights and responsibilities of patients with regard to clinical information and documentation
- Law 16/2003 on the cohesion and quality of the National Health System.
- Law 14/2007 on Biomedical Research
- Law 14/1986 on General Health
- Law 33/2011 on General Public Health
- Organic Law 3/2018 on Data Protection and guarantee of digital rights.
- Royal Decree 1030/2006 of 15 September, establishing the portfolio of National Health System shared services and the procedure for updating them
- Royal Decree 69/2015 creating the RAE-CMBD
- Royal Decree 183/2004 of 30 January 2004 regulating the individual health card
- Royal Decree 1277/2003 of 10 October, establishing the general bases for the authorisation of health centres, services and establishments.
- Royal Decree 1093/2010 establishing the Minimum Dataset of Clinical Reports (CMDIC) in the SNS.

The outcome of the European Union's draft "Data Governance Act" regulation will be applicable.

On the other hand, a digital health regulatory project must be prepared that regulates and frames the new relationship between health services and professionals and users, resulting from the incorporation of digital services and their capabilities, as well as the secondary use of clinical information and the application of AI for therapeutic purposes, under the necessary conditions of security and respect for people's privacy.

7.1.2 Standards

In this respect, the Strategy must provide resources to all projects to define and adopt shared models and standards in all areas where they do not exist (including the necessary extensions to the Digital Health Record) and the definition and implementation of ontologies.

Insofar as possible, international open standards shall be used, with special reference to those certified by UNE, CEN, and ISO.

7.2 Training

As part of any project, a training and support component is required for all users (citizens and health professionals) both before the project comes online and throughout its lifetime.

The training of professionals is a critical aspect for the development of the Strategy. On the one hand, there is a need for digitally literate health professionals, as well as digital professionals with knowledge of the health sector. These profiles should be available for all projects launched, if necessary by organising prior training activities for the project teams.

As part of the initiatives of the Digital Spain 2025 plan, in the area of "Digital training", there is a plan to develop a general training and specialised digital training project for professionals in the health sector, with which the training actions of the projects of this Digital Health Strategy should be coordinated.

7.3 Time and economic framework

The Digital Health Strategy will run from 2021 to 2026, within the context of the implementation of the European funds associated with the Recovery and Resilience Mechanism; this funding will be complemented with funding from the budgets of the Ministry of Health and those of the autonomous regions themselves.

The funding managed by the Ministry of Health, whether using European funds or funds from the Ministry of Health itself, will be conditional on the implementation of the projects within the framework defined as part of this Strategy and the fulfilment of the proposed milestones.

Projects shall be planned, together with the associated economic programming, by the subcommittees of the National Committee for Digital Health, with global planning for the entire Strategy, global annual planning by areas of action and annual operational planning for each sub-project.

These operational plans shall incorporate information on the associated resources, as well as the project's progress indicators and expected results.

7.4 Communication and stakeholder involvement

The participation and collaboration of all stakeholders in the SNS is a critical element, first of the preparation of the Strategy and then its implementation.

An important part of SNS stakeholders, in particular the autonomous regions and mutual insurance companies, are represented on the Interterritorial Health Council, which will therefore be the preferred forum for communication.

Furthermore, collaboration with other stakeholders, in particular other public sector organisations, professional, patient and SNS user associations, and business associations, both in the health and technology sectors, is of paramount importance, and dialogue with all of them shall be encouraged.

8 Risks and Opportunities

Risk is defined as any uncertain event or condition that, if it occurs, has a negative impact on one or more objectives of the Digital Health Strategy and its contents, such as scope, schedule, cost and quality.

An opportunity, on the other hand, is a possible circumstance that, if realised, must be seized with a view to having a positive impact on the Digital Health Strategy and its contents.

In this sense, it is essential to analyse and manage the risks and opportunities of the Strategy, making it possible to establish a standardised process to increase the probability and impact of opportunities and decrease the probability and impact of negative risks as part of a project.

The Committee on Digital Health, as the competent body for the management, monitoring and control of implementation, shall have an updated risk inventory of the Strategy and its projects, which will be drawn up by the subcommittees.

8.1 Risks

The risk analysis shall be carried out individually for each project that forms part of the Strategy to be launched and the subcommittees Committee for Digital Health shall maintain an updated risk catalogue for the entire Strategy and its projects.

The Strategy's initial risk inventory is described below:

Risk: Lack of Governance Model	
Prevention:	<ol style="list-style-type: none"> 1. Development of an overall governance model for the Strategy 2. Definition of roles and responsibilities of each of the participants 3. Use of management techniques, analysis and generation of high performance teams.
Risk: Resistance to the new Governance Model	
Prevention:	<ol style="list-style-type: none"> 1. Establishment of the Committee on Digital Health 2. Sharing of the model within the Committee on Digital Health
Risk: Ongoing regional digital strategies limiting the applicability of a national strategy	
Prevention:	<ol style="list-style-type: none"> 1. Analysis of needs by the Committee on Digital Health
Risk: Failure to meet project implementation deadlines	
Prevention:	<ol style="list-style-type: none"> 1. Definition of detailed and realistic planning 2. Preparation of alternative plans 3. Capacity building among project teams
Risk: Reduced human resources at the General Secretariat for Digital Health and Innovation for the SNS	
Prevention:	<ol style="list-style-type: none"> 1. Provision of new positions for public employees. 2. Tender for technical assistance to strengthen the Project Office's capacities.
Risk: Reduced human resources in the autonomous regions	
Prevention:	<ol style="list-style-type: none"> 1. Inclusion in the draft budget for the call for tenders of Technical Project Offices. 2. of options for undertaking projects in a collaborative manner between two or more communities 3. Project implementation by the Ministry
Risk: Lack of acceptance of projects by health professionals or users	
Prevention:	<ol style="list-style-type: none"> 1. Work on all projects with mixed teams consisting of health and digital professionals. 2. Incorporating patient groups into the definition and validation 3. Carry out concept testing with groups not involved in project development throughout the development cycle. 4. Provide users with adequate training and support 5. Use of motivational and interpersonal communication techniques that facilitate the dissemination of the project.
Risk: Complexity of solutions, lack of technological or economic sustainability	
Prevention:	<ol style="list-style-type: none"> 1. Promote collaboration with the private sector in the definition of projects and in the search for solutions. 2. Attracting innovators to facilitate the assessment of new proposals 3. Implement strategies for the implementation of new projects in other sectors 4. Incorporate tools to motivate professionals and citizens in the implementation of projects.
Risk: Lack of adequate European funding	
Prevention:	<ol style="list-style-type: none"> 1. Preparation of solid and realistic projects, with the participation of several autonomous regions and a modular structure. 2. Improvement of public procurement and management tools 3. Development of co-financing models with the private sector
Risk: Conflicts of interest between autonomous regions in the definition and implementation of shared projects.	

Prevention:	<ol style="list-style-type: none"> 1. Political impetus for the definition of national projects 2. Prioritisation of European funding based on project size
Risk: Heterogeneity in implementations, lack of standards	
Prevention:	<ol style="list-style-type: none"> 1. Set up the Data Office of the Ministry of Health. 2. Start work with the autonomous regions
Risk: Lack of quality monitoring mechanisms and ethical and ethical standards	
Prevention:	<ol style="list-style-type: none"> 1. Implement a specific working group between the two subcommittees, with support from the Spanish Data Protection Office and professional associations.
Risk: Cybersecurity	
Prevention:	<ol style="list-style-type: none"> 1. Promote shared projects in the field of cybersecurity. 2. Enhance collaboration with CCN

8.2 Opportunities

In terms of opportunities, at the time of preparing the Strategy, the most relevant are:

- Experience of collaboration between all SNS stakeholders in terms of data exchange and analysis.
- Definition of spaces for public-private collaboration that allow initiatives of particular interest to the SNS to be undertaken, within the framework defined by its governance bodies, with the participation of business associations.
- Boosting the European Union and the World Health Organisation's initiatives for collaboration and the exchange of information and best practices, which will help to make progress with standards and interoperability, which are critical to the Strategy. In this connection, Spain's position in European E-Health and E-Prescription projects is an asset that should be capitalised on as part of the Strategy.
- Availability of funding within a sufficiently broad time frame to undertake the Strategy's projects with adequate consideration of change management and support for professionals.

As is the case with risks, a specific analysis of opportunities must be performed for each of the projects to be launched, maintaining an updated catalogue for the entire Strategy and its projects.

9 ANNEXES

9.1 ANNEX I Digital Health Strategy

9.1.1 IRELAND

In 2013, **Ireland** adopted an "**eHealth strategy**", which could be considered "first generation", focusing on the aspects of setting up an IT infrastructure and services dedicated to the health system (electronic patient identifier, electronic prescriptions, remote care for chronic patients and electronic health records).

Its new Strategy, updated in 2018³⁸, focuses on using digital technologies to place the patient at the centre of the health system; a patient to whom these same technologies offer capabilities of action and decision as regards their own health that force the reformulation of the relationship models of the system as a whole.

9.1.2 NEW ZEALAND

In the same vein, **New Zealand's "Digital Health Strategic Framework"**³⁹ sets out the concept of the "health ecosystem", the complex web of interactions between individuals, organisations, technologies, information and resources that make up the health sector, as a basis for a better understanding of possible interventions and courses of action on the health system.

Its strategic framework aims to identify how services should be provided in this ecosystem, creating a digital environment that encourages innovation and the effective use of data and technologies. The principles guiding the strategic framework are: "people-centric", 'user-driven', 'accessible', 'privacy and security by design', 'cloud-operated' and 'maximise value'.

In terms of the strategic objectives pursued, the framework aims to ensure people's control over their own health information, improve health outcomes and system equity, increase the quality of services provided and use data for evidence-based decision making in both care and management.

³⁸ eHealth Strategy for Ireland <https://ehealthireland.ie/Knowledge-Information-Plan/eHealth-Strategy-for-Ireland.pdf>

³⁹ <https://www.health.govt.nz/our-work/digital-health/digital-health-strategic-framework>

9.1.3 UNITED KINGDOM

The **United Kingdom**, as part of its strategic plan, the "**NHS Long Term Plan**"⁴⁰ has established "**Digital Transformation**"⁴¹ as one of the 13 areas of action, and while identifying the contribution of technologies as critical to the achievement of the objectives defined for the remaining 12 areas, it establishes the following as specific objectives for this transformation:

- Providing digital access to NHS services, making it easier for patients and their carers to manage their own health;
- Ensuring healthcare staff can access and interact with patient data from any location;
- Using decision support systems and Artificial Intelligence to help healthcare staff apply best practices, eliminating unnecessary clinical variability and assisting patients in the management of their health;
- Using predictive techniques to support local services to plan their operations;
- Using intuitive tools to capture data as part of the healthcare process in a way that increases the autonomy and capabilities of healthcare staff and reduces their administrative workload;
- Protecting patients' privacy by giving them control over their data;
- Linking clinical, genomic and other data for the development of new treatments to improve the NHS, making captured data accessible for research and obtaining aggregate metrics on NHS performance and services.
- Ensuring that NHS systems and data are properly protected, through security policies, monitoring systems and training NHS staff.
- Generating and rigorously applying the necessary standards for ensuring interoperability and data accessibility.
- Driving forward a world-leading digital health industry by fostering an attractive environment for developers and innovators.

9.1.4 UNITED STATES

Finally, as part of this overview of the global context, in the United States, the **Department of Health and Human Services (HHS)** has incorporated the overall Digital Government Strategy, with its "data-centric", "shared platform", "user-centric", "security and privacy" principles and through the **FDA, the Federal Food and Drug Administration**, it has launched a **Digital Health Center of Excellence**⁴².

This **Centre of Excellence** aims to "empower stakeholders to improve the health system by driving high quality, responsible digital health innovation", via the following objectives:

- **Connecting and building partnerships** that accelerate progress with digital health.
- **Sharing knowledge** to increase awareness and understanding, fostering synergies and disseminating best practices.

⁴⁰ <https://www.longtermplan.nhs.uk/>

⁴¹ <https://www.longtermplan.nhs.uk/online-version/chapter-5-digitally-enabled-care-will-go-mainstream-across-the-nhs/>

⁴² <https://www.fda.gov/medical-devices/digital-health-center-excellence>

- **Innovating as regards regulatory models** to reduce the associated overload and increase the efficiency of the system, while maintaining product safety and efficacy standards.

9.1.5 German digital patient record project

After sixteen years of preparation, many doubts and resistance as regards data security, Germany has decided to launch its own electronic health record (elektronische Patientenakte - ePA) as of 1 January 2021, as a means of moving away from the fragmented systems in place and with a view to progressively covering the population affiliated to one of the 105 statutory health insurances.

Capitalising on the impetus provided by Covid, after a draft law in July, on 14 October 2020 the Bundestag adopted the law for the regulation of personal data and the operation of the German FSE (electronic patient register) and its automatic creation. As in other countries, citizens are the owners of the data and has the right to know this and verify who accesses it. Its implementation will take some time: from mid-2021, German family doctors should be able to connect, only from 2022 onwards will they include reports, X-rays or paediatric information as well as historical vaccination data.

(https://www-bundesgesundheitsministerium-de.translate.goog/elektronische-patientenakte.html?_x_tr_sl=de&_x_tr_tl=es&_x_tr_hl=es&_x_tr_pto=nui,sc)

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- c) European Health Data & Evidence Network (EHDEN), created using EU IMI2 funds <https://www.ehden.eu/>
- d) Projects associated with the EU data space:
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 - European Health Data Space (EHDS) <https://tehdas.eu/>
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Lady's glove

