Digital Transformation of the Healthcare System for the incorporation of Personalized Precision Medicine

- Proposal of recommendations -

Anticipating the future.

Accelerating changes.

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Executive Summary

In the current healthcare context, Digital Transformation is a fundamental step towards achieving patient-centered preventive, diagnostic and therapeutic care that, ultimately, contributes to improving people's health. Moreover, for the complete incorporation of Personalized Precision Medicine, this Digital Transformation of the Healthcare System will be fundamental.

This transformation is one of the most important challenges in the healthcare environment that will require not only a cultural and structural change, but also the implementation of improvements and the search for solutions to guarantee good management of healthcare data, the acquisition of adequate digital capabilities, interconnected and interoperable information systems, among others, as well as funding that must be up sustained over time.

The healthcare crisis triggered by the COVID-19 pandemic has highlighted the main challenges and needs in terms of Digital Health faced by our Healthcare System and has accelerated the changes that will allow to achieve its transformation and, consequently, the complete incorporation of Personalized Precision Medicine.

As a basis for the development of this report, the most relevant initiatives in the field of Digital Health were analysed as a starting point for identifying and extracting common elements, as well as good practices or successful experiences that could be adapted to our country. International organizations, such as the World Health Organization, are working on tools, guides and strategies aimed to detect priority areas of work and recommendations to advance in the incorporation of Digital Health into healthcare environments. At the European level, countries such as France and the United Kingdom, as well as the European Commission itself, are also working on the Digital Transformation linked to healthcare. Along these lines, at the national level and from the Public Administrations at different levels, actions are beginning to be defined that place Digital Health and, therefore, the Digital Transformation of the National Health System in a preferential position.

This report highlights the relevance of such important aspects as the need to promote technological innovation and to have an interconnected digital infrastructure, as well as to establish actions to ensure governance and regulation to guarantee the effective implementation of e-Health under the fundamental values of bioethics. It also emphasizes the need to guarantee the organization, standardization and interoperability of health data, ensuring its security, as well as to train both healthcare professionals and the managers and stakeholders of the Healthcare System. In addition, this Digital Transformation will contribute to the improvement of key aspects linked to Personalized Precision Medicine in different areas, such as the healthcare model, public health, biomedical research, healthcare management and organization, and patient participation in decision-making.

Based on the analysis carried out and with the vision of a multidisciplinary group of experts, 50 recommendations are proposed, distributed in the 5 areas identified as priorities for the Digital Transformation of the Health System that contribute to the incorporation of Personalized Precision Medicine in our country.

Acknowledgments

To the Working Group of experts formed for the development of the project and the preparation of this document, for sharing their perspective on the diagnosis of the current situation, needs and key elements of the National Health System, and their vision of the future scenario necessary to promote the Digital Transformation of the Health System, which will allow the complete incorporation of Personalized Precision Medicine. Their knowledge, multidisciplinary vision and valuable contributions have made it possible to draw up a proposal of recommendations for this transformation, which is so necessary in the current socio-health context.

To the experts in different fields of knowledge, whose valued participation through individual interviews, has allowed to incorporate their knowledge and vision on the subject to complete and enrich this document from the position and criteria of all the areas of knowledge considered fundamental for the Digital Transformation of the Healthcare System.

Thank you very much for your collaboration and commitment to the Digital Transformation of the Healthcare System that allows a complete incorporation of Personalized Precision Medicine.

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1. Introduction

Currently, **Digital Transformation** is one of the most important challenges in the healthcare environment, requiring a **cultural and structural change**. Its main objective is to improve people's health and well-being. It is also a **fundamental instrument for promoting Personalized Precision Medicine**, understood as the identification and application of the most effective preventive, diagnostic and therapeutic approach for each patient, using Precision Medicine as a tool.

In this context, it is crucial to begin by defining what we mean by Digital Transformation of the National Health System:

The Digital Transformation of the National Health System involves a **cultural and organizational change** compared to traditional medicine. It is a **comprehensive and integrated process of information, management and research based on technological tools and data,** which seeks to achieve a **model based on the generation of knowledge and the measurement of results to obtain value**. In addition, it will make it possible **to achieve care based on prevention and personalization of healthcare**, always centered on the patient in order to achieve the **complete incorporation of Personalized Precision Medicine**.

To achieve this, it is necessary to:

- Ensure good data management, starting with the incorporation of all available patient health information in the Electronic Health Record.
- To have the appropriate digital, interconnected and interoperable capabilities for the representation and computation of existing information.
- To have collaborative tools between professionals and health services.
- Ensure that care and research are aligned and advance together.

Digital Transformation is an essential tool for **increasing the effectiveness of preventive and healthcare actions** and im**proving the efficiency and sustainability of the National Health System**. Our National Health System is a health system with universal coverage, whose management is decentralized in the Autonomous Communities, which increases heterogeneity both between autonomous systems and within the same Autonomous Communities, between Primary Care and Hospital Care and between organizations.

Likewise, during the **COVID-19 health crisis**, some of the **main challenges and weaknesses faced by the National Health System** were highlighted, and which make this **Digital Transformation even more necessary**. Some of them are:

- The rigidity of the healthcare system and the lack of interoperability between infrastructures.
- Lack of investment and renewal of existing information systems and technological tools.
- Lack of human and financial resources and lack of training for professionals to ensure the successful use of advanced technologies.
- The lack of infrastructures and digital support to optimize the time of professionals, and thus obtain better care and adaptation to the needs of patients.

- The need for centralized, accessible and quality information repositories that guarantee the organization and access to information.
- The need for data generation and analysis capacity.
- The need to share and collect quality data in real time, allowing decision-makers to base decisions on evidence and scientific-technical criteria.

In 2019, the total expenditure of the Spanish Healthcare System accounted for 9%[1] of Gross Domestic Product (GDP), considering the sum of public (6.4% of GDP) and private (2.6% of GDP) healthcare resources.

One of the aspects identified as a priority is the need to increase public health financing in order to reach European levels. Our country, with an expenditure of 6.4% of GDP, is below the European average, which currently stands at around 7.2% of GDP, significantly distancing it from countries such as Germany and France with 9.9%1 and 9.4% of GDP respectively. Furthermore, in 2019, only 1%[2] was allocated to investment in Information and Communication Technologies in healthcare.

Aware of the relevance and need for this Digital Transformation, the Ministry of Health has begun to define actions that make Digital Health an absolute priority. As an example of this, a new General Secretariat for Digital Health, Information and Innovation of the National Health System has recently been created and a Digital Health Strategy has been launched, which will have the collaboration of the Autonomous Communities and the participation of the sectors and actors involved. In addition, as part of the draft General State Budget for 2021, the Ministry of Health has proposed the investment of 400 million euros for the Health Technology Renewal Plan, more than 295 million euros for the Digital Health Strategy of the National Health System and the creation of a new State Public Health Center, among other healthcare measures[3] . Moreover, the Government has launched the new infrastructure for Precision Medicine, IMPaCT, which has 25.8 million euros in grants and is the first step to implement the Spanish Strategy for Personalized Medicine; it includes three new programs managed by the Carlos III Health Institute: Predictive Medicine, Data Science and Genomic Medicine.

This report aims to provide the basis for promoting the Digital Transformation of the National Health System for the complete incorporation of Personalized Precision Medicine. To this end, a multidisciplinary group of experts drew up a consensus proposal of recommendations for the Digital Transformation of the National Health System in areas identified as priorities.

We hope that this work will be useful for the Digital Transformation of the National Health System with the maximum benefit for patients and our Health System.

[1] OECD, Health Spending, 2019. Available at: https://data.oecd.org/healthres/health-spending.htm
[2] In 2019, 722 million euros were allocated to Information and Communication Technologies in healthcare, information extracted from the report: SEIS INDEX 2019.
[3] Ministry of Health, Presentation of the Ministry of Health Budget for 2021, available at https://www.lamoncloa.gob.es/serviciosdeprensa/notasprensa/sanidad14/Documents/2020/301020_PGE2021_Sanidad.pdf.

2. Objectives

The main objective of the project is to define a **proposal of recommendations** to serve as a reference to promote the Digital Transformation that facilitates the incorporation of Personalized Precision Medicine in the National Health System.

To achieve this objective, the following **actions** were undertaken:

- An analysis was made of relevant initiatives at **international level** on the incorporation of Digital Health in the Health System, as a dynamizing element for the development of Personalized Precision Medicine. This analysis has allowed us to recognize and extract good practices for their possible application at the national level.
- The same analysis was carried out at **national and regional level** in order to evaluate the current situation regarding the incorporation of e-Health in our country.
- Both analyses have made it possible to identify **trends, lines of work, resources and initiatives** to be considered and incorporated, when issuing recommendations aimed at promoting Digital Transformation.
- Based on the above analyses, together with interviews and workshops with experts, the **key elements and needs** for the Digital Transformation of the National Health System were identified to enable the incorporation of Personalized Precision Medicine.
- Finally, a **proposal for consensus recommendations** was made to lay the necessary foundations for the Digital Transformation of the National Health System in our country.

3. Work methodology

The development of the project was designed from a broadly participatory approach, allowing the incorporation of different perspectives. We have relied on relevant experiences and on the current framework for the development of Digital Health strategies that facilitate the incorporation of Personalized Precision Medicine.

To this end, a Working Group of experts was formed, whose functions included, among others, the identification of successful initiatives at national and international level, the issuing of opinions and recommendations on different aspects, and the review and validation of the documentation generated within the framework of the project.

At the same time, other experts from different fields of knowledge were identified who, through individual interviews, complemented the vision of the Working Group in specific areas.

The selection of all the experts who participated in the project guaranteed a multidisciplinary approach, counting on the vision of specialists in areas of knowledge considered fundamental, such as experts in Digital Health and Artificial Intelligence, Bioinformatics, Genetics, experts in Ethical and Legal Challenges, Healthcare Management, in addition to experts in the following clinical specialties: Anatomic Pathology, General and Digestive Surgery, Infectious Diseases, Hospital Pharmacy, Hematology and Hemotherapy, Preventive Medicine and Public Health, Genetic Medicine, Neurology, Oncology, Pediatrics, Psychiatry and Rheumatology.

In addition, the opinion of professionals with different profiles of responsibility in the sector, including those responsible for the Autonomous Administration, those responsible for Information Systems at hospital level, scientific directors of Health Research Centres and representatives of Patients' Associations, was also taken into account.

Both the members of the Working Group and the other experts interviewed participated individually in the project.

The development of the actions was structured in three work phases:

Phase 1: Analysis of experiences in the implementation of strategies, plans or actions aimed at promoting Digital Health for the implementation of Personalized Precision Medicine.

During this phase:

- An analysis of relevant international, state and autonomic initiatives in Digital Health for the implementation of Personalized Precision Medicine was carried out, with the aim of identifying good practices and key elements related to Digital Health.
- Interviews were conducted with the experts of the Working Group and other selected professionals, to pre-identify the key elements and current needs of the National Health System to be able to carry out this Digital Transformation.

Phase 2: Identification of the key elements and needs of the National Health System for its Digital Transformation to enable the incorporation of Personalized Precision Medicine.

During this phase:

- Based on the conclusions drawn in Phase 1, key areas were identified that cover the main contents for the issuance of recommendations, which will allow to drive the Digital Transformation that facilitates the implementation of Personalized Precision Medicine.
- The key elements to be considered and the real needs of the National Health System were identified for the incorporation of Digital Health in the Health System, as a key point for the development of Personalized Precision Medicine.
- **FIRST WORKSHOP**. After this analysis, a workshop was held with the Working Group to reach a consensus on the key elements and needs of the Health System to be taken into account for the Digital Transformation of the National Health System as a tool for the implementation of Personalized Precision Medicine.

Phase 3: Proposal of recommendations consensus for the Digital Transformation of the National Health System as a tool for the implementation of Personalized Precision Medicine.

During this phase:

- Based on the information obtained in Phase 1 and the key elements and needs of the National Health System for Digital Transformation, a proposal of practical recommendations was drawn up as a reference to drive the implementation of Digital Health in the National Health System, thus facilitating the complete incorporation of Personalized Precision Medicine.
- **SECOND WORKSHOP.** A consensus was reached on the recommendations for the Digital Transformation of the National Health System. These recommendations were prioritized in terms of impact and feasibility.

4. Analysis of relevant initiatives in digital transformation

The World Health Organization (WHO), European Union countries such as France, Denmark, Estonia and Germany, as well as countries such as the United Kingdom, the United States, Argentina, Australia and Israel, among many others, are committed to the Digital Transformation of their healthcare systems, implementing Digital Health strategies and plans or initiatives. This analysis of relevant international initiatives has allowed us to identify and extract common elements and good practices for their application or adaptation in our country.

Likewise, an analysis of the initiatives developed at national and regional level was carried out, with the aim of making a diagnosis of the situation, as well as identifying the needs and key elements to be considered for the Digital Transformation of the National Health System that will allow the promotion of Personalized Precision Medicine.

The current situation derived from the COVID-19 health crisis has meant that, far from weakening, all these initiatives and the actions proposed in them have been reinforced by the challenges and weaknesses that, as previously mentioned, are becoming evident throughout this period.

The list of analyzed initiatives is given below and the most relevant initiatives are detailed in Annex I.

International initiatives

WHO	Digital Health global Strategy (2020 – 2024) Digital Health interventions guide (2019) Digital Health Atlas (2019) Manual for monitoring and evaluation of Digital Health interventions (2016) Toolkit for a National Digital Health Strategy (2012)
European Union	European Recovery Fund (2020) Communication from the European Commission on the transformation of Digital Health (2018) EHDEN. European Health Data & Evidence Network (2018) HARMONY Project (2017)
Germany	Digital Health Law (2019) E-Health Law (2016)

Denmark	Digital Health Danish Strategy (2018-2022)
Estonia	Estonian Genome Center of the University of Tartu
France	White book: contributions of digital tools to the transformation of healthcare organizations (2019) Health System Transformation Strategy "*Ma Santée 2022*" (2018) Physicians and patients in the world of data, algorithms and artificial intelligence: analysis and recommendations from the National Council of the Order of Physicians. (CNOM for its French acronym), (2018) E-Health National Strategy 2020 (2016)
United Kingdom	Topol Report: "Preparing the healthcare workforce to deliver the digital future" (2019) NHS Report: "Capability Review" (2017) Genome England (2013)
United States	American Medical Informatics Association (AMIA)
Argentina	Digital Health National Strategy (2018-2024)
Australia	Digital Health Strategy (2019-2029) Australian Digital Health Agency Digital (2016) Certified Health Informatician Australasia (CHIA) (2014)
Israel	Israel's National Digital Initiative: The Government of Israel's National Digital Program (2017-2022) Digital Health collaboration initiative (2019) Five-year strategic program for Digital Health (2018) Digital Health Pilot Program (2018)

Initiatives at the national level

Spain	España Digital Agenda 2025 (2020) Statement of the Commission for Social and Economic Reconstruction (2020)

	Artificial Intelligence National Strategy (2020) Infrastructure for Precision Medicine associated with Science and Technology (IMPaCT for its Spanish acronym) (2020) R+DI Spanish Strategy in Artificial Intelligence (2019) FENIN (Spanish Federation of Healthcare Technology Companies) Index of Digital Maturity in Healthcare (2019) Report "Towards the digital transformation of the Health Sector", Spanish Society of Health Informatics (2018) "Report on digital transformation in healthcare in Spain: commitments vs. realities" Digital Health Association(2018) Applied Personalized Medicine Project (MedeA for its Spanish acronym) (2018)

Analysis of relevant initiatives conclusions

1 **Digital Health is one of the most important challenges in the healthcare world**. Major international organizations such as the World Health Organization have shown their firm commitment to the **potential of data and digital technologies to solve health problems**. The World Health Organization has recently published a Global Digital Health Strategy and multiple manuals related to the monitoring and evaluation of interventions.

2 **The World Health Organization's Global Digital Health Strategy (2020 - 2024)** has a vision to improve people's health through the incorporation of digital solutions and has established as its main strategic objectives, to involve and engage the participation of all stakeholders and to improve measurement, monitoring, research and practice in Digital Health.

3 Health systems must have **technologies that facilitate the recording of information in interoperable systems**, so that data can be shared between all levels of care and between different jurisdictions, thus improving health care in the field of Personalized Precision Medicine.

4 Health systems need to position **patients at the center** and **steer the system to meet patients' needs**, with tools that increase their participation in the management of their health. In addition, it is important to change the approach to disease management to one **based on preventive and personalized medicine**.

5 The main institutions must increase **operational and management effectiveness** in health systems through governance agreements, communication policies and a funding program. In this sense, it is also necessary to ensure **optimal governance and data management in a context of Personalized Precision Medicine.**

6	An adequate **regulatory framework with an international scope** must be guaranteed to ensure the security, protection and confidentiality of information, the interoperability of systems, transparency and the validity and robustness of digital solutions.
7	A **cultural and structural transformation of the health system** is necessary. For the cultural change, which will allow the complete incorporation of Personalized Precision Medicine, it is necessary to promote prevention, qualified information, early detection and pathological and therapeutic follow-up.
8	The availability of **large anonymized databases in real time and in real life** will make it possible to develop better access to treatments and better care for patients. These repositories must guarantee the **security** of the information, as well as comply with all the corresponding **ethical and legal requirements**. It is necessary to create structured databases to **generate knowledge and promote Personalized Precision Medicine.**
9	There is also the possibility of creating a **federated network, standardized to a common data model** that manages and shares clinical data for research, and promotes open science education and collaboration.
10	One of the priority objectives for the incorporation of Digital Health is to ensure **equal participation of society in digitization**, by promoting their skills in Digital Health. Dependent people, people with disabilities, the elderly and those who do not have access to the Internet should not be excluded from the digital society. In this sense, there must be a **safe and personalized Digital Health space** for each user and Digital Health platforms that allow users and healthcare professionals to find their way around in reliable and easily accessible digital spaces.
11	Need to establish **close collaboration between the private and public health sectors** to generate knowledge and find new solutions for urgent issues.
12	Importance of promoting research and implementation of systems for the **evaluation, control and traceability of interventions in Digital Health and of methods and models based on algorithms.**
13	Support and stimulate **research and innovation proposals from healthcare professionals,** by training and motivating them, "co-innovation" with patients and providers and development of systems for decision-making, among others. **Pilot facilities in the field of Digital Health** should also be promoted. Creating a **culture of innovation and learning**, as well as sharing **best practices based on evidence**, are necessary instruments for the complete **incorporation of Personalized Precision Medicine.**

14	The **education, training, accreditation and certification of new professionals** in the field of informatics is highly relevant for the incorporation of Digital Health. There is a need for the training of **data scientists, physicians with dual degrees in medicine and engineering and biomedical informatics**. It is also important to attract technical talent through new training and exchange programs to encourage collaborative work.
15	Personalized Precision Medicine is driven by emerging **technologies such as Artificial Intelligence and the analysis of large amounts of data** based on machine learning and computer vision. There is a need for **Artificial Intelligence that is "explainable" to medical professionals**, in which decisions are made based on clear parameters, improving human-computer interaction

5. Proposal of recommendations for the Digital Transformation of the Healthcare System that contribute to the incorporation of Personalized Precision Medicine

The analysis of relevant initiatives, the interviews with a multidisciplinary group of professionals and the workshops held with the Working Group have made it possible to identify the key elements and needs of the National Health System to be considered in order to promote the Digital Transformation of the Health System to enable the incorporation of Personalized Precision Medicine.

Based on this information, a proposal of priority recommendations for carrying out the Digital Transformation of the National Health System was drawn up and agreed upon, distributed among the five areas identified as key, which are listed below:

1. Technological innovation and digital infrastructure
2. Governance, ethics and regulation
3. Information organization and security
4. Talent, training and specialization
5. Healthcare and Public Health model

Each area follows the same structure, beginning with a brief contextualization and justification, in which the main issues considered for analysis are specified. Subsequently, the needs and key elements of the National Health System detected in each area are presented and, finally, the recommendations for promoting the Digital Transformation of the National Health System, prioritized in terms of impact and feasibility by the Working Group, are listed.

AREA 1: TECHNOLOGICAL INNOVATION AND DIGITAL INFRASTRUCTURE

Digital Transformation is a key tool for increasing the efficiency, effectiveness and quality of healthcare through new information systems and secure data sharing and interoperability, among others. For this reason, one of the main areas detected as a fundamental part of the Digital Transformation of the National Health System that allows the incorporation of Personalized Precision Medicine is the need to promote technological innovation and guarantee the availability of the necessary IT infrastructure. The following points were analyzed in this section:

- Technological challenges and difficulties of the National Health System.
- Technological priorities of the National Health System.
- Infrastructure and resource needs.
- Actions to promote technological research and innovation.
- Actions to promote co-innovation among professionals, citizens and economic actors.

Needs and key elements

- There is **insufficient investment in R+D+I at the state level**. It is also necessary to establish **state coordination of all initiatives**, also promoting **public-private partnerships.**

- Globally, The National Health System has the **necessary infrastructure and resources at the state level.** Although it is true that it is lagging behind technological advances, especially in terms of analytical tools for research. Furthermore, the new professional profiles linked to Digital Health are not sufficiently incorporated. It is therefore necessary to **change the philosophy of the organization and overcome the barriers of resistance to change.**

- The design of a **state strategy for Digital Transformation in healthcare** should be a national approach to **promote investment in research**, **attract talent**, promote initiatives and **common strategies between the public and private sectors**. This strategy should also be endowed with the necessary technical, human and economic resources and a roadmap for investment in technology should be established.

- The **fragmentation of healthcare systems at the digital level** and the **wide variety of systems used at the state level** make it difficult, to some degree, for the Autonomous Communities to advance in terms of Digital Transformation in a coordinated manner.

- **Little participation in international Digital Health forums** has been detected. In addition, the lack of leadership in projects of the World Health Organization and other international organizations by Spanish professionals has been highlighted. It is necessary to increase the presence of Spanish experts in international forums.

- With the aim of **boosting the development of digital and innovative solutions**, **innovation and digitalization programs** could be implemented in the National Health System to finance collaborative projects involving research groups in Information and Communication Technologies, engineering and Artificial Intelligence with healthcare professionals to provide imaginative solutions. Likewise, strengthening from the health

services the **development of innovation units at hospital level, through the Platform of the Carlos III Health Institute** for the Dynamization and Innovation of the industrial capacities of the National Health System and their effective transfer to the productive sector (previously ITEMAS), in which all agents participate, as a tool to promote research and innovation.

- The **management of Digital Health projects**, including knowledge of methodologies, formal theories, international experiences, role of different actors, characterization of data quality, evaluation of results, among others, is a fundamental element to be included in **the training of professionals**.

Proposal of Recommendations AREA 1
TECHNOLOGICAL INNOVATION AND DIGITAL INFRAESTRUCTURE

1	Increase **investment in both public and private R+D+I in a continuous and sustained manner**, as indicated in the Spanish Strategy for Science, Technology and Innovation 2021-2027, until **reaching the European average** (approximately 2.12 % of GDP-data 2018) to drive the Digital Transformation of the National Health System, ensuring the availability of the necessary IT infrastructure, and boosting the **creation of platforms and public-private collaboration partnerships with the participation of healthcare professionals.**
2	Promote the incorporation of **innovation for the Digital Transformation of the National Health System** by encouraging innovative **public procurement procedures**, **cooperation and co-innovation** between agents and the development of innovation units at hospital level.
3	Identify the **most relevant technological solutions for their subsequent scalability and replication** throughout the national territory, guaranteeing **interoperability**, through the prioritization of pilot projects with reusable elements.
4	Develop a **monitoring system** at national level in coordination with the Autonomous Communities, which will allow the **reporting of incidents and the reception of proposals and solutions** (success stories) to advance in the Digital Transformation of the National Health System.
5	Establish a**ccreditation systems for new Digital Health technologies, tools and algorithms** that guarantee their usefulness and validity in clinical practice.
6	Promote the creation of a **repository of good practices in Digital Health** at the national level with the aim of promoting their development in the different Autonomous Communities.
7	Enhance the creation and development of platforms that strengthen the link between science and society through actions that promote **education from the earliest stages and scientific dissemination**, positioning science as a key value for the development and welfare of society and for the creation of wealth.
8	Promote the participation of national researchers and experts in **European projects and in international Digital Health forums,** as well as the leadership of projects of international organizations.

9	**Involve empowered and trained patients** from the earliest stages of the research and development process of future Digital Transformation tools to **drive scientific research and patient-centered innovation.**

AREA 2: GOVERNANCE, ETHICS AND REGULATION

Given the importance of the Digital Transformation of the National Health System in the current social and healthcare context, it is essential to ensure governance and leadership at the state and autonomous community level to guarantee the effective implementation of Digital Health in the Healthcare System. Three fundamental points were analyzed in this area:

- Governance: main agents in the sector, ministerial and regional departments involved in the National Health System's Digital Health Strategy.
- Ethics: bioethics and applied ethics as fundamental values in all phases of the Digital Transformation process.
- Regulation: main regulatory needs and legislative aspects for the Digital Transformation.

Needs and key elements

- The need to draw up a **Digital Health Strategy for the National Health System led by the Ministry of Health at the proposal of the Interterritorial Council of the National Health System and approved by Parliament** with the participation of all the agents in the sector and guaranteeing **co-governance with the Autonomous Communities**.
- This Digital Health Strategy of the National Health System must precede the legislative developments and should be accompanied by a **multi-year Budgetary Program**.
- The **organizational and process infrastructures must be adapted between Autonomous Communities and with the central administration, between levels of care, between public and private healthcare**. This requires a pact between Autonomous Communities that guarantees communication between all the agents in the sector. Likewise, there must be a digital connection at all levels, as well as centralized digital services.
- A **cultural change** is needed by all the actors through training and information, as well as funds and tools to promote new innovation projects, given that **digitalization must be considered the driving force behind the transformation of the National Health System**.
- From the Ministry of Health, and with the participation of private operators, it will be necessary to **reduce digital divides** through investment and training to ensure that the Digital Transformation of the National Health System reaches the entire population equally.
- **Bioethical principles** must be present from the design of the National Health System's Digital Health Strategy. It is necessary to train and involve society in the Bioethics Committees, which are also present in all data exploitation projects.
- Raise awareness of the existing legal framework at the national and European level, since inadequate knowledge of this framework is a major limitation in many research contexts. In addition, certain aspects or specificities that could be modulated are detected.
- There is a need to **introduce innovative mechanisms in the public procurement of new systems** in order to adapt the National Health System to a changing environment such as the Digital Transformation.

Proposal of Recommendations AREA 2

GOVERNANCE, ETHICS AND REGULATION

1	Continue working on the **National Health System Digital Health Strategy led by the Ministry of Health** with the participation of the Ministerial Departments involved and all the agents in the sector, guaranteeing its co-governance and implementation with the Autonomous Communities at the level of the Interterritorial Council, and ensuring its evaluation, subsequent follow-up and accountability under criteria of transparency. It would be advisable for the Strategy to be endorsed by the Spanish Parliament.
2	Consider the possibility of creating an **independent body under the umbrella of the General Secretariat for Digital Health, Information and Innovation of the National Health System** to regulate and develop all Digital Health initiatives.
3	Encourage **research and innovation in Digital Health by the Carlos III Health Institute** within the framework of the Strategic Action in Health.
4	Contemplate within the Sta**te Digital Health Strategy, optimal data management and data governance**, ensuring that **bioethical principles are present** throughout all stages of the design and with the involvement and **participation of patients**.
5	**Ensure the funding of the programs and initiatives proposed** in the National Health System's Digital Health Strategy, always ensuring **funding based on the generation of value and equity in access to healthcare and Digital Health infrastructures**, such as through: • The promotion of projects linked to European funds received for the promotion of digitization in Spain. • The launching of calls for subsidies to promote plans and programs in Precision Medicine, such as IMPaCT[4] • The development of macro projects such as those led by AMETIC in Digital Health.
6	Ensure that the **National Health System's Digital Health Strategy is aligned with the Spanish Personalized Medicine Strategy** through the development of coordination mechanisms, such as the IMPaCT[4] initiative
7	Ensure that the **Health Care Ethics Committees and Research Ethics Committees have knowledge of data science and incorporate professionals with expertise in the omics sciences** to enable them to provide an optimal response to new research in this field, especially in the area of AI.
8	**Guarantee a homogeneous and flexible interpretation of the LOPDGDD[5]** by training researchers and healthcare professionals and identifying those aspects or specificities that may need to be modulated to promote the development of competitive projects for the Digital Transformation of the National Health System, facilitating the primary and secondary use of the data, as well as other uses included in the Law.
9	**Have legal knowledge** on the use of **clinical data in research on individuals and organizations, in addition to facilitating acces**s to professionals who have this knowledge, and to update in this sense the **Law on Biomedical Research.**

[4] Infrastructure for Precision Medicine associated with Science and Technology (IMPaCT)
[5] Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights.

10	Ensure, through **the development of software specific requirements**, that from a technical point of view, the **handling of data complies with the legal framework**, for example, by preventing inappropriate data extraction.
12	**Avoid digital divides between citizens through training and investment in infrastructure** ensuring the connection to the whole society.
12	**Adapt Law 9/2017 on Public Sector Contracts** to be more innovative in public procurement of new systems.

AREA 3: INFORMATION ORGANIZATION AND SECURITY

One of the most relevant areas for the Digital Transformation of the National Health System is the promotion of data analytics and the exploitation of information, based on collaboration and access to shared information between institutions. It is essential to guarantee the organization of information for its analysis, allowing the generation of knowledge for better decision making, the measurement of results, as well as an improvement in the quality and efficiency of the Health System itself. For all this, an adequate security framework must be in place to solve privacy and cybersecurity problems. Consequently, these two main topics were addressed in this block:

- Organization of information: registration model, integration and access to data.
- Information security: current privacy and security problems, as well as the legal framework that guarantees potential data protection problems.

Needs and key elements

- According to the International Bioethics Committee (IBC) of UNESCO and as the Report of the Spanish Bioethics Committee also points out, Big Data can be considered a **humanity common well**. However, the provision of such data **cannot be carried out at the cost of violating the right that each individual has to his or her personal data.**

- The Digital Transformation makes necessary the development of **public records and shared and pseudonymized databases** since the combination of that information allows obtaining new knowledge for the improvement of the quality of life of many individuals and greater efficiency in the services provided. The goal of any research project on a dataset should be the common interest. Likewise, any project must be based on the corresponding safety and ethical and legal principles.

- There are certain trends in the use of data at present, such as **open data, federated databases and the generation of highly realistic synthetic patient data**, which are key elements to be taken into account in the Digital Transformation of the National Health System.

- There is a **lack of standardization and technical, semantic and organizational interoperability** of current information systems.

- The security systems available to the different Autonomous Regions must ensure that possible **cybersecurity and cybercrime risks** that could compromise the principles of confidentiality and privacy are detected and controlled.

Proposal of Recommendations AREA 3
INFORMATION ORGANIZATION AND SECURITY

1	To promote the **creation and establish the governance of a national health data space**, harmonized at European level, based on the implementation of **federated databases in the Autonomous Communities**, ensuring automation and pseudonymization in data collection, as well as data quality.
2	Establish a catalog of standards that guarantee the functionality and quality of data complying with the FAIR (*Findable, Accessible, Interoperable, Reusable*) principles and recommend their use in order to promote the harmonization and homogenization of data, as well as the integration of all interfaces and interoperability between systems.
3	Promote legal protection to **solve privacy and cybersecurity problems**, as well as to **establish public and individual responsibility**
4	To guarantee the **secondary use of clinical data through access to repositories or aggregated databases** for research or educational projects, subject to prior assessment by the Healthcare and/or Research Ethics Committee, guaranteeing the ethical principles of confidentiality and privacy and their pertinence of use.
5	Encourage technology suppliers to adopt the defined concepts and standards
6	Ensure a **record of data access and justification of use** by ensuring that systems are **based on European security standards** and that **users are informed** about the current legal framework.
7	Promote that the financing conditions of research and innovation projects for the development of digital solutions are linked to **compliance with standards.**

AREA 4: TALENT, TRAINING AND SPECIALIZATION

In order to ensure an effective Digital Transformation of the Healthcare System, it is necessary for both healthcare professionals and the managers and actor involved in the National Health System to have the appropriate knowledge. To know the key elements and needs of the National Health System in terms of training, the following sections were analysed:

- New professional profiles to be incorporated into the system
- Measures to attract, recruit and retain talent
- Necessary training actions
- Training in the digitalization of society

Needs and key elements

- The **incorporation of new professional profiles** within the healthcare structures is a key point for the complete transformation of the National Healthcare System, as well as to ensure the implementation and integration of Personalized Precision Medicine in healthcare. Political impetus is required to bring about a change in the definition, structure and size of the National health System workforce.
- As part of a general strategy, it is necessary to design a **training plan** at all level (undergraduate, postgraduate and Specialized Healthcare Training programs) to enable **healthcare professional to incorporate technical and practical knowledge linked to Personalized Precision Medicine digitalization and related tools.**
- A cultural change is needed to contribute to the complete incorporation of Personalized Precision Medicine through digital Transformation. The **involvement of the administration** and **training in Digital Health for manager** and **professionals involves in decision making** will be key aspects in driving this change.
- Although **society has advanced in terms of digitalization in an autonomous manner,** in the field of health it will be convenient to **carry out dissemination and training actions** around a Plan of digital competences that **guarantee the equal participation of patients and citizens in a context of Personalized Precision Medicine.**

Proposal of recommendations AREA 4 TALENT, TRAINING AND SPECIALIZATION

1	Incorporate into the National Health System's Digital Health Strategy a **training plan to ensure that healthcare professionals, decision-makers and managers have adequate knowledge in the digital field.**
2	Define the **competencies required by a Digital Health expert** by developing and accreditation system through the completion of an accredited educational program o through an individual certification scheme that allows the experts to be recognized.
3	**Incorporate new professional profiles in the field of data science in the National Health System** (primarily, medical informaticians specialists in data interpretation,

	analysis and management, bioinformaticians/experts in computational biomedicine and information security officers (CSIOs), among others)
4	Recognize the **speciality of clinical genetics and develop an accredited master's degree in genetic counselling** in order to be able to incorporate **specialist in clinical genetics** and genetic counsellors into the services of hospital centers, integrating them into the healthcare structure.
5	To develop and incorporate a speciality within Specialized Health Training in medical informatics or clinical bioinformatics, **creating the position of Resident Biomedical Informatician** and to promote **rotations o health specialists** in training in services with recognized experience in the field of clinical bioinformatics.
6	Incorporate **new cross-cutting competencies in genetics, genetic counselling and data science** (including training on methods of information analysis and on ethical and legal issued related to new technological tools) into **the undergraduate training in Medicine and Nursing,** as well as, **structuring the training in genetics** within the undergraduate training.
7	Include a **cross-cutting module for Personalized Precision Medicine and Digital Health** in Specialized Health Training, including training in molecular biology, genomics, genetics and medical informatics, Artificial Intelligence and the use of digital tools.
8	Encourage **double degrees** such as bioinformatics and biomedicine.
9	Promote the establishment and recognition of the **professional career of the researcher**, as well as to **incorporate more decisively the merits in research and innovation in the scales of talent recruitment and evaluation of the professional career** of the personnel of the National Health System.
10	Incorporate **specific postgraduate training in Precision Personalized Medicine and Digital Transformation through different agents.**

AREA 5: HEALTHCARE MODEL AND PUBLIC HEALTH

Digital transformation and Personalized Precision Medicine are two essential elements in the future of the National Health System and are completely interconnected. Digital services can help to promote health and improve prevention, as well as favoring the reform of healthcare systems and their transition towards new care models focused on the needs of the patient. In addition, digitalization will make it possible to move towards more integrated care structures, promoting a comprehensive, preventive, participatory and personalized care model. The following were addressed in this block:

- Healthcare model that fully incorporated Personalized Precision Medicine
- How Digital Transformation favors the incorporation of Personalized Precision Medicine into de healthcare model
- Needs for transferring advances in Digital Health to the healthcare practice of Personalized Medicine
- Healthcare and Public Health services that can generate more value for Digital Transformation and the incorporation of Personalized Precision Medicine.

Needs and key elements

- **Digital Transformation and Personalized Precision Medicine** are two **completely interconnected** elements. Without Digital Transformation of the National Healthcare System, the incorporation of Personalized Precision Medicine into healthcare practice will not be complete. **Digital Transformation will contribute to the improvement of key aspects linked to Personalized Precision Medicine** in different areas such as the healthcare model, public health, biomedical research, healthcare management and organization and patient participation.

- The **lack of impetus or commitment to Personalized Precision Medicine, budget shortages, the prioritization of urgent areas, training needs and the lack of digital culture** in some area are some of the **major barriers** that must be overcome to ensure the Digital Transformation an the complete incorporation of Personalized Precision Medicine into the healthcare practice.

- Personalized Precision Medicine is a **paradigm shift** that will impact, in one way or another, all medical specialities and the field of Public Health. The **multidisciplinary approach and cooperation and between the different levels of healthcare and socio-healthcare** will therefore be a fundamental pillar that will benefit from the Digital Transformation.

- Digital Transformation, in addition to promoting the **empowerment of chronic patients** by increasing their **quality life** and allowing **savings in resources**, will improve personalized care for chronicity, frailty and aging by **deepening the knowledge** we have about these conditions with a **socio-health approach**

- Digital Transformation **will not mean the dehumanization** of healthcare, but will facilitate the work of the professional by increasing the time he/she dedicates to the **relationship with the patient**. In addition, it will boost **patient participation in decision making** with the citizen as the center of healthcare.

Proposal of recommendations AREA 5
HEALTHCARE MODEL AND PUBLIC HEALTH

1	Strengthen shared information structures from the Administrations that **break down the silos between levels of care and with the research field, ensuring continuity of care and connecting the Electronic Health Record with other sources of information** as a tool for research and the generation of new knowledge in the field of Personalized Precision Medicine.
2	Integrate the **healthcare model with the social-healthcare model through Digital Transformation**, ensuring access to all clinical and social information available to the citizens.
3	Create working groups that are responsible for **redesigning processes based on a digital model**, **ensuring that the Digital Transformation facilitates the healthcare professional's work** and provides **more time for the patient**, promoting human contact and the bond with the patient.
4	Promote the **creation of the Public Health Agency**, included in the Statement of the Commission for Social and Economic Reconstruction, **incorporating the principles and tools of the National Health System's Digital Health Strategy** with a model that enhances health information and epidemiological surveillance systems to obtain real-time information for decision-making.
5	Boost the **evaluation and measurement of health outcomes** in the context of Precision Personalized Medicine through the collection and analysis of relevant and quality data.
6	Support the design of **digital tools** for **data analysis** from a **population-based perspective, epidemiological surveillance, prevention, clinical epidemiology and value-based care.**
7	Encourage the creation of **"core" laboratories**, understood as healthcare and research **environments and platforms** for professionals to meet in order to share information, generate knowledge, seek synergies in research and innovation and, ultimately, generate value for the entire system.
8	Establish **accreditation and evaluation systems for Precision Personalized Medicine and Digital Health units in the National Health System.**
9	Promote multicenter studies to obtain **omics data representative of the Spanish population**, as is planned in the IMPaCT initiative, as a first step so that both patients and the healthy population will have this type of data integrated into their Electronic Health Record in the future.
10	Carry out studies to **better understand the needs of patients and their families** in order to design tools based on Digital Health that will help the National Health System to provide more efficient and personalized solutions.
11	Evaluate and subsequently promote the use of **new validated technological tools** (such as wearables or telemedicine) to facilitate patient follow-up, **design personalized actions** to improve their quality of life and encourage **self-care and co-responsibility**.
12	Ensure the **incorporation of the results obtained in Digital Health research projects applied to Personalized Precision Medicine in healthcare practice** through the development of proofs of concept that demonstrate their usefulness, return on

investment and scalability for their subsequent incorporation into **clinical guidelines and protocols.**

Annex 1: Detail of relevant international and national initiatives in Digital Health

World Health Organization (WHO)

Global Digital Health Strategy (2020 – 2024)

In May 2018, the 71st World Health Assembly (WHA) adopted Resolution WHA71.7 on Digital Health. Among other issues, the Resolution called for the development of a Global Strategy on Digital Health, identifying priority areas, including where the World Health Organization should focus its initiatives. It also urged Member States to identify areas for improvement and to prioritize, as appropriate, the **development, evaluation, implementation, scale-up and increased use of digital tools as a means of promoting equitable, affordable and universal access to health**.

VISION

- Improving health for everyone and everywhere, accelerating the implementation of Digital Health.

STRATEGIC OBJECTIVES

1. Engage all stakeholders in a shared global agenda on Digital Health.
2. Develop and consolidate global capacity in Digital Health that reflects national needs.
3. Engage and involve stakeholders to advance in the field of Digital Health in all countries.
4. Improve measurement, monitoring, research and practice in Digital Health.

ACTION FRAMEWORK

1. Engage: encourage countries and engage stakeholders to commit to the Digital Health Strategy.
2. Catalyze: create an environment and processes that facilitate and induce collaboration.
3. Measure: create processes for monitoring and evaluating the Strategy.
4. Increment and iterate: take a new cycle of actions based on what has been experienced, measured and learned.

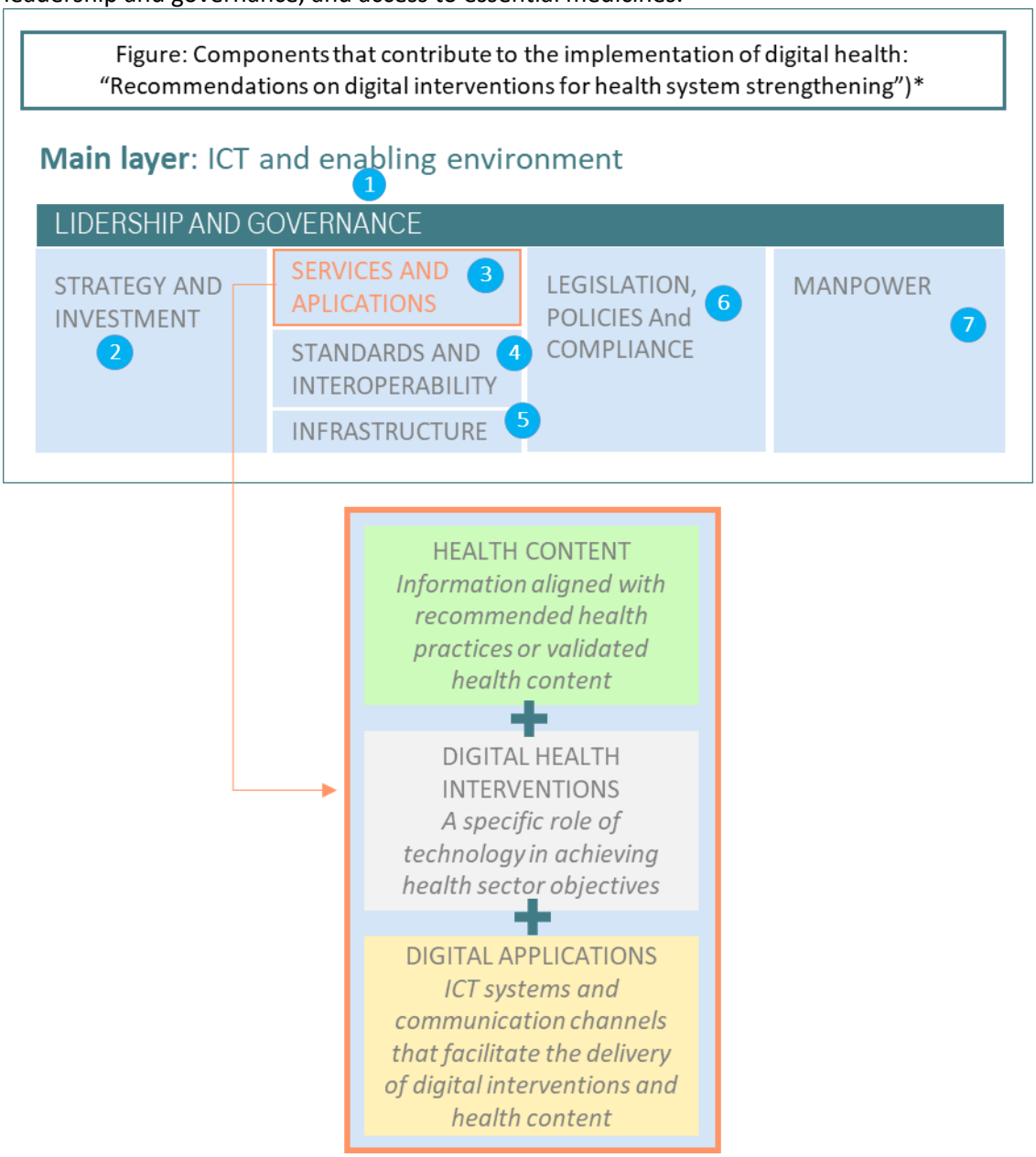
World Health Organization (WHO)

Global Digital Health Strategy (2020 – 2024)

The guide aims to provide **recommendations to consider, based on a critical evaluation of the evidence, for making informed investments in Digital Health interventions**.

It also states that Digital Health interventions should **complement and enhance health system functions through mechanisms** (i.e. accelerated information exchange), but will **not replace the fundamental components needed by health systems**, such as human resources, financing, leadership and governance, and access to essential medicines.

Figure: Components that contribute to the implementation of digital health: "Recommendations on digital interventions for health system strengthening")*



The strategy includes:

1. Coordination mechanisms at the national level, alignment with health objectives and political support, and stakeholder awareness and engagement.
2. Aligning funding with health priorities and securing funds to achieve the strategy's objectives.
3. The systems and functionalities to be implemented to enable stakeholders to access, use and share health information.
4. The standards that enable consistent and accurate collection and exchange of health information across health systems and services.
5. The physical infrastructure, core services and hardware (as well as networks) that support a national Digital Health environment. One example is identification authentication services.
6. A legal and policy environment to establish trust and protection for individuals and industry.
7. The education and training programs available in Digital Health.

Source: WHO guideline recommendations on digital interventions for health system strengthening, https://apps.who.int/iris/bitstream/handle/10665/311941/9789241550505-eng.pdf?ua=1

European Union

Communication from the European Commission on Digital Health Transformation (2018)

The Commission's Communication on Digital Health Transformation of April 2018 aims to **improve the digitization of the health and healthcare sectors.**

The Communication identifies **3 pillars** around which activities will be based:

Pillar 1 **Secure data access and sharing:** to facilitate greater cross-border access to healthcare, the Commission is setting up a digital eHealth services infrastructure that will enable the exchange of electronic prescriptions and patient summary records between healthcare providers. The first cross-border exchanges started in 2019 and the aim is for all other EU countries to participate by 2020. In the longer term, the Commission is working on a European format for the exchange of electronic health records to which all EU citizens can have access.

Pillar 2 **Connect and share health data for research, faster diagnosis and improved health:** a decentralized European Digital Health infrastructure will facilitate personalized diagnosis and treatment, help health services be better prepared to respond to cross-border health threats, and improve the development and surveillance of medical products.

Pillar 3 **Strengthening citizen empowerment and individualized care through digital services:** digital services can improve the prevention and management of chronic diseases, and enable patients to provide feedback to healthcare providers. Health systems will also benefit from innovative care models that use telehealth and mobile health to address the growing demand for healthcare.

European Union

Harmony Project (2017)

The **HARMONY Alliance**, European Network of Excellence for Big Dara in Hematology, will enable the **collection of a critical mass of data on recent developments in pharmacology as well as hematology in real time and in real life**. Big Data will empower clinicians, patients and policy makers to develop better access to therapy and improved care for patients with various hematological malignancies

HARMONY Hematology Big Data is a central repository where **anonymized data** donated by partners and Associate Members is **securely collected following all legal and ethical requirements, harmonized and then analyzed.**

This platform **combines and harmonizes data from multiple** hematological cancer patient data sources, including **registries, hospitals, biobanks and pharmaceutical clinical trials.**

OBJECTIVE

Accelerate the development of more effective treatments for people with hematological cancers.

More than 90 organizations from across Europe have joined and **more than 45,000 patient datasets** have been identified by December 2019.

Source: European Public-Private Partnership for Big Data in Hematology, https://www.harmony-alliance.eu

Denmark

Danish Digital Health Strategy 2018-2022

The Ministry of Health, the Ministry of Finance, the Danish Regions and the Danish Local Government have launched the new National Digital Health Strategy that aims to foster the sustainable development of the **Danish Health System.**

MAIN OBJECTIVES

- **Digitalization**.
- **Use of health data** in the context of prevention, care and treatment as currently data is mainly used for primary purposes. With new data-driven technologies, primary and secondary purposes in data use increasingly complement each other. This is why the Danish Health System also works strategically with, among other things, personalized medicine with the aim of strengthening reciprocity in the use of health data for care and research.

AREAS OF INTEREST

- **The patient as an active partner.**
- **Knowledge in time.**
- **Prevention.**
- **Reliable and secure data.**
- **Progress and common building blocks.**

In addition, they are establishing a framework for private companies, research institutions and individual researchers to gain access to public registries and specialized data sets for specific purposes. The overall goal is to **establish close collaboration between business and the health sector** so that they can find new solutions to pressing issues.

Source: Healthcare Denmark, https://www.healthcaredenmark.dk/news/danish-digital-health-strategy-2018-2022-now-available-in-english/

France

Healthcare System Transformation Strategy (march 2018) "Ma santée 2022“ (2018)

For the preparation of the Health System Transformation Strategy, **healthcare professionals, users and their representatives** have been mainly involved.

The Strategy is made up of 5 axes:

1. Putting quality of care at the center of organizations and practices.
2. Establish new models of remuneration, financing and regulation.
3. Accelerate the Digital Transformation of the system.
4. Adapt training to the challenges of the system.
5. Rethink the territorial organization of healthcare.

Axis number 3, "Accelerate the Digital Transformation of the System" has a roadmap with 5 key points for this Digital Transformation:

1. Strengthening Digital Health governance
2. Enhancing the security and interoperability of health information systems
3. Accelerating the deployment of basic digital services
4. Implement nationwide Digital Health platforms that allow users and healthcare professionals to find their way around in reliable and easily accessible digital spaces
5. Stimulating innovation and encouraging stakeholder involvement

Source: Ma Santée 2022, un engagement collectif, https://solidarites-sante.gouv.fr/IMG/pdf/ma_sante_2022_pages_vdef_.pdf

United Kingdom

Informe Topol: "Preparing the healthcare workforce to deliver the digital future" (2019)

This is a report commissioned by the National Health Service (NHS), which attempts to design the future of the Healthcare System taking into account the influence of Digital Health.

Principles to support the deployment of technologies:

- **Patient involvement** in this process and ensuring equitable access;
- Experience and guidance for the **evaluation of new technologies** by healthcare professionals.
- Provision of **more time by professionals for patient care.**

Key aspects to ensure leadership that integrates and adopts new technologies:

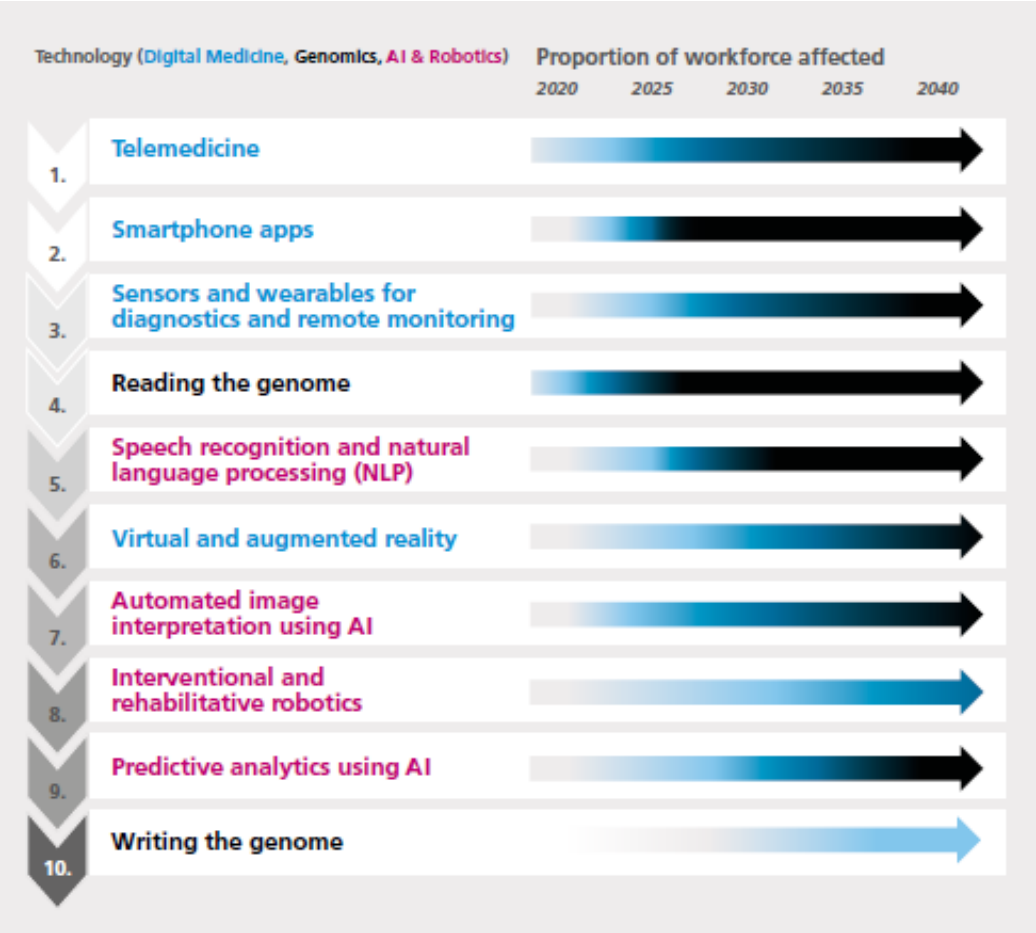
- Cost savings, investment in IT systems, hardware, software and connectivity, as well as training of healthcare professionals and the public can take up to 10 years so **planning** is necessary.
- **Transparent, robust and legally enforceable governance** policies should be ensured, and evidence-based guarantees of the safety of health technologies should be provided. It is necessary to develop a cadre of **specialists in the regulation and evaluation of digital technologies.**
- **Responsibility** should be taken **for effective knowledge management** to support innovation and change.
- **Information governance** is needed, as well as guidance to support the evaluation and purchase of AI products. Capacity must be developed to identify and understand algorithmic bias and ensure that data does not reflect bias inherent in social structures, and reinforce structural discrimination and inequalities.
- Need to **invest in human resources** to develop specialized skills, including the evaluation and commissioning of genomics and digital technologies. Networks must also be created to enable collaborative learning and accredited continuing professional development, lifelong learning and career opportunities.
- Need to **attract technical talent** through new training and exchange programs to promote collaborative work. Need to attract new technical profiles (robotics engineers, data scientists...).

Source: NHS, https://topol.hee.nhs.uk/

- Creating a **culture of innovation and learning** will be fundamental, as well as sharing best practices based on evidence.La comprensión de cómo **implementar mejor las tecnologías basadas en datos** para respaldar y mejorar las prácticas laborales será parte del desarrollo del mercado laboral. Esto tendrá como objetivo mejorar la asistencia sanitaria.

- Understanding how best to **implement data-driven technologies** to support and improve labor practices will be part of labor market development. This will aim to improve healthcare.

The report sets out what the top 10 Digital Health technologies will be and their projected impact on the NHS workforce from 2020 to 2040:



Australia

Digital Health Strategy (2019 – 2029)

The Digital Health Strategy presents a vision to guide future activities and investments in technology across the territory. It describes the Public Health System's direction in building the digital capabilities needed to support a sustainable and innovative health system. The Strategy also establishes principles to guide the design and development of Digital Health capabilities that support the delivery of safe, quality patient-centered healthcare. The Strategy illustrates a desired future state for Australia with respect to Digital Health.

The Australian Digital Health Agency is the institution charged with developing and driving the Strategy through innovation, collaboration and leadership.

The Strategy outlines a vision for 2022 based on the benefits that will result from the nationwide prioritization of Digital Health activity:

- Avoided hospital admissions
- Fewer adverse drug events
- Reduced duplication of medical tests.
- Improved care coordination for people with chronic and complex conditions; and
- Better informed treatment decisions.

The seven strategic priorities of the Digital Health Strategy are:

1. Health data will always be available to every Australian citizen through "My Health Record", unless they choose not to have this record. In addition, a data platform will be provided to support healthcare professionals to improve health outcomes by increasing the availability and relevance of data content.

2. Ensure that healthcare data can be exchanged securely between healthcare providers. To this end, the technology industry and healthcare stakeholders will have to work together towards the adoption of agreed-upon tools, processes and standards to solve interoperability problems through secure messaging and clinical information systems.

3. The enablement of high quality data exchange, with commonly understood meaning that can be used with confidence, will be guided by a national interoperability roadmap to be developed in conjunction with all stakeholders in the Digital Health ecosystem and the wider Australian community. It will result in an agreed set of national interoperability specifications and standards, accreditation regimes and procurement requirements, and a range of initiatives required as a result of engaging the wider population in a debate about how best to access and benefit from health information.

4. Improved availability and access to information on prescriptions and medicines will be provided. Priority will be given to the joint development of a digital medicines program to implement digital services and solutions to increase the safety, quality and efficiency of medicine use in health and patient care.

Source: Digital Health Strategy 2019–2029, https://www.digitalhealth.gov.au/about-us/national-digital-health-strategy

5 Digitally enabled models of care that improve accessibility, quality, safety and efficiency will be tested through a series of pioneering initiatives addressing priority areas such as better use of telemedicine or chronic disease management.

6 Healthcare professionals will be required to confidently use Digital Health technologies, which will therefore require support so that they can better adapt and adopt the changes and opportunities created by innovation in digital health, always with the aim of improving the health and care of patients.

7 A Digital Health industry that delivers world-class innovation will be led by a digital industry that works closely with healthcare professionals, patients and the research community, with research being a key priority for the technology sector.

Australia

Australian Digital Health Agency (2016)

Better use of data and technology can help people live healthier, happier and more productive lives. Digital Health can make a real difference to people's health by giving them greater control and better access to information.

The Australian Digital Health Agency is responsible for national Digital Health services and systems, with a focus on engagement, innovation and clinical quality and safety. It aims to **put data and technology securely at the service of patients, consumers and healthcare professionals.**

OBJECCTIVE

Improving the health of all Australians through **efficient and secure Digital Health technologies** and services that provide a range of innovative and easy-to-use tools for patients and providers.

Used effectively, **digital information** can help save lives, improve health and wellbeing and support a sustainable health system that delivers safe, high quality health services for all.

MISION

Has responsibility for the **strategic management and governance** of the National Digital Health Strategy and for the **design, management and operations of the national digital health system.**

TASKS

- Coordinate and contribute to the **ongoing development of the National Digital Health Strategy.**
- **Implement those aspects of the National Digital Health Strategy** directed by the Ministerial Council.
- Develop, implement, manage, operate and continuously innovate and improve **specifications, standards, systems and services** in relation to digital health, consistent with the national Digital Health program.
- Develop and implement **comprehensive and effective clinical governance** that ensures clinical safety.
- Develop, monitor and manage **specifications and standards to maximize effective interoperability** of public and private sector digital health systems.
- Develop and implement **compliance policies** in the adoption of agreed specifications and standards.
- **Liaise and cooperate with foreign and international entities** on issues related to digital health.

Source: Australian Government, Australian Digital Health Agency, https://www.digitalhealth.gov.au/

Australia

Certified Health Informatician Australasia (CHIA)

CHIA is awarded by the Australian Institute of Digital Health and the Health Information Management Association of Australia (HIMAA) and was created to address the **lack of formal recognition of health informatics knowledge and skills** in Australia.

CHIA certification plays a key role for the health informatician profile in Australia, contributing to wider **recognition of the profession and more clearly defining the body of knowledge** that underpins this discipline. Today, more than 1,000 people have become CHIA certified.

The CHIA certification is an exclusive and unique professional certification that will help to integrate these new profiles into the system and thus create a **broad network of certified health informaticians** in the country. Every three years the certification must be validated by attending courses, congresses, projects and publications...

There are currently two levels within the governance model of the CHIA program:

- Board of Directors (CB)
- Evaluation Committee (EC)

Two other entities:

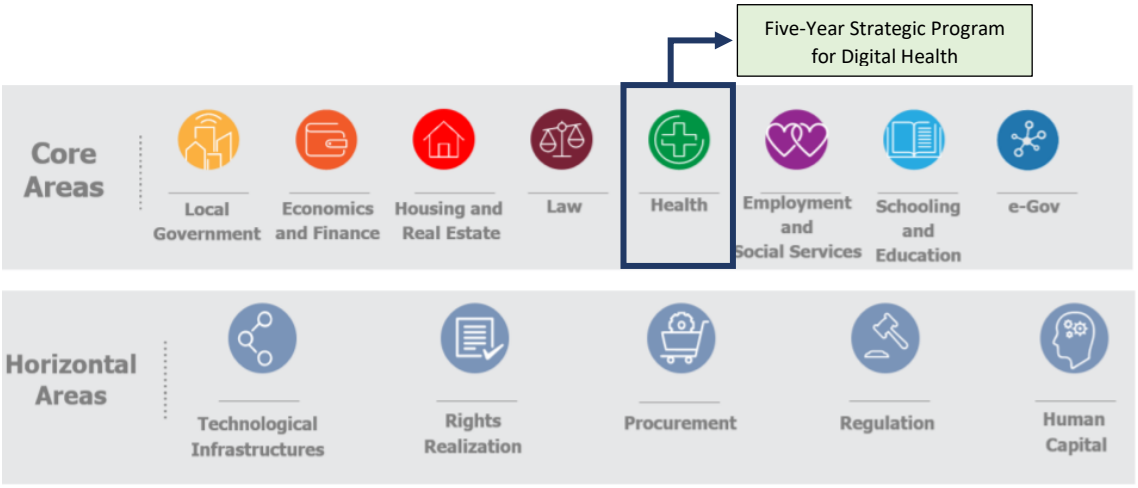
- An Evaluation Development Advisory Group (EDAG) of the EC.
- A Stakeholder Reference Group (SRG) of the governing body whose input is essential to the success of the program in areas such as required competencies, workforce needs, legislation and regulation, industry issues and related professions.

Source: Certified Health Informatician Australasia, https://www.healthinformaticscertification.com/

Israel

Israel's National Digital Initiative: The Government of Israel's National Digital Program (2017-2022)

The National Initiative's activity is broad and covers a wide range of areas, divided into two levels, main areas and horizontal areas:



The **Five-Year Digital Health Strategic Program** seeks the implementation and integration of five key changes in the healthcare system:

1. Put the patient at the center and steer the system to meet the needs of patients, with tools that increase their participation in the management of their health.
2. Advance the development and adaptation of tools for personalized and individualized treatment.
3. Shift the focus from disease management to preventive medicine.
4. Increase operational and management effectiveness in the health system.
5. Improve and streamline communication between the Ministry of Health and the entities that receive its services.

Source: The Digital Israel National Initiative: The National Digital Program of the Government of Israel, https://www.gov.il/BlobFolder/news/digital_israel_national_plan/en/The%20National%20Digital%20Program%20of%20the%20Government%20of%20Israel.pdf

Spain

Digital Agenda 2025 (2020)

Table of contents of the **Digital Agenda 2025:**

0. Introduction and Executive Summary
1. Digital Connectivity
2. The 5G Technology Push
3. Digital Competencies
4. Cybersecurity
5. Digital Transformation of the Public Sector
6. Digital Transformation of the Business and Digital Entrepreneurship
7. Sector Digitalization Tractor Projects
8. Spain, a pole of attraction for investment and talent in the Audiovisual Sector
9. Data Economy and Artificial Intelligence
10. Digital Rights

Sector 7 de "Sector Digitalization Tractor Projects", among the areas with the greatest potential for transformation highlights:

Digital Health, towards prediction, personalization and efficiency, which aims to increase the efficiency, effectiveness and quality of healthcare by streamlining information systems and promoting the secure sharing and interoperability of data, and will contribute to the personalization of the services provided.

The Government will promote a driving force for the **Digital Transformation of the healthcare sector through innovation, research, assistance and patient empowerment, with the ultimate aim of increasing the quality of life of the population.** This project may cover three main areas of action:

(1) Research to measure and improve health outcomes and design preventive systems;
(2) Patient assistance to automate and provide tools to citizens so that they have greater knowledge for decision-making;
(3) Patient empowerment with telemedicine tools, self-diagnosis or improved accessibility.

*All this will contribute to the transformation of the National Health System towards a **coordinated, interoperable, integrated, multidimensional** development that develops applications for the entire biosanitary ecosystem: Public Health and Epidemiology, clinical practice, health management, Universities, research centers and a thriving sector of emerging and innovative companies around health and lifestyles, with synergies between all of them.*

Source: Digital Spain 2025 Plan, https://www.lamoncloa.gob.es/presidente/actividades/Documents/2020/230720-Espa%C3%B1aDigital_2025.pdf

Spain

National Artificial Intelligence Strategy (2020)

The National Artificial Intelligence Strategy provides the backbone for the actions of the different administrations and provides a framework of reference and impetus for the public and private sectors. In fact, the promotion of Artificial Intelligence is one of the main elements of the Spain Digital Agenda 2025, presented in July 2020, in its line of action 9 on Data Economy and Artificial Intelligence. It is a key cross-cutting element to transform the production model and boost the growth of the Spanish economy in the coming years.

Spain's National Artificial Intelligence Strategy has seven strategic objectives:

1. **Scientific excellence and innovation in Artificial Intelligence.** To position Spain as a country committed to promoting scientific excellence and innovation in Artificial Intelligence.

2. **Projection of the Spanish language.** To lead worldwide the development of tools, technologies and applications for the projection and use of the Spanish language in the fields of application of AI.

3. **Skilled job creation.** Promote the creation of qualified employment, boosting training and education, stimulating Spanish talent and attracting global talent.

4. **Transformation of the productive fabric.** Incorporate Artificial Intelligence as a factor for improving the productivity of Spanish companies, efficiency in public administration, and as a driver of sustainable and inclusive economic growth.

5. **Environment of trust in relation to Artificial Intelligence.** Generate an environment of trust in relation to AI, both in terms of its technological development and its regulatory and social impact.

6. **Humanistic values in Artificial Intelligence.** Promote the global debate on the technological development of humanistic values (Human-Centered AI), focused on ensuring the welfare of society when making technological advances or developments, creating and participating in forums and outreach activities for the development of an ethical framework that guarantees the individual and collective rights of citizens.

7. **Inclusive and sustainable Artificial Intelligence.** To promote inclusive and sustainable Artificial Intelligence as a transversal vector to face the great challenges of our society, specifically to reduce the gender gap, the digital divide, support the ecological transition and territorial structuring.

The objectives of this strategy are in line with the 2030 Agenda and with the Recommendation of the Organization for Economic Cooperation and Development (OECD), so that public action integrates the economic, social and environmental spheres. Along the same lines, it incorporates the need for the design of these systems to be robust, secure and impartial, in order to move towards a reliable, explainable, transparent and inclusive Artificial Intelligence that ensures compliance with fundamental rights and applicable regulations, as well as respect for

Source: National Artificial Intelligence Strategy, Ministry of Science and Innovation, https://www.lamoncloa.gob.es/presidente/actividades/Documents/2020/ENIA2B.pdf

fundamental principles and values, and takes into account the collective aspirations of the citizenry.

Spain

Infrastructure for Precision Medicine associated with Science and Technology. (IMPaCT, for its acronym in Spanish) (2020)

The Networked Biomedical Research Center Consortium (CIBER, for its acronym in Spanish) and the Barcelona Supercomputing Center (BSC) are the centers selected to lead the implementation of the new Infrastructure for Precision Medicine associated with Science and Technology (IMPaCT). The call associated with this initiative has 25.8 million euros in direct grants, which will be managed by the CIBER and the BSC-CNS.

This call, which is part of the Strategic Action in Health 2017-2020 of the Carlos III Health Institute, an agency under the Ministry of Science and Innovation, represents a new step towards the implementation of Precision Medicine in the National Health System, through a strategy based on science and innovation, which will have 77.3 million euros in 2020 and 2021 for its development.

The programs included in IMPaCT are aligned with three areas that will be developed in the future national strategy: Predictive Medicine, Genomic Medicine and Data Science. The CIBER will be in charge of managing the first two, for which it will have funding of 14 million and 7.24 million, respectively, while the BSC-CNS will tackle the third, with funding of 4.55 million.

Objetctives of each Program

1. IMPaCT's first program, Predictive Medicine, is oriented towards the design and implementation of a population-based cohort with clinical, epidemiological and biological data to represent the entire resident population of Spain. The objective is to generate a dynamic registry of individual and population data, clinical, epidemiological and lifestyle data, which, through its follow-up and updating over time, will be the basis for better health decision-making; it will make it possible to build predictive models of disease, identify health inequalities, monitor key indicators and evaluate the impact of health policies.

2. The Genomic Medicine Program will develop infrastructures and coordination protocols to carry out genomic analysis and other 'omic' data throughout the national territory, using state-of-the-art sequencing technologies and existing experiences for their application to the diagnosis of human diseases. In essence, the aim of this program is to place experimental 'omics' diagnostic technologies at the service of all those people who, after making the maximum diagnostic effort with the most advanced healthcare technology, do not have a diagnosis of certainty. It is therefore a basic step towards placing high-level science at the service of people and the National Health System.

3. The third program, Data Science, aims to support the development of a common, interoperable and integrated system for the collection and analysis of clinical and molecular data by contributing the knowledge and resources available in the Spanish Science and Technology System. This development will make it possible to answer research questions

Source:
https://www.ciencia.gob.es/portal/site/MICINN/menuitem.edc7f2029a2be27d7010721001432ea0/?vgnextoid=22ff08f8ee076710VgnVCM1000001d04140aRCRD

based on the different clinical and molecular information systems available. Fundamentally, this program aims to provide researchers with a population perspective based on individual data.

Thus, the resolution of IMPaCT allows progress to be made in the development of the Spanish Strategy for Personalized Medicine, as indicated in the Plan de Choque para la Ciencia y la Innovación (Shock Plan for Science and Innovation). This national strategy will consist of specific plans on data science and health; genomic medicine; advanced and personalized therapies; predictive medicine; training in precision medicine; and Spain's relationship with the European level in personalized medicine.

Glossary of terms:

Digital Health: digital health is understood as the field of knowledge and practice related to the development and use of digital technologies to improve health[18].

Digital Transformation: The Digital Transformation of the National Health System involves a cultural and organizational change compared to traditional medicine. It is a comprehensive and integrated process of information, management and research based on technological tools and data, which seeks to achieve a model based on the generation of knowledge and the measurement of results to obtain value. In addition, it will make it possible to achieve care based on prevention and personalization of health care, always centered on the patient in order to achieve the complete incorporation of Personalized Precision Medicine.[19].

Artificial Intelligence: The European Commission has recently referred to Artificial Intelligence as "software (and possibly also hardware) systems designed by humans that, when faced with a complex objective, act in the physical or digital dimension: perceiving their environment, through the acquisition and interpretation of structured or unstructured data, reasoning about the knowledge, processing the information derived from this data and deciding on the best actions to achieve the given objective.[20].

Personalized Precision Medicine: Personalized Precision Medicine is understood as the identification and application of the most effective preventive, diagnostic and therapeutic approach for each patient, using Precision Medicine as a tool.[21].

[18] Global Strategy on Digital Health 2020–2025, Wolrd Health Organization, available at https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf
[19] This definition has been developed by the Working Group formed for this project.
[20] National Artificial Intellligence Strategy (2020), available at https://www.lamoncloa.gob.es/presidente/actividades/Documents/2020/ENIA2B.pdf
[21] Proposal of Reco,,emdations for a Personalised Precision Medicine National Strategy, Fundación Instituto Roche, available at https://www.institutoroche.es/static/pdfs/Propuesta_de_Recomendaciones_MPP.pdf