PERSONALISING NAVARRA

Navarra is focusing on Personalised Medicine for your health and wellbeing

INTEGRATED
PERSONALISED MEDICINE STRATEGY FOR NAVARRA

PRESENTATION

Precision Personalised Medicine is going to be a reality in Navarra. This medicine will become a reality in an orderly, planned, sustainable and generalised manner, so that the inhabitants of our Region have access and benefit from this new way of understanding medical practice.

Medical care always considers the person, the individual, at the centre of its activity. Personalised medicine incorporates, in addition to this central vision, the latest advances in scientific knowledge to provide the most individualised healthcare possible and ensure the sustainability of our health system.

From a practical point of view, personalised precision medicine seeks the best possible adaptation of medical treatment to the individual characteristics of each patient. This means classifying patients to its maximum, so that each person can be identified according to their susceptibility to disease, prognosis, if they are ill, and possible response to treatment.

To reach such a detailed classification, science and technology offer us very powerful tools: electronic and interoperable medical records, epidemiological data, image analysis (resonances, X-rays, etc.) and, in particular, **genomic data**. In other words, it is about ensuring that medical decisions are based on a solid collection of all the data that we can obtain from the patient's situation.

With all these components it will be easier and more effective to develop better preventive medicine (acting before it causes irreparable damage to the patient) and apply more effective therapies, with more adjusted doses and with fewer side effects, at the most appropriate time of treatment. In this way, unnecessary expenses derived from the absence of diagnosis and treatment failures are avoided.

Of all the data that can be gathered to diagnose and treat a medical problem, perhaps the most relevant, from a person's perspective, is knowing their genome. Knowing all the variants that the approximately 20,000 genes that make us who we are (the inheritance that we receive) can have, and that allow us to develop and respond to the outside (disease, food, activity, environment), and become unique and unrepeatable individuals.

In our 20,000 genes, and in how they express themselves, reside our biology in natural and pathological conditions, and our predisposition to suffer from certain diseases and the answer we give to pharmacological treatments. Therefore, knowing our individual genome (the exact and specific sequence of the 20,000 genes of each individual) is an enormous help to control our general and reproductive health.

The composition (the exact sequence) of those 20,000 genes is what we name the genome. The discipline that studies them on their whole is called Genomics and it is one of the most solid scientific bases on which personalised precision medicine is based on.

Until a few years ago, knowing the sequence of all our genes, our genome, was not possible in the quick, inexpensive and efficient way that is needed to include it in the clinical routine. Yes, it was possible to sequence a single gene, or a few, when faced with a medical question of diagnosis or disease. This is something which is already being done in the Health System in Navarra. However, going from sequencing a few genes to all genes and making it available to clinical practice is not common. It requires, among other things, a great methodological leap that includes large infrastructures, regulatory and ethical modifications, an agile integration in the resources of the health system, a specialised training program at all levels (undergraduate and postgraduate) and acceptance by the citizens.

In short, the implementation of Personalised Precision Medicine requires a well-planned strategy to be a reality that improves patient care, a source that feeds scientific and technological research and a booster for economic development. The Government of Navarra set this goal, to create a Personalised Medicine Strategy, as one of the first priority challenges to be faced by our Region, and created an Interdepartmental Commission made up of the University, Innovation and Digital Transformation department, the Health department and the Economic and Business Development department.

This challenge has activated a team of more than 50 professionals, coordinated by a Technical Committee, who have devoted their work, time, knowledge and professionalism to prepare this document. Thank you all.

The Strategy for Personalised Medicine in Navarra is a commitment to improve the health service we provide to citizens. Bringing science, technology and the laboratory even closer to clinical consultation, to the healthcare we receive from healthcare professionals. It means providing ourselves with tools to make medicine increasingly sustainable, inclusive, personal, predictive, preventive and participatory. Ultimately, it implies that Navarra continues to be a leading region in Europe in the health service it provides to its inhabitants.

María Chivite Navascués
President of the Government of Navarra

VALIDATED BY THE INTERDEPARTAMENTAL COMMISSION

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INTRODUCTION

1.1. EXECUTIVE SUMMARY

Personalised Medicine represents an evolution in the way of approaching medical practice that places the person at the centre of health care linked to scientific knowledge and sustainability. This new vision will generate a substantial change in the health system and will also become an engine of innovation and development in the coming years.

The most advanced countries in the world are promoting the implementation and development of Personalised Medicine in their health systems, creating a strong stream of opportunities on the national and international scene, to which Navarra is no stranger and should take advantage for an improvement of the healthcare in our territory. However, the transformation towards this new paradigm requires timely adjustments in the health system, in the chain of generation and transfer of ideas, and in the production of solutions for the progress of the region. To find the most appropriate solutions to the strategic design of Personalised Medicine in our Region, more than 50 professionals and experts have analysed and proposed the specific changes in the areas of health, research and development, and economic development that are detailed in this document. Also, and to make them feasible, they have identified key operational actions necessary in fundamental areas, which in themselves constitute the basis for new developments in our region, such as training, technological development in infrastructures and information systems, the ethical and legal frameworks, and communication and citizen participation initiatives that will guarantee the involvement of all the agents in a shared collective task in which all of us can participate in one way or another.

The collaborative effort that is proposed is large, and depends to a large extent on the solidarity support of all citizens, which must be coordinated and supported by the Government of Navarra and its institutions through the appropriate financing channels during the successive design, deployment and execution phases of the Strategy to achieve the objective of personalizing Navarra and its medicine, and generating regional specialization that will place our Region as a leader in Personalised medicine by 2030.

1.2. WORK METHODOLOGY

The preparation of the Comprehensive Strategy for Personalised Medicine of Navarra for the period 2020-2030 was carried out through the creation, at the proposal of the Interdepartmental Commission, of a Technical Committee that carried out the functions of coordination and advice throughout the project.

The action plan proposal was formulated through the constitution of different **Working Groups (WG)**, coordinated by the **Technical Committee**, made up of experts and relevant professionals from the different Health areas involved in the development of Personalised Medicine.

Likewise, there was the vision of other complementary profiles such as managers of international health innovation projects, scientific-technological directors of health research institutes, heads of technology and biomedical research centres, hospital managers, patient associations, managers of R&D&i policy developments in other Spanish Autonomous regions, etc.

The supervision, review and validation of the documentation generated was carried out by the **Interdepartmental Commission** made up of the heads of the different departments of the Government of Navarra involved in the implementation, progress and development of Personalised Medicine in the Foral Region.

1.2.1. ORGANISATION

Interdepartmental Commission. Constituted by the heads of the Health Departments; University, Innovation and Digital Transformation; and Economic and Business Development of the Government of Navarra. The Interdepartmental Commission was created within the framework of the previous Agreement established by the aforementioned Departments and published on November 6, 2019. The Commission was in charge of defining a mission and an ambitious but realistic vision of transformation of the health system based on Personalised Medicine, establishing the time frame for the deployment of the Strategy in 2030. Likewise, the Interdepartmental Commission validated this document.

Technical Committee. It was constituted by representatives of the three aforementioned Departments of the Government of Navarra: the department of Health; the department of University, Innovation and Digital Transformation; and the department of Economic and Business Development. This Committee was in charge of coordinating the different working groups, collecting and analysing their proposals and preparing, based on its criteria and the different contributions, this document. This committee was appointed by the president of the Interdepartmental Commission by agreement with the other departments, on January 8, 2020.

Working groups. Formed by more than 50 technicians of the 2nd and 3rd level of the Administration of Navarra with related experience, and by independent experts from the main Strategic Areas and Transversal Axes of the Integrated Strategy for Personalised Medicine in Navarra: (i) Health, (ii) Research , Development and Innovation, (iii) Economic and Business

Development (iv) Infrastructures and Systems, (v) Regulations, (vi) Training, and (vii) Communication and Participation. Their main task was to provide knowledge of the current state of the art and the future vision of Personalised Medicine, focusing on improving Personalised treatments for citizens, reducing expenses in the health system and research and innovation for the development of new medical approaches adapted to the singularities of each person. Each work group was made up of: a facilitator, represented by a high-level representative from the Government of Navarra (General Directors); at least one representative of the Technical Committee, with coordinating and secretarial functions; and a group of between 7 and 10 additional experts. The task of these working groups was carried out through shared documentation and periodic meetings for debate, and was reflected in a final report of each group that is attached as an annex in book 2.

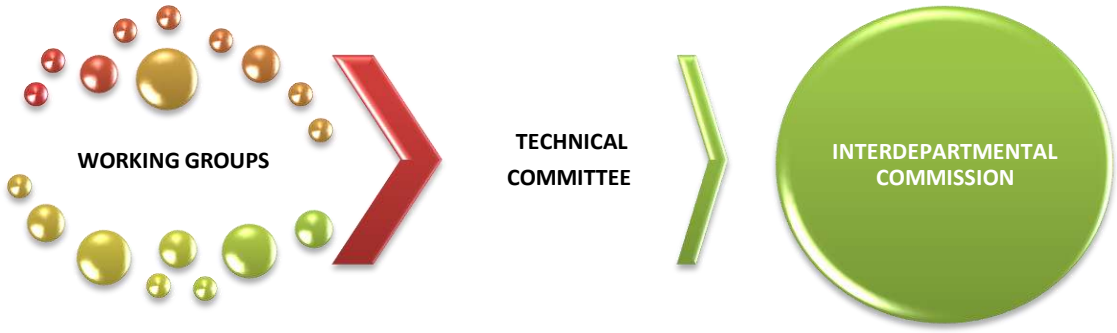

Figure 1. Interaction between Working Groups, Technical Committee and Interdepartmental Committee.

The methodology of the Health WG had to be significantly modified from the initial design due to the work overload of the technicians in the healthcare area derived from the fight against the COVID-19 pandemic. Thus, the Health Department made the decision to substitute the tasks of the work group designated by the document called *'Draft Strategy of Personalised Medicine of the Department of Health'*, presented to the heads of the Department of Health on February 20, 2020.

Likewise, for the WG of Ethical and Legal Regulations, given the novelty and the absence of local experts within the administration, the decision was made to hire the advice of the Chair of Law and Human Genome of the University of the Basque Country, of recognized national and international reputation in the field. These experts developed their advisory work within a work group with the same composition and procedures as the rest of the groups.

1.2.2. ELABORATION STAGES

The actions were structured in **four Stages**. Stages 1 and 2 were developed by the Government of Navarra, prior to the signing of the interdepartmental agreement, as exploratory actions and analysis of Personalised Medicine at both national and international level. In them, a SWOT analysis of the *Foral* region of Navarra in Personalised Medicine was carried out and different exploratory missions were performed to reference regions and countries on the subject.

Stages 3 and 4 were developed by the Technical Committee, the Interdepartmental Commission and the Working Groups. It consisted in the elaboration of the different action plans of the Integrated Strategy, carried out by the Technical Committee; the enrichment of the document by the WGs; and the validation of the documentation generated, which was carried out by the Interdepartmental Commission.

The tasks performed at each stage are detailed below:

1. Diagnosis and analysis of the current situation

- Diagnosis and analysis of the current situation in the Foral Region of Navarra with regard to Personalised Medicine, showing the main existing strengths in the fields of health, economy, R&D&i, technology and transformation of the health system. With this, the starting point of this Integrated Strategy was established, and the main areas of action were agreed.

- SWOT analysis (Strengths, Weaknesses, Opportunities and Threats), compilation of information from previous works in the field of health, and a schematic summary of those aspects that directly affect the development and implementation of Personalised Medicine in the region.

2. Analysis of national and international strategies

- Analysis of different national and international experiences of interest in research and innovation, regulations and legal aspects, infrastructures and economic development in Personalised Medicine that could serve as a reference in the design of this Integrated Strategy.

- Exploratory missions to the main reference technology and research centres, hospitals and European and American organisations in Personalised Medicine, in order to learn about success stories in the implementation of similar Strategies and analyse the good practice developed to achieve them.

3. Elaboration and consensus

- Definition of a clear and ambitious mission and vision, with quantifiable and measurable improvement elements that allow the design of a regional Strategy in Personalised Medicine focused on defining and prescribing treatments adapted to each patient and optimizing the resources of the health system.

- Definition of the strategic objectives to be developed in a time frame for the deployment and execution of the Strategy in 2030, and preparation of the first draft indicating the lines of action, associated actions and key players by strategic area and transversal axis.

- Contrast and debate of the first proposal for the structure of each of the Action Plans of the Integrated Strategy for Personalised Medicine with the different Working Groups selected with the Technical Committee and with the Interdepartmental Committee.

- Collection and analysis of the contributions made in the different Working Groups. Preparation of a second draft of each Action Plan including the lines of action, the associated specific actions and the monitoring indicators and adequate compliance.

- Contrast and alignment with the progress of the deployment process of RIS3 and other departments of the Government of Navarra.

4. Validation

At a final stage, this document was reviewed and agreed upon by the **Technical Committee**, approved by the **Interdepartmental Commission**, publicly exposed through **Open Government** in order to allow access to information and citizen participation and comply with the democratic principles of transparency, participation and citizen collaboration, and finally sent over to the **Government of Navarra** for proper **Processing.**

1.3.3. WORKFLOW IN THE PREPARATION AND CONSENSUS OF THE STRATEGY

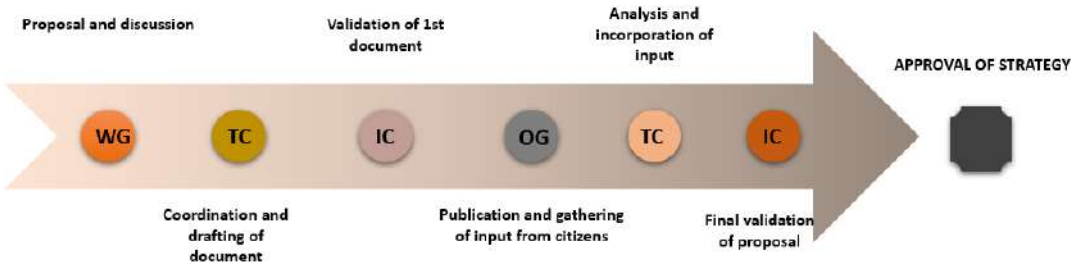

Figure 2. Workflow in the preparation and consensus of the PM Strategy of Navarra. (WG) Working Groups; (TC) Technical Committee; (IC) Interdepartmental Commission; (OG) Open Government; (GN) Government of Navarra

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STRATEGIC DIAGNOSIS

2.1. SITUATION OF PERSONALISED MEDICINE

Nowadays, the most advanced countries are promoting the implementation and development of Personalised Medicine in their health systems, with the aim of improving prevention, diagnosis and treatments applied to each patient. This opportunity **for improvement makes the Health System of Navarra (SNS-O)** consider different initiatives through which they can not only face the needs of today, but those of the future. The search for a transformation of the health system by incorporating new knowledge from research, technology, etc., makes the implementation of new tools such as Personalised Medicine essential.

Although there is no universally accepted definition, according to the European Commission, **Personalised Medicine** is defined as 'a medical model that uses the characterization of people's phenotypes and genotypes (for example, molecular profiling, the use of medical imaging or data on lifestyle) to tailor the therapeutic strategy that best suits the person at a given time or to determine the predisposition to the disease or facilitate timely and adapted prevention' (2015 / C 421/03).

In February 2001, the publication of the results obtained in the **Human Genome Project** (HGP) gave us the opportunity to better understand Genomic Medicine and be aware of its value. HGP was a starting point that has now given way to several similar projects that are being developed in different countries through various initiatives. The knowledge obtained from these investigations has made a 180 degree turn in the area of genomics, being today a target area to be integrated in Clinical Medicine and Primary Care. The novel Personalised Medicine, where genome sequencing and data analysis are essential components, enables personalised diagnosis and treatment according to the patient's genome information and specific environmental factors. P4 medicine (predictive, preventive, Personalised and participatory) is introducing new concepts, challenges and opportunities (Carrasco-Ramiro F et al., 2017).

Through genome sequencing, doctors can improve personalised treatment, predict disease susceptibility, and even prevent life-threatening adverse drug reactions. The possibility of sharing such data will cause an expansion of knowledge and a clinical application, with an improvement in the efficacy of treatments and, ultimately, significant savings in health systems.

All the aforementioned can bring Navarra the opportunity to position itself as a benchmark in genomics applied to Personalised Medicine at an international level, always aligned with an ethical and legal framework to share high privacy data, thus facilitating the development of new markets. This would translate into a possible contribution to investment, economic growth and employment. For this reason, Personalised Medicine is expected to bring significant socioeconomic benefits, including a more efficient health system, and thus be able to become a leading internationally competitive region.

The implementation of these new technologies and knowledge in the health systems of many countries is successfully taking place thanks to strategic plans designed according to the needs and resources of each country. The rapid pace of change in this area requires a clear strategy to ensure that the opportunity to be at the forefront of development is not missed. For the creation of the strategic plan for Personalised Medicine in Navarra, numerous initiatives and strategies from other countries with similar conditions have been taken as a reference in order to establish realistic and achievable objectives.

Sources:

1. European Council Conclusion on personalised medicine for patients (2015/C 421/03) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XG1217(01)&from=EN

2. Carrasco-Ramiro F, Pieró-Pastor R, Aguado B. Human genomics projects and precision medicine. *Gene Ther*. 2017; **9**:551-561.

2.1.1. INTERNATIONAL FRAMEWORK

Within the framework of international programs, such as the **United States, the United Kingdom, Denmark, Germany, France or Finland**, these countries have already begun to integrate Genomic Medicine into their Health Systems. A significant investment is observed in this area, activating various organisations such as universities, research centres, large companies, etc. with the aim of finding new innovative solutions to the problems that arise such as data storage, treatment and analysis. For this purpose, it is essential to have infrastructures tailored to these needs, as well as international collaborations or the commitment of the Government itself through public policies in order to build an industrial fabric of Genomic Medicine specializing in Big Data and standardizing the steps to follow from now on.

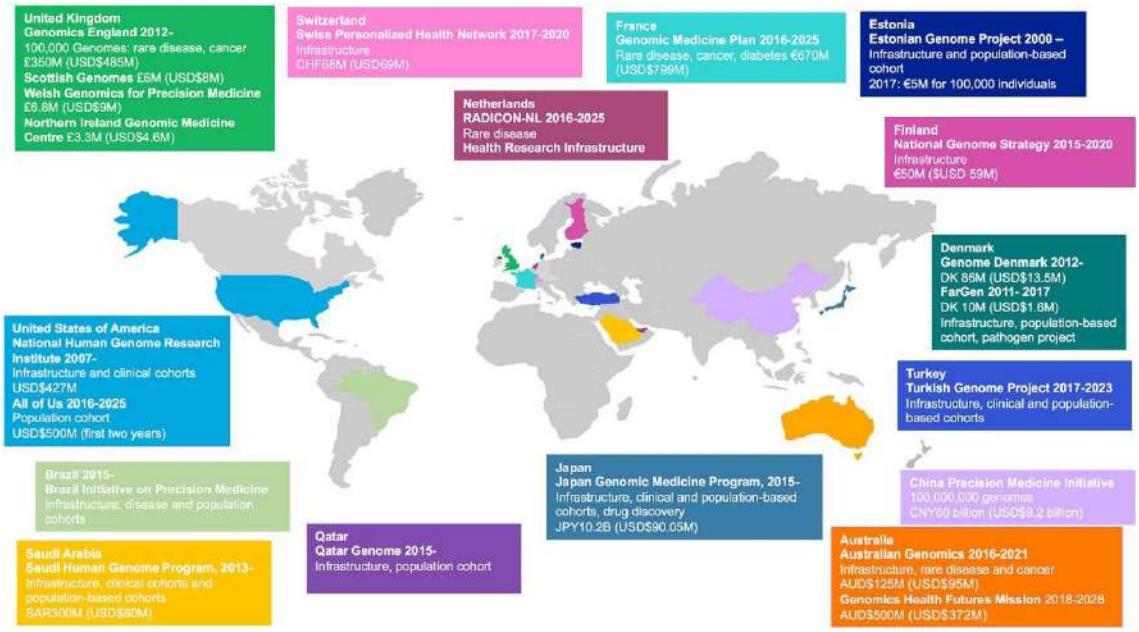


Figure 3: Map of current national Genomic Medicine initiatives supported by the governments of different countries (Stark Z et al., 2019)

Several countries have launched Personalised Medicine initiatives, with significant investments in Genomic Medicine and in the large-scale storage and analysis of Health data:

Table 1. Representative examples of international Personalised Medicine initiatives

Country	Project	Objective	Year	Financing
USA	Personalised Medicine Coalition (PMC)	Academic organisation established in 2004, with more than 250 participating institutions today, whose objective is to share the opinion of experts on the area of Personalised Medicine in its different aspects raising awareness on its benefits at different levels (industry, academia, etc.). PMC considers education and counseling a priority. Their work group published a guide for the integration of Personalised Medicine in the North American health system where the key points are: • Training to different stakeholders (dissemination activity) • Empowerment of patients • To prove value (organisation of studies) • Management of clinical information (to facilitate access to data) • To guarantee access to data (economic measures)	2004	-
	The Precision Medicine Initiative (PMI)	The objective of this initiative is to develop an individualized medicine making use of technological and research advances. This initiative includes two key elements: • Oncology: implementation of prevention and treatment strategies through genomics. • Cohort program: creation of a cohort of 1M patients for research in order to collect multiple biomedical data that will allow the investigation of numerous diseases.	2016	215M$
United Kingdom	100,000 Genomes	This project aims to sequence 100,000 patient genomes of seven common cancers and more than 100 rare diseases and their relatives and integrate these data with clinical data to develop specific therapies for these diseases.	2012	Project financed by the UK government (National Health Service, NHS) with over £ 300M
	Personalised Medicine Strategy (England)	Project whose objective is the integration of Personalised Medicine in the healthcare field, it has four critical elements in its work plan: infrastructures, introduction of changes at a clinical level, incorporation of innovative technologies and alignment of the system's policies. This new initiative taken by the National Health Service of England (NHS) is based on the 100,000 Genomes project, which aims to carry out 5 million sequences.	2015	-
	Personalised Medicine Strategy (Scotland)	Scottish strategy developed by two infrastructures: Scottish Genomes Partnership (SGP) and Stratified Medicine Scotland Innovation Center (SMS-I). This strategy has a fund that acts as a catalyst for the Genome industry and aims to develop an ecosystem of Personalised Medicine	2016	6M£
Denmark	Danish Government and Regions National Strategy for Personalised Medicine 2017 – 2020	This plan has established a National Genome Centre at the University of Tartu. This initiative has been built on the basis of investments in biobanks, sequencing infrastructure and research data.	2017	100M Danish Crown

Estonia	Estonian Genome Project	This project carries out the sequencing of 50,000 genomes (5% of the population) with the aim of creating a database which will be included in the health service and will directly have an impact in the population. This initiative is based on six key elements: • Research to generate knowledge • Electronic medical record • Automated support systems in decision making • Training of specialists • Powerful infrastructure biobanks to promote secure data exchange	2014	4.4B €
Finland	Finland's Genome Strategy	It is an initiative led by the Finnish Ministry of Health. A national genomic centre has been created to implement this strategy, including the development of a reference genomic database. Its seven key goals are: • Use of data: accessible and secure • Integrated into the healthcare scene • Training of health staff • Computer systems: efficient use of data • Genomic data are widely used. • Citizens capable of making use of genomic data in their lifetime • Finland, an attractive country for genomic research	2015	50M€
France	*France Médicine Génomique 2025*	France has 12 sequencing centres, a data analysis centre (*CAD*) and a centre for innovation, evaluation and transfer (*CRefIX*) to implement its genomic medicine strategy. This project contemplates the realization of 235,000 complete sequences of 20,000 patients with rare diseases and their families, and 50,000 cancer patients. It has 3 goals: • To position France as a leading country in Personalised Medicine. • Integration of Personalised Medicine in the healthcare field • Establishment of a national Personalised Medicine Industry that could generate innovation in different areas	2016	670M€
Germany	*Personalised - Action Plan*	This initiative aims to: • Obtain a fast and accurate diagnosis with validated biomarkers. • Improve treatments thanks to the integration of genomic data. • Increase investment in Personalised Medicine • Achieve knowledge about Personalised Medicine in population	2013	360M€

Sources:

1. Daryl Pritchard and Christopher Wells. Beyond the promise: A clinical adoption “Road Map”. Personalised Medicine in brief. Vol.7, Fall 2016
2. Precision Medicine Initiative. https://www.nimhd.nih.gov/programs/collab/pmi/
3. Personalised Medicine Strategy. BOARD PAPER - NHS ENGLAND. https://www.england.nhs.uk/wp-content/uploads/2015/09/item5-board-29-09-15.pdf
4. Personalised Medicine Strategy Scotland. https://www.nhsinform.scot/care-support-and-rights/nhs-services/using-the-nhs/realistic-medicine
5. Danish Government and Regions National Strategy for Personalised Medicine 2017 – 2020. https://sum.dk/~/media/Filer%20-%20Publikationer_i_pdf/2017/Personalised-Medicine-Summary/SUM_klar_diagnose_summary_UK_web.ashx
6. Estonian Genome project. https://genomics.ut.ee/en/about-us/estonian-genome-centre
7. Health through the use of genomic data. Finland´s Genome Strategy Working Group Proposal. https://www.julkari.fi/bitstream/handle/10024/126940/URN_ISBN_978-952-00-3598-3.pdf?sequence=1
8. France Médecine Génomique 2025.http://www.gouvernement.fr/sites/default/files/document/document/2016/06/22.06.2016_remise_du_rapport_dyves_levy_-_france_medecine_genomique_2025.pdf
9. Personalised Medicine- Action Plan. February 2013. http://gesundheitsforschung-bmbf.de/_media/Action_Plan_IndiMed_englisch.pdf

European Union (EU): general initiatives at the European level have been carried out by consortia and institutions, which have been able to identify joint lines of work contributing to the creation of common policies and the alignment of the Personalised Medicine strategies developed in the different European countries.

Currently, between 30 and 40 million Europeans are affected by rare diseases, 80% of which are of genetic origin. Genome sequencing and complementary molecular analysis will help in the future to adapt treatments and adopt preventive health measures. The **1+MG Roadmap** project, initially signed by 13 EU member countries, expects to have access to one million sequenced genomes by 2022 and ten million by 2025. Since then, more than 20 countries have signed a declaration committing to work in a joint manner to establish a federated cross-border network that allows sharing the information obtained from the different sequencing carried out by the different countries in this initiative. By signing this declaration, a unique opportunity has been created to address the challenge of getting local, regional, national and European healthcare systems aligned around a common framework, mutually benefiting all participants in facilitating a rapid implementation and efficient use of funds.

Secure and authorized cross-border access to genomic data and other health data in the European Union is necessary for:

- Progressing in the understanding of the genetic associations that cause or predispose complex diseases.
- Learning to identify and treat cancer at a much earlier stage.
- Improving preventive options and identifying new target genes for the development of new target drugs in less time.
- Strengthening prevention effectiveness by improving detection accuracy and reducing costs.
- Improving patient outcomes and ensuring the sustainability of healthcare provision in the EU.
- Contributing to investments, economic growth and employment.

The target of this project of obtaining 1 million genomes, provides a tangible, ambitious but achievable goal. This project aims to generate the momentum necessary to create an infrastructure with established policies and processes, as well as to support capacity building and communication efforts. In the longer term, it is expected that each European country will operate centres with its own resources to provide an access service to transnational computational data, with approval processes for access to regulated data suitable for accessing the national genome and related phenotypic data. These centres will constitute a federated secure cross-border infrastructure based on common standards that will provide transnational access to genomic and health data in accordance with local, regional, national and European regulations.

In this project, three objectives have been defined that provide the basis for the 2018-2022 roadmap, along with the objectives set out in the declaration:

✓ Objetive 1: To involve local, regional, national and European stakeholders to define the requirements for cross-border access to genomics and personalised medicine.
✓ Objetive 2: To translate data quality requirements, standards, technical infrastructure and ELSI (Ethical, Legal and Social Issues) into technical specifications and implementation guidelines that capture European best practices.
✓ Objetive 3: To boost adoption and support long-term operation by organisation at local, regional, national and European level, providing guidance for development in stages through a maturity model and a methodology for economic evaluation.

All these international strategies or initiatives share the following points:

- ❖ Institutional support
- ❖ Appropriate financing initiatives for their development
- ❖ Generation of new advances by promoting R&D&i projects
- ❖ Change in the healthcare system generated by the implementation of the different tools that Personalised Medicine entails
- ❖ Development of P4s: prediction of pathologies, prevention of diseases, personalisation of care and patient participation
- ❖ Specialized training (incorporation of new educational programs)
- ❖ Creation of a collaboration network between different institutions, both public and private
- ❖ Implementation of IT solutions for data processing and recording
- ❖ Provision of ICT infrastructures where the generated data can be stored, its processing and exploitation, in order to standardize and generate quality information through the creation of a platform
- ❖ Regulatory framework through which the generated data can be shared safely
- ❖ Integration of data with clinical information.

Source: European '1+ Million Genomes' Initiative https://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative

2.1.2. NATIONAL FRAMEWORK

At the national level, over the last few years different aspects involved in the implementation of Personalised Medicine in the National Health System (*SNS*) have been developed, both at a regional and state level, thanks to various initiatives and strategies with the aim of guaranteeing improvement in quality and efficiency in the healthcare field.

Making a comparison between the initiatives developed in the different Autonomous Regions in Spain, an uneven rhythm is observed among them. The resources that each region has, how they are being used and how their use can be maximized, is one of the factors that differentiates the various initiatives that are being promoted in the different territories. The approach with which different key factors are being given prominence defines the degree of development of Personalised Medicine in each Autonomous region.

The following table describes the most outstanding initiatives taken in the different Autonomous regions:

Table 2. Representative examples of different initiatives of Personalised Medicine (PM) in different Spanish Autonomous Regions.

Region	Regional strategy	Infrastructures	R&D&i	Training	Integration of Personalised Medicine in the Healthcare field	Collaboration Network
Andalusia	Medical Genome Project (MGP). It has always prioritized this type of health strategies: the Genetics Plan in Andalusia, the Advanced Therapies Plan and the Andalusian Research, Development and Innovation Plan (PAIDI 2020)	La Cartuja Science and Technology Park, in Seville. It has a mega-sequencing platform and a bioinformatics platform for data processing, and equipment with high capacity for analysis and computation.	Projects where a large number of genetically based diseases are studied, known and characterized. It has research groups of recognized leadership.	There are specific master's degrees in the area of genomics.	Network configuration of Clinical Genetics Units (CG). No centralized management.	Health Cluster, it has numerous companies in the Personalised Medicine environment.
Catalonia	Health Plan and Oncology Plan with Personalised Medicine development actions	Several reference centres.	It has leading research groups and a large number of European projects	With PM specialty master's degrees. It has specific training for health staff participating in pilot projects	Several translational projects with wide scope	Collaboration with private companies.
Madrid	The Rare diseases Strategy and Comprehensive Plan Against Cancer	No designated centres	It has leading research groups and a large number of European projects.	They have specific Master's degrees.	No translational projects	Health and Wellbeing Cluster; no innovative public procurement, collaboration initiatives, high concentration of biotech companies.
Basque country	Health Plan, Genetics Plan and Oncology Plan .	Reference centres organized in a network.	With important Data Mining projects / omic data integration / Healthcare Big Data	With specific PM Master's degrees	No translational projects	Collaboration with private companies. Health Cluster.
Region of Valencia	Incorporation of molecular technology platforms for hereditary cancer in the Health Plan. Strategy of Complex diseases.	No designated centres	It has leading research groups and a large number of European projects.	With specific PM Master's degrees	No translational projects	No innovative public purchase collaboration initiatives. It has a large number of biotech companies. Health Cluster.

Source: Proposal of Recommendations for a State PM Strategy. https://www.institutoroche.es/static/pdfs/Propuesta_de_Recomendaciones_MPP.pdf

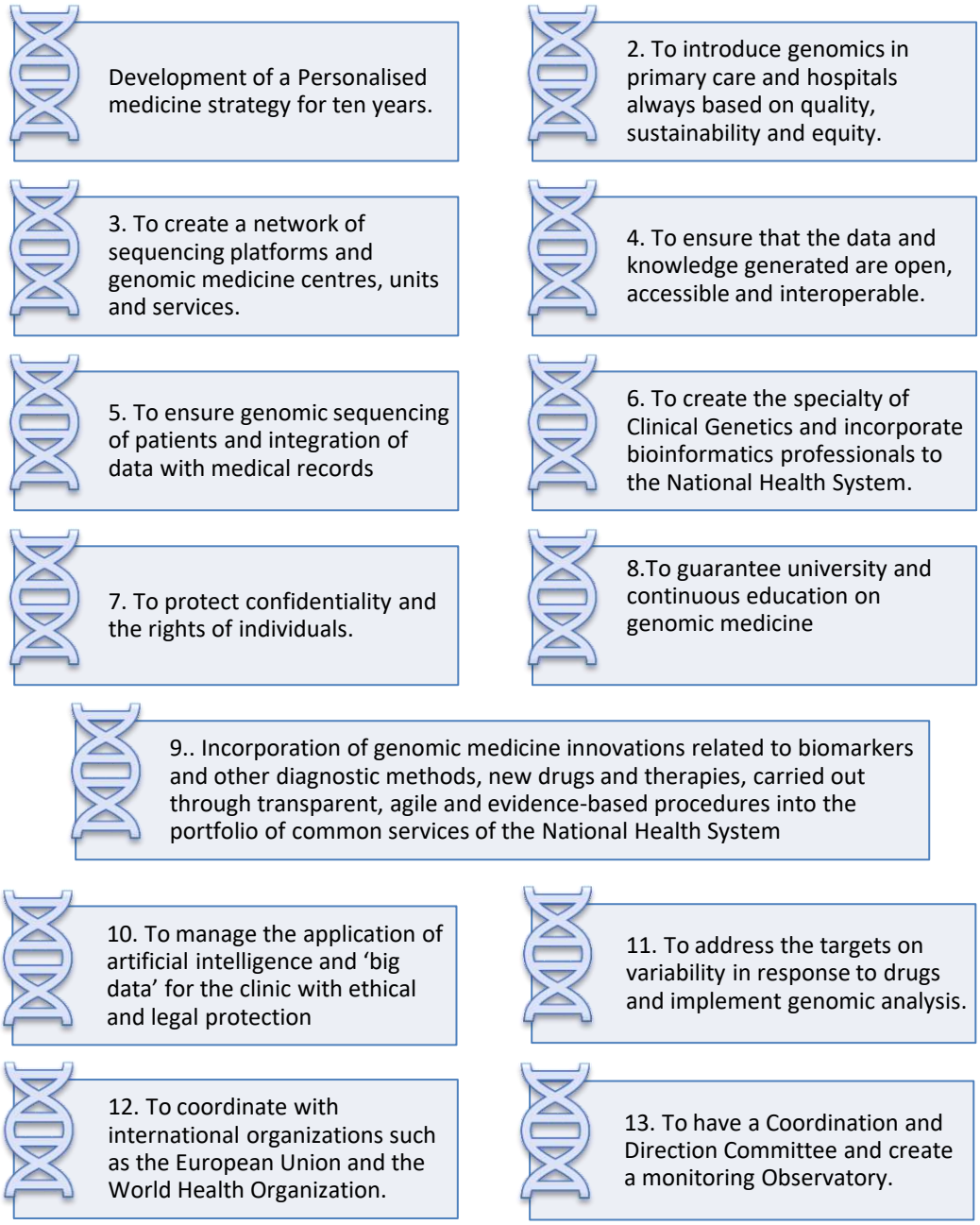
The **need for a transversal strategy of Personalised Medicine in our country** makes visible the need of public policies that help its generation and consolidation. For this reason, in recent years, a series of steps have been taken regarding Personalised Medicine at a national level:

- In **2018**, during the **Plenary Session of the Interterritorial Council of the National Health System**, the launch of the first Personalised Medicine plan was approved in order to respond to the needs of patients and face the demographic challenges that the country faces ahead.

- In **2019**, the **Senate** recommended (*BOCG_D_12_341_2574*) the creation of a Health and Social Services commission with the aim of analysing the regulatory, ethical and organisational implications of the application of genomics, genetic engineering, predictive medicine and precision medicine.

  In this appearance, numerous specialists from different areas contributed their point of view on the importance of the implementation of Personalised Medicine in the National Health System.

  The Senate, after the different appearances by the specialists, unanimously approved the **following Conclusions and Recommendations** in relation to the incorporation of Genomic Medicine into the National Health System:


Development of a Personalised medicine strategy for ten years.
2. To introduce genomics in primary care and hospitals always based on quality, sustainability and equity.
3. To create a network of sequencing platforms and genomic medicine centres, units and services.
4. To ensure that the data and knowledge generated are open, accessible and interoperable.
5. To ensure genomic sequencing of patients and integration of data with medical records
6. To create the specialty of Clinical Genetics and incorporate bioinformatics professionals to the National Health System.
7. To protect confidentiality and the rights of individuals.
8.To guarantee university and continuous education on genomic medicine
9.. Incorporation of genomic medicine innovations related to biomarkers and other diagnostic methods, new drugs and therapies, carried out through transparent, agile and evidence-based procedures into the portfolio of common services of the National Health System
10. To manage the application of artificial intelligence and 'big data' for the clinic with ethical and legal protection
11. To address the targets on variability in response to drugs and implement genomic analysis.
12. To coordinate with international organizations such as the European Union and the World Health Organization.
13. To have a Coordination and Direction Committee and create a monitoring Observatory.

After the publication of these recommendations, the Ministry proposed to develop a Personalised Medicine strategy following the **strategic lines described** below:

- Sequencing, storage and support infrastructures
- Integration and analysis of large data sources
- Training of health personnel and development of new professions
- Regulatory and ethical framework
- Research and Innovation Promotion

- With the purpose of achieving cohesion when it comes to being at the forefront of development, **on February 20, 2020,** the Ministry of Science and Innovation announced that the Government already has **a draft of a specific program of the future National Strategy of Personalised Medicine.**

- In **May 2020**, the Minister of Science and Innovation, Pedro Duque, explained in Congress the **advances in Personalised Medicine**, which have helped in the knowledge of COVID-19 and can be particularly useful for future health emergencies. The technological possibility of interrelating clinical and genomic data of patients can help to find better clinical practices. Also, in this context, he explained the new actions that his Department has implemented in order to promote the Spanish Strategy for Personalised Medicine. This initiative will be accelerated in the short term with an initial endowment that will provide the technological infrastructure and the genomic analysis capacity necessary to make an important qualitative leap.
- Finally, on **July 9, 2020**, the President of the Government, Pedro Sánchez, presented the **Action Plan for science and innovation** that commits € 1,056 million of direct investment (2020-2021). This plan, made up of 17 measures, places science, R&D&i and talent at the centre of the recovery strategy after a decade of budgetary cuts and the absence of reforms. This plan contributes to science and innovation leading the solutions to the COVID-19 crisis but also enables the generation of competitive industries and companies with high added value and the possibility of moving towards a more sustainable, technological, fair and safe society.

This plan is articulated in three axes:

- AXIS 1: Research and Innovation in Health
- AXIS 2: Transformation of the science system and attraction and retention of talent
- AXIS 3: Promotion of business R&D&i and science industry

Within the first axis, measure 3 aims to launch a **Spanish Strategy for Personalised Medicine** for the prevention and treatment of diseases. This plan emphasizes the importance of promoting a new way of doing medicine, linked to scientific knowledge and the ability to exploit all available information to increase the quality and efficiency of the health system.

This strategy has been launched in the second half of 2020 and, between 2020 and 2021, it will include the following actions:

- ✓ **Big-Data Health Plan**. Integration and use of data for public health and research objectives, to improve prevention, diagnosis and Personalised treatment.
- ✓ **Genomic Medicine Plan**. To strengthen infrastructures and create coordination protocols to carry out genomic analyzes in an efficient and equitable accessible manner throughout the national territory.
- ✓ **Plan for Advanced and Personalised Therapies**. It will lead to the creation of a State Centre for Advanced Therapies in the next two years, focusing towards research, development and potential manufacturing and distribution in the National Health System of personalised advanced therapies.
- ✓ **Predictive Medicine Plan: prevention and public health**. Creation of a large-scale multipurpose population cohort with clinical, epidemiological and biological samples to represent the entire Spanish population.
- ✓ **Precision Medicine training plan**. In collaboration with the Ministry of Health, and with the purpose of training current health professionals and future ones for the interpretation of genomic data and its integration with other data sources.
- ✓ **Positioning of Spain in the European environment in the field of Personalised Medicine**. To increase resources to finance joint transnational programs and projects of Personalised Medicine, including different European and international initiatives, such as the creation of national nodes for 1 Million Genomes (1 + MG), ICPerMed and ERAPerMed.

- In **September 2020**, the Council of Ministers approved the **Spanish Strategy for Science, Technology and Innovation 2021-2027 (*EECTI*)**. This strategy will give an answer to the need of a sustainable recovery and ensure the future for next generations, aligning with the EU's science and innovation framework program, Horizon Europe (2021-2027)
  - ✓ To face the priorities of our environment
  - ✓ To promote R&D&i and its transfer
  - ✓ To develop, attract and retain talent
  - ✓ To catalyse innovation and business leadership

Sources:

1. Draft of a specific program of the future National Strategy for Personalised Medicine. http://www.mscbs.gob.es/gabinete/notasPrensa.do?id=4322
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2.1.3. NAVARRA

The **Foral Region of Navarra**, given the fact that it meets the features mentioned below, can be defined as a potential strategic region for the implementation and development of Personalised Medicine:

- It has an autonomous Administration.
- The existence of an electronic medical record (EMR) for each citizen that will allow to link the information obtained in the genetic analysis with the rest of the clinical record in a very simple manner.
- The existence of a single tertiary referral hospital that coordinates the medical specialties of the entire region.
- A small but sufficient size for the selection, recruitment and follow-up of patients.
- The existence of preserved family nuclei that enables the access and study of close relatives of the patient.

In this context, it is important that Navarra takes advantage of the opportunity to develop different solid channels (medical, scientific, industrial and economic) in order to execute this strategic plan for Personalised Medicine.

Regional strategy:

The implementation of a Personalised Medicine Strategy entails a series of challenges involving different areas such as healthcare, training, R&D&i, regulatory framework and the economic segment.
Until now, there was no strategic health document as such. This document is considered the first Personalised Medicine strategic plan described to date, but many steps have been taken to reach this point:

- The correct progress in some key elements such as genetics, omic sciences or biomedical technologies, have been possible by establishing these as key lines of research in the **Health Plan in Navarra 2014-2020.**

- In **2015**, Navarra established as **Challenge 8 of the Smart Specialization Strategy S3, Personalised Medicine**. One of the first measures taken was the call for Strategic R&D&i Projects named **GEMA** (Genomics and Advanced Medicine) supporting projects such as NAGEN 1000, DIANA, MINERVA, GENEURONA, PharmaNAGEN or NAGENCOL.

- The participation of Navarra in international organisations of Personalised Medicine such as the International Consortium of Personalised Medicine (**ICPerMed**) or the European Network of Personalised Medicine (**ERA PerMed**), makes our region closer to reaching its goal in this area.

- **The Science, Technology and Innovation Plan for Navarra 2017-2020**, whose aim was to relocate Navarra as a leader in innovation, improving investment, scientific excellence, talent, transfer, cooperation and internationalization.

- Approval of the **regional law 15/2018 on Science, Technology and Innovation.**

- Presentation of the **Initiative to Strengthen Competitiveness (IRC) for Health in Navarra**, in July 2019 by Sodena.

- Incorporation of Nasertic, public company dependent on the Government of Navarra, to the **Spanish Supercomputing Network (RES)** with its supercomputing cluster **Urederra**, in May 2020.

- Creation of the **IRIS Platform**, a pilot virtual platform for the Digital Innovation Pole, in June **2020.**

- Presentation of the **Navarra 2030 Digitization Strategy**, on October 1, **2020**. This strategy, which contributes directly to the promotion and development of Personalised Medicine, has as one of its goals to evolve towards a new care model focused on people, a 100% digital prevention model with reinforcement of healthy habits and disease prevention.

All these measures adopted over the last few years have been possible thanks to institutional support through public policies in the field of R&D&i accompanied by direct investment in research projects that accelerate the healthcare practice of Personalised Medicine. The commitment of the Regional Government working in a digital vanguard paves the way towards the integration of Personalised Medicine in Navarra, assuming a benefit for citizens, companies and the Administration.

Healthcare: Translation in the healthcare field

The Health System of Navarra (SNS-O) works on this strategy in order to contribute directly to the evolution of a healthcare model focused on patients. This search for improvements that ensure efficient and quality management requires the incorporation of knowledge and the implementation of new technologies.

The use **of high-throughput technologies**, such as massive genome sequencing, represents a change in the future of the clinic due to its application in the discovery of disease genes or the development of treatments adapted to certain genetic profiles.

The incorporation of tests associated with Personalised Medicine in the portfolio of common services of the SNS-O, as well as the access to the Genetic Advice in the field of hereditary cancer or rare diseases, make the Hospital network of Navarra *(*CHN) a reference centre. The **CHN has a Genetics Service** which consists of a clinical area and a laboratory area that develop their activity in a coordinated manner. This Service gives the possibility of accessing advice, diagnosis, prognosis, prevention and treatment of genetic diseases.

Research, Development and Innovation (R&D&i)

Navarra's commitment to regional development using smart policies based on knowledge and technology has been evident in recent years, with numerous advances:

1. Thanks to economic initiatives such as **the Aid Program for carrying out Strategic R&D Projects,** Navarra wants to promote the implementation of strategic industrial research and experimental development projects that are aligned with the European research and innovation strategy Horizon Europe and that will present innovative solutions to some of the challenges that are faced by society. It is about promoting the development of new technologies seeking their materialization in the creation of new products and services.

   Likewise, the aim is to promote the transfer of knowledge between companies and research and knowledge dissemination organisations based in Navarra, that is, Technological Centres, Universities and Research Organisations, through the joint implementation of R&D projects.

   Within these Strategic Projects, Navarra has Challenge 3, **GEMA**, dedicated to Genomics and Advanced Medicine, where it is proposed to execute R&D projects in the field of Personalised Medicine in Navarra connected to its health system. Currently, several projects have been financed by means of these initiatives, such as: NAGEN 1000, DIANA, MINERVA, GENEURONA, FARMANAGEN or NAGENCOL.

   An example of these projects, awarded for **'best international practice in Personalised Medicine'** by **ICPerMed** in 2018, is the **NAGEN 1000** project. The Genome 1000 Navarra research project (NAGEN 1000) is a pilot project that has given the possibility to Navarra to sequence 1000 complete genomes of patients in the Navarra Hospital network (CHN) with rare diseases or with certain types of cancer of possible genetic origin, of unknown cause, and that of concrete relatives. The combination of these two sources of information, genomics and clinical, has helped medical teams to know the causes of some diseases, reach a diagnosis and/or provide a more personalised treatment to some patients.

   This information derived from the sequencing of complete genomes has been used as a clinical tool for the development of the new Genomic Medicine in the CHN. Thanks to this project it will be possible to improve patient care, promote research and develop and implement new technologies in Navarra.

2. Another milestone that has been achieved after strategic decisions, is the accreditation of the CHN as a **university hospital**, providing the necessary infrastructures and means for the development of teaching and research functions.

3. **IdiSNA Accreditation**: it is the first accredited public-private health research institute in Spain. This recognition confirms IdiSNA's compliance with all the strict technical quality requirements established in Royal Decree 279/2016.

4. Creation of a registry of Agents of the Innovation System in Navarra (**SINAI**), an innovation system that eliminates barriers between academic and business innovation, encourages the optimization of infrastructures, raises the level of technology and research centres, and ensures an inclusive R&D with a minimum number of male and female doctors.

The will of establishing **a socioeconomic model based on the generation of knowledge, its transfer and subsequent transfer to the healthcare field**, makes us aware of the needs that we must cover in the R&D&i area in order to be able to offer progresses in new discoveries and new treatments that improve patient survival thanks to the promotion of R&D&i projects, guaranteeing the quality and sustainability of the SNS.

Economic and Business Development

After assessing the different aspects that make Navarra a potential region for the development of Personalised Medicine, Sodena developed in 2019 a **Health Competitiveness Reinforcement Initiative** (*IRC*), through which it may be possible to implement the different measures defined in the strategic plan.

According to the **Health IRC**, the economic development strategy of Personalised Medicine in Navarra requires the creation of the necessary data infrastructures (Supercomputing and genetic sequencing) and seeks to lead the development of personalised drugs and personalised solutions in prevention and well-being, in food and physical exercise and develop technical equipment specially oriented to aging, dependency and chronic diseases. As stated in the IRC, the Personalised Medicine field has the potential to become an important area of health, economic and research development in Navarra, which will offer promising possibilities for public-private collaboration in new forms of treatment that will benefit patients.

The **economic impact** and the **industrial tractor effect** that can be given thanks to the implementation of such avant-garde technologies, as is the case of Personalised Medicine based on genomics and multiple data science, has been revealed in other countries that have opted for this type of strategies: UK (100,000 genomes), Finland (Finland`s Genome Strategy) or USA (The Human Genome Project).

The **generation of these data** is a new tool that is creating an economic fabric based on a new business model (national and international) that gives Navarra the opportunity to open up to new markets. The possibility of having a library of data generated in genomic studies implies the participation of various **agents**: the Administration, companies in the technological field, legal ethical regulation services, analysis services, universities, professional training institutes, research centres and hospitals.

In order to improve the competitiveness of Navarra as a reference region in Personalised Medicine, it is essential to take into consideration several **key aspects:**

- ✓ To forecast changes in the business
- ✓ To access to higher value markets and product innovation
- ✓ Knowledge of the future consumer
- ✓ Greater integration between agents and possible alliances

To do so, it is necessary to improve **the quality of the business environment** by:

- ✓ Human capital (new skills and abilities)
- ✓ New provider network
- ✓ Public investment policies focused on business challenges-specialized infrastructures
- ✓ Policies to attract investment
- ✓ Positioning of the region

Infrastructures and Systems

The integration of Personalised Medicine increases the need for collaboration between the public and private sectors in infrastructure to collect and store samples and biological data, carry out genome sequencing and for the registration, processing and exchange of data. The infrastructure must provide services both in healthcare treatment and in R&D&i and in economic development.

Initiatives such as the creation of the **Digital Innovation Pole (IRIS)** already consider unique scientific-technological infrastructures (*ICTS*) for the necessary supercomputing and sequencing. At the IRIS Digital Innovation Pole, it is expected to host research and experimentation capacities and to have a campus with supercomputing facilities, sequencing, laboratories, and meeting points to stimulate creativity and entrepreneurship. Navarra is committed to the IRIS Digital Innovation Pole, with a significant investment where it brings together the most relevant agents in the region in Artificial Intelligence, the Public University with its virtual research institutes, Naitec, ADItech, Ain, Tracasa, Cein, Sodena, the Nasertic supercomputing and sequencing infrastructures and the collaboration of other agents such as professional associations, the Chamber of Commerce or clusters to facilitate an environment of creativity, research and entrepreneurship around Artificial Intelligence applied to the areas of the Intelligent Specialization Strategy , with special attention to the requirements of the Personalised Medicine and Biotechnology Strategy.

The **Urederra** supercomputing cluster, established since January 2018 and located in the **Data Processing Centre of the Government of Navarra (CPD)** managed by Nasertic, is an infrastructure designed for use by all public and private agents belonging to the Innovation System in Navarra (SINAI), by all technology centers, research and universities integrated in ADItech and of the public companies that request it. This cluster has already had the opportunity to work on various projects such as the aforementioned NAGEN 1000. This new

HPC (High Performance Computing, supercomputing) infrastructure has been specifically designed for intensive loads of artificial intelligence and can improve training times by four, allowing to build artificial intelligence applications more quickly. Since May 2020, Urederra has been incorporated as a node in the Spanish Supercomputing Network (RES).

The commitment in the year 2020 to the **Massive Sequencing Centre**, an infrastructure provided thanks to the agreement by which the Government of Navarra authorized a capital increase of the public company Nasertic, will give Navarra the possibility to undertake its own studies as well as the provision of services to different agents of the public environment and the generation of new lines of business.

One of the steps to be taken in the progress of this strategy will be the **provision of an ICT infrastructure** for the storage of the generated data and its large-scale processing, as well as the new creation of a bioinformatic analysis unit that outputs and exploits the data generated.

Regulatory framework

To date, data belonging to citizens has been regulated under the following framework:

- Law 41/2002 regulating **patient autonomy and rights and obligations regarding information and clinical documentation.**
- Regional Foral Law 17/2010 on the **rights and duties of people regarding health matters** in the Foral Region of Navarra.
- Resolution 1387/2017 of the Managing Director of the Health Service in Navarra, determining the content of the **Research Projects Registry** and establishing the procedures for **accessing clinical documentation for research purposes.**
- Organic Law 3/2018 on **Data Protection and Guarantee of Digital Rights** (LOPDGDD). In particular, Additional Provision 17. It develops the provisions of the GDPR. The description of the **data pseudonymisation procedure** is particularly interesting **when it is used for research.**
- **Regional Foral Law 15/2018 on Science, Technology and Innovation.**
- Foral Decree 20/2019, which approves **the data protection and information security policy of the administration** of the Foral Region of Navarra and its public bodies.

These laws and decrees are not enough. Ensuring adequate protection of the rights, health, integrity and self-determination of researchers and patients is key. Therefore, **it is essential that the areas of action are supported by a solid ethical and legal basis.**

Education and Training

Personalised Medicine will require training of health professionals in the use of new tools and genomic data. New profiles will also be needed for sequencing, development of data processing and analysis tools, data storage, access and security. Universities must offer new educational programs and adapt existing ones to offer the professional capital required by this strategy.

The measures taken to date are:

- In the educational field, new degrees have been added to the Public University of Navarra **UPNA** portfolio: **Medicine, Biotechnology, Biomedical Engineering and Data Science.**
- New **graduate** and **postgraduate** training will be added in order to meet the needs of specialists in the area who can carry out the work involved in incorporating these genetic tools into the healthcare system.
- Provision of training to professionals **specialized in different fields** that make up clinical groups within the framework of the transfer of Personalised Medicine to the healthcare field.

This strategy aims to adapt existing professional profiles, as well as creating new specialisations in Personalised Medicine to generate human capital that could drive our region towards progress and become an international benchmark in this field.

Collaboration network

Collaboration between health, education, research and economic development, both in the **public and private sectors**, is necessary to fully benefit from this strategy.

Collaborative programs such as the existing ones: R&D&i Projects, Strategic Projects, etc., and others of new creation, will help to strengthen interdisciplinary networks of essential knowledge to achieve a boost in cooperation between technology centres, universities, industry, administration and society.

Private Environment in Navarra

The Foral Region of Navarra has a very competitive **public-private network**. Agents belonging to the **private sector** are:

- Large companies
- Startups
- Hospitals, private clinics.
- Private University of Navarra: UNAV
- Research Centre: CIMA

This **private environment** in Navarra has the following **values**:

- At an industrial level, a very heterogeneous mass in terms of business segments and companies within each segment.
- Excellence in the provision of private medical services and the ability to attract clients nationally and internationally.
- International excellence in certain areas of knowledge and R&D&i initiatives.
- Technology transfer policies highly focused on the transfer from creation to market (especially at an economic level) and less intensive in the ideation phase.
- Possibility of working on the sophisticated local demand to attract the rest of the agents.

Data Processing Plan

Data use will grow along with this rapid development. It is **crucial to manage the data generated through a clear definition of its uses and services**, trying to use its full potential by linking what we already know about diseases in the population with genetic knowledge.

Access to the data generated must be given in a safe, fast and easy manner so that doctors can diagnose with greater precision and guide treatment more accurately, and researchers can develop new knowledge and new treatments for the benefit of patients.

2.2. KEY FACTORS FOR SUCCESS

After the review of the situation of Personalised Medicine, it is possible to identify **11 key factors** that will support the tailor-made development of the Integrated Strategy for Personalised Medicine in Navarra in order to **guarantee its operation**, ultimately obtaining a tangible impact on the citizenship. The key factors are:

1. **Institutional support**.
2. Adaptation of the **Health System** to the implementation of the different tools that Personalised Medicine entails.
3. Generation, integration and interoperability of **big omics data, clinical data and data from multiple sources.**
4. Generation of **new advances** by promoting R&D&i projects and the transfer of knowledge.
5. Appropriate **financing** initiatives for their adequate development.
6. Provision of **infrastructures** for data sequencing, storage, processing and analysis.
7. **Regulatory and ethical framework** to ensure the generated data can be shared safely.
8. **Specialised training** in Personalised Medicine (incorporation of new educational programs).
9. Creation of a **collaboration network** between different institutions, both public and private.
10. To have an effective **Coordination system** able to conduct care management, scientific and technological innovation, business impulse, by synchronizing the different actions, always based on transparency and regulatory rigor, ensuring the adequate use of the resources.
11. To guarantee the right to information through an **effective dissemination process** that raises the interest of citizens, ensuring their **participation** in the development of the Personalised Medicine strategy.

2.3. SWOT

Table 3. General SWOT for the Integrated Personalised Medicine Strategy for Navarra 2020-2030.

Weaknesses	Threats
• Lack of **infrastructures and coordination** for the development of the PM in Navarra, which reduces the competitiveness of the Foral Region as a reference region in PM. • **Few Professionals and experts in PM** to implement the Strategy in the Foral Region. • Difficulty and misalignment in **stable financing** that guarantees sustainability. • Need for significant changes in the current **health system** (SNS-O) for the real implementation of the PM. • Lack of knowledge about PM among professionals and the general public, **culture of innovation**. • Lack of **business ecosystem** related to PM, which is hampered by ignorance of the opportunities offered by digital / innovative technologies to opt for new markets.	• Fragmented and insufficient **regulatory framework** for the complete development of the Strategy. • Inappropriate and outdated **training itineraries** to provide informed, trained, committed and responsible professionals with the challenges of the PM strategy. • Current uncertain **economic environment**, with a high risk of negative impact on investment in R&D&i. • **Citizen perception of the use of medical data**, there is a certain general distrust towards the use of health data in an inappropriate or fraudulent manner. • Existence of **barriers** and bottlenecks in the **technological transfer** of health innovation to the market.
Strengths	**Opportunities**

• **Institutional support**, through public policies on Health, R&D&i and economic development adopted over the last few years to the present.
• **Framework**: **Law of Science and Technology of Navarra**, for the adequate development of the different actions of the Strategy.
• **Experiences**: Extensive background in **public-private collaboration in PM** through the ***GEMA*** Challenge and calls for the development of **R&D projects**. Previous studies and analysis: **Initiative to Strengthen Competitiveness (IRC) in Health** (Sodena).
• **Instruments:**
  • Institute **IdiSNA**, accredited and consolidated: multidisciplinary and translational biomedical research space.
  • **Registry of *SINAI* agents**: public-private collaboration space.
  • Platform of infrastructures and scientific equipment for public-private use (***SIESS***).
• **Infrastructures** for sequencing, and supercomputing (Nasertic).
	• **Appropriate strategic alignment:**
	  • Regional: **Navarra 2030 Digitization Strategy**; establishment of the **Digital Innovation Pole** in the Foral Region.
	  • National: **Action Plan for Science and Innovation 2020-2021; Spanish Strategy for Science, Technology and Innovation 2021-2027.**
	  • International: Framework Program of the European Union, **Horizon Europe 2021-2027**; **Innovative Public Procurement** instruments.
	• Pioneering strategy with a competitive advantage of **positioning** at a national and international level.
	• Rapid favourable **technological development**; global commitment to disruptive digital technologies such as Big Data or Artificial Intelligence.
	• **New market niches** related to PM, which will generate industrial stability and may reach self-sufficiency.
	• **Empowerment and awareness** of the patient, who takes a more active role in their recovery and treatment.

2.4. STRATEGIC AREAS, TRANSVERSAL AXES AND COORDINATION

With this strategy, we lay the foundations for an improved healthcare based on Personalised Medicine, to progress in the area of research and innovation thanks to the potential of Personalised Medicine. Below, we describe the Strategic Areas and Transversal Axes that will be necessary for the progress of Personalised Medicine in the coming years.

STRATEGIC AREAS

HEALTHCARE AREA

According to the Agreement of the Government of Navarra, November 6, 2019, Navarra is a leading region in healthcare, with an outstanding quality public and private health system, with healthcare being a priority sector in the smart specialization strategy. The implementation of the Personalised Medicine Strategy and public-private collaboration will place us at the forefront of medicine.

R&D&I AREA

Navarra faces numerous challenges within this strategy, which can be achieved thanks to the advances by strategic industrial research and experimental development projects, which present innovative solutions to some of the challenges that society faces. The development of new technologies is possible thanks to innovation, providing the opportunity to materialize the creation of new products and services. For this, it is essential to promote the transfer of knowledge between companies and research and dissemination organisations based in Navarra.

ECONOMIC AND BUSINESS DEVELOPMENT AREA

In the area of competitiveness, a determining factor is the implementation of an economic development strategy aimed at supporting the development of the business fabric in Navarra and complementing its need to absorb knowledge to generate new innovative products and services and bring them to the market. To consolidate a promising future in the integration of Personalised Medicine in Navarra, we must focus on being catalysts of innovation, thus creating an ideal ecosystem for this purpose.

TRANSVERSAL AXES

INFRASTRUCTURES AND SYSTEMS

The implementation of the Personalised Medicine Strategy for Navarra requires an initial investment that provides specific infrastructures to be able to sequence biological samples, store the data generated, and carry out its subsequent processing and exploitation, in order to standardize and generate quality information.

EDUCATION AND TRAINING

In this strategy, it is essential to have professionals from different fields with specific skills in Personalised Medicine. It is therefore necessary to prepare the future professionals in this strategy, as well as the creation of new educational programs to achieve a new generation of informed, trained, committed and responsible health suppliers in the very near future.

REGULATIONS

The Personalised Medicine strategy for Navarra should identify the legal basis on which the necessary data processing is based. For this, it is required an adequate ethical-legal framework that guarantees processing of the data generated for differentiated purposes in a safe, efficient and easily accessible way.

COMMUNICATION AND PARTICIPATION

In this strategy, it is key to reinforce communication and dissemination of results by bringing science and innovation closer to citizens. Citizen participation in this strategy must be an essential principle, necessary to guarantee the effective exercise of the right of access to information.

COORDINATION MODULE

COORDINATION

In this kind of strategy, which brings together the efforts of many professional fields, involves multiple internal and external agents, and pursues different objectives, it is essential to dedicate a section to planning how an adequate coordination of all collaborative processes involved in the system will be carried out.

3

PURPOSE

3.1. MISSION, VISION AND VALUES

MISSION

Our mission is to promote the Integrated development of a new Personalised Medicine focused on the individual as a key element in improving and achieving a sustainable health system based on the human genome, as an argument of value for biomedical research and innovation, an as a tool to drive economic development in an environment of technological expansion that is secure, ethical and fair.

VISION

Our aim is to offer the entire population of Navarra some healthcare services that are centred on the individual, implemented through high-quality collaborative research based on the integration of large volumes of biomedical data from different multi-omic technologies. We also seek to generate a regional specialisation that, by 2030, positions the Foral Region of Navarra at the forefront of the major regions that are leaders in Personalised Medicine.

VALUES

PERSONALISED MEDICINE centred on the patient.

EMPATHY in solving the healthcare problems and interests of the population, based on evidence, sustainability and the rational use of resources.

DESIRE TO INNOVATE directed at investigative excellence, the achievement of results in terms of healthcare, social profitability, the attraction and retention of talent, and interdisciplinary cooperation and transversality.

PROTECTION, with full observance of the legislative framework, individual rights, ethical principles, citizen empowerment in the handling and administration of biomedical data.

SOLIDARITY, with equal, efficient and secure access to infrastructures for the production, processing and storage of biomedical and advanced multi-omic data.

TRANSPARENCY in the governance and distribution of resources.

COMMITMENT to an Integrated educational and training model, to guarantee the education and training of professional profiles that are flexible and adapted to the challenges of the future.

CATALYST for innovation, collective talent and entrepreneurship as promoters of economic development and generators of employment.

COOPERATION at a national and international level, in the research and generation of healthcare solutions derived from the collaborative and federated analysis of biomedical data.

3.2. STRATEGIC GOALS

HEALTHCARE

PERSONALISATION FOR ENCHANCED HEALTHCARE

Improve the quality of the healthcare service through the application of state-of-the-art technology in order to position each person at the centre of a system that is linked to scientific knowledge and sustainability.

R&D&i

RESEARCH, DEVELOPMENT AND INNOVATION FOR THE PERSONALISED MEDICINE OF THE FUTURE

To ensure that the Foral Region of Navarra becomes a región of excellence in research directed at achieving results in terms of healthcare, social rate of return, talent attraction and retaining, transversality and interdisciplinary cooperation.

EBD

LEADING THE PERSONALISED MEDICINE SECTOR

To be a leader in the advancement of Personalised Medicine thanks to the promotion and creation of a new industry in this sector, as well as in the different sector in the value chain, for the purpose of contributing to the wealth of the region and to the wellbeing of its society, serving as a role model.

4

ACTION PLAN

4.1. DESCRIPTION

The use of **Strategic Areas** and **Transversal Axes** in this document structure the Integrated Strategy for Personalised Medicine in Navarra. These Areas and these Axes are focused on improving the efficiency and quality of the Health System, as well as the positioning of research and innovation as key tools for the economic development of the region.

The proposed **Strategic Areas** are: **Healthcare, Research, Development and Innovation (R&D&i), and Economic and Business Development (EBD).** These Areas form the basis of the development of the strategy itself, which will deepen its reason for achieving its Mission and will guide its development through the fulfilment of the Strategic Objectives described in each Area with their consequent lines of action.

The **Strategic Objectives** outlined in this Integrated Personalised Medicine Strategy aim to improve and strengthen the excellence of the Health System, guaranteeing the development and regional positioning from the integration of scientific and technological knowledge. To achieve this, each Strategic Objective will have a series of **Specific Objectives** that, articulated together with the **Operational Objectives** belonging to the different Transversal Axes and their corresponding Lines of Action, will make it possible to comply with the proposed strategy.

The **Specific Objectives** in the Action Plan of the strategy will be fulfilled through the execution of a series of complementary and transversal actions included in their corresponding lines of Action.

The proposed **Transversal Axes** are: **Infrastructures and Systems, Regulations, Education and Training and Communication and Participation**. The approach of these Transversal Axes will determine the development of this Integrated Personalised Medicine Strategy, articulating in a complementary way with the Strategic Areas described above, providing the necessary resources. For this, within each Transversal Axis, a series of **Operational Objectives** will be defined which will allow us to address the fulfilment of the **Strategic Objectives** established in each Area initially described.

The approach of the different **Lines of Action**, both in the Strategic Areas and in the Transversal Axes, gives us the opportunity to guide the different **actions** to be developed in order to achieve the different proposed objectives. The success of the results achieved will be assessed through measurable **indicators**, both regarding quality and quantity.

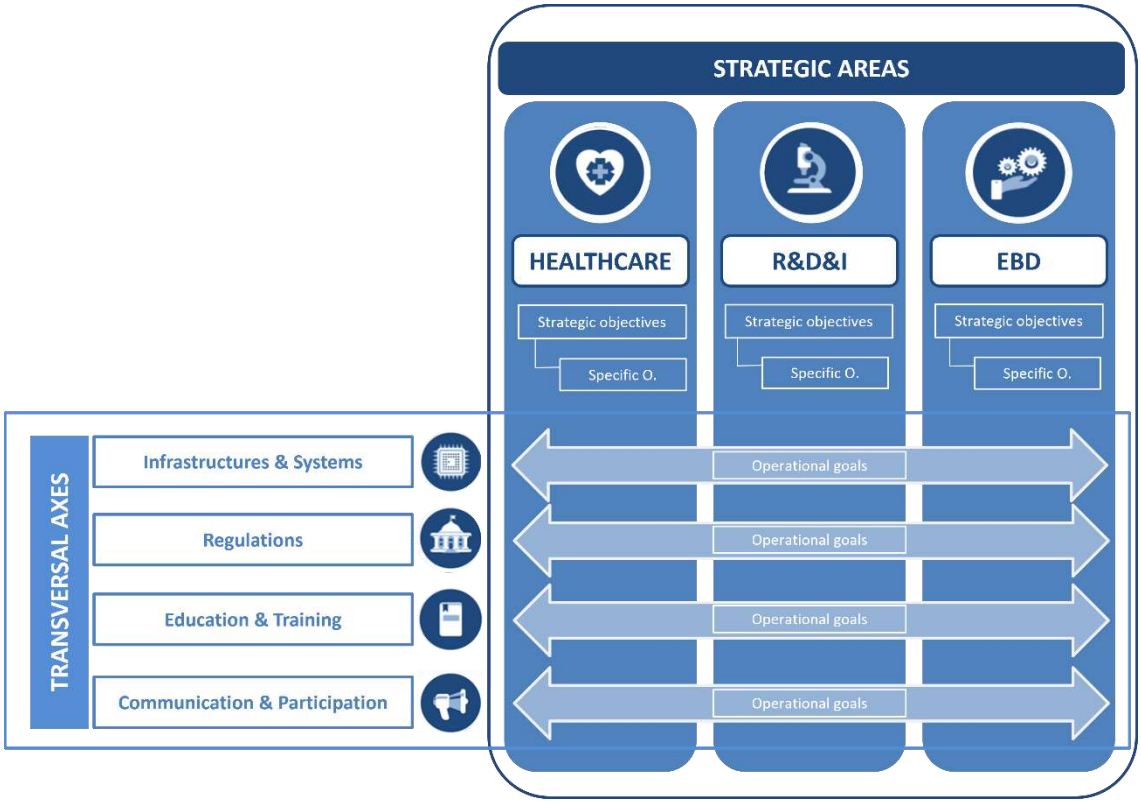


Figure 4. Diagram representing the interrelation between the Strategic Areas and the Transversal Axes and the different types of objectives of the Personalised Medicine Strategy for Navarra.

4.2. ACTION PLAN IN STRATEGIC AREAS

4.2.1. Healthcare Action Plan.
4.2.2. Research, Development and Innovation Action Plan (R&D&i).
4.2.3. Economic and Business Development Action Plan (EBD).

HEALTHCARE ACTION PLAN

4.2.1. HEALTHCARE ACTION PLAN

FACT SHEET

AREA OF HEALTHCARE PERSONALISATION FOR ENHANCED HEALTHCARE

Enhance the quality of the healthcare service through the application of state-of-the-art technology in order to place the individual at the centre of a system that is linked to scientific knowledge and to sustainability.

Specific Objectives		Lines of Action	
H.SO1	Adapt the Planning of the Healthcare Strategy	H.LA1	Connection with the Planning of the Healthcare Strategy
H.SO2	Strengthen Genomic Medicine	H.LA2	Coordination and strengthening capacities genomic services in SNS-O
H.SO3	Integration and interoperability of big data	H.LA3	Enhanced healthcare service based on integration of big data in SNS-O
H.SO4	Management of Knowledge and Sustainability	H.LA4	Management of Knowledge and Sustainability.

OPERATIONAL LINES OF ACTION INVOLVED IN THE HEALTHCARE AREA

Transversal Axes	Lines of Action	
Infrastructures and Systems	IS.LA1	Infrastructures
	IS.LA2	Systems
	IS.LA3	Data platforms
Regulations	R.LA1	Data Processing Plan (DPP)
	R.LA2	Regulatory Framework Revision
	R.LA3	Monitoring Committee
Education and Training	ET.LA1	Training Map
	ET.LA2	Undergraduate Education
	ET.LA3	Experts in Health Sciences
	ET.LA4	Postgraduate Education
	ET.LA5	Continuing Education
	ET.LA6	Vocational Education
Communication and Participation	CP.LA1	Cohesion and Alignment of Expectations
	CP.LA3	Public Awareness

INTRODUCTION

The **Healthcare Plan for Navarra 2014-2020**, approved by the Health Commission of the Parliament of Navarra within the framework of the Foral Health Law modified in 2002, sets the priorities for health intervention and defines the objectives and programs necessary to improve health outcomes in the region, establishing as general values and principles a new health care model based on patient focus, integrated quality (technical quality, perceived quality, and social efficiency), clinical practice based on data, and commitment to the sustainability of the system.

In this regard, the Integrated Personalised Medicine Strategy for Navarra proposes a way to **focus on a medical practice that places the individual at the centre of a healthcare service that is linked to scientific knowledge and to sustainability**. This approach is based on the new individualisation capacities offered by genomics and other biomedical sciences, and on the possibilities of integrating this type of complex biological information with clinical, environmental and lifestyle data for the purpose of tailoring prevention strategies, diagnosis, treatment or prognosis of the state of health and illness to each specific patient.

This approach seeks to **enhance the quality of healthcare by applying state-of-the-art technology and processes.** The two main technological pillars that support this cycle are genomics and data integration that, in addition to introducing a current improvement in care, they also provide the basis for the development of new knowledge and processes aimed at optimizing the adequacy of health services that are evolving towards sustainability, contributing to a healthcare system of greater efficiency and quality in which people are at the centre of healthcare, and are both the beginning and the final destination of the entire process.

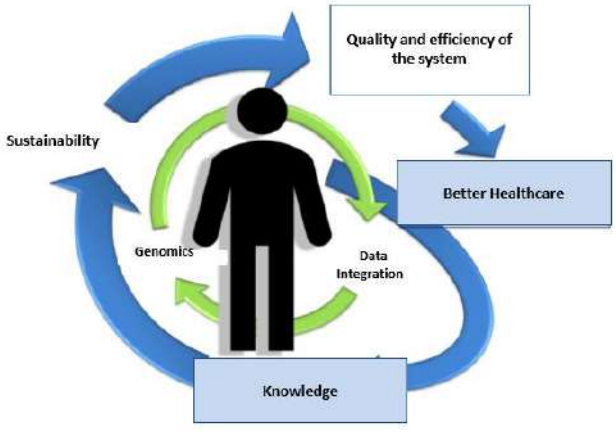


Figure 5. Personalised Health Medicine cycle.

Sources:

1. Health Plan in Navarra 2014-2020. http://www.navarra.es/home_es/Temas/Portal+de+la+Salud/Ciudadania/Nuevo+Modelo+asistencial/Plan+Salud+Navarra/Plan+de+Salud+de+Navarra+2014-2020.htm
2. Walking for Health. http://www.navarra.es/home_es/Temas/Portal+de+la+Salud/Ciudadania/Nuevo+Modelo+asistencial/Caminando/

HEALTHCARE ACTION PLAN SWOT

This SWOT analysis is a synthesis of the strengths and opportunities, weaknesses and threats, identified in the health system in Navarra regarding Personalised Medicine and in the ecosystem in which it operates. The analysis has been specifically oriented to the objectives pursued by the Personalised Medicine Strategy in general and referring to the health area in particular.

Regarding the health system itself, a **lack of knowledge and lack of training of professionals for Personalised Medicine** is immediately detected. In reference to the capacity of the public system to generate genomic results and integrate them with other biomedical variables, **a significant deficit and high work overload of specialised professionals** is observed, which is difficult to solve within the extremely rigid framework in which human resources policy operates in the public system. This weakness is, to a certain extent, contributed by the existence in the ***SNS-O*** of solid and solvent **health information systems**, but highly saturated by healthcare priorities, and a centralized **Genetics Service** with a long track record that coexists with the intervention of an increasing number of physicians from other services with progressive genomic results management capacity, although actions between these actors are highly uncoordinated and often inefficient. In addition, **new protocols and functionalities** such as the study of the **whole genome** and the **methodology of data science** must be incorporated into this environment in the coming years, which will exponentially increase the demand for benefits, while multiplying needs and challenging existing capabilities.

In reference to other matters, the existence of **important pioneering successful local pilot experiences** is noteworthy, both in the clinical use of genomics, as well as in the integration of multiple-source medical data, and projects to support the market arrival of healthcare innovation, favoured by **a rich ecosystem of biomedical research that is very active in the area**, although it is necessary to adequately consolidate and enhance these experiences to ensure that their benefits finally reach the patients. In this sense, there is no doubt that having **adequate infrastructure and development plans for sequencing and supercomputing in our environment is an essential support**. On the other hand, it should be noted that there is a **very well-positioned private participation** in the sector, although here it should be mentioned that **a closer and two-way public-private collaboration is missed.**

On an external level, Personalised Medicine **can** sometimes **be** perceived as something expensive and with long-term results that are far from the objectives maintained by health managers, more usually conditioned by immediacy and healthcare pressure. However, the **evidence of the benefits that Personalised Medicine** can bring to the individual **is overwhelming**, and the **support** and enormous **expectations** that professionals and patients

have placed in these initiatives, nor the **investment of unprecedented** resources that this new area is producing both nationally and internationally cannot be ignored. The main arguments of this analysis are summarized below:

Table 4. Healthcare Action Plan SWOT.

Weaknesses	Threats
• Little training and lack of knowledge by professionals. • Heterogeneous, uncoordinated and inefficient genomic test management circuits in SNS-O (corporatism among specialized areas). • Data projects in a public system with limited availability. • Burnout of specialised professionals. • HR strategy in SNS-O and public function too rigid for the new profiles. • Difficulty in the translation of Innovation to Implementation. • Limited budget allocation. • Misalignment of Personalised Medicine and the Health Plan and the Osasunbidea Walk for Health Strategy.	• Reluctance of professionals to the change from common practice. • Concern from health managers about the increase in costs of new services. • Care pressure and 'short-term' results as a priority in health. • Deficit of available professional experts in Personalised Medicine (genomics and biodata sciences). • Lack of medical specialisation in clinical genetics in Spain. • Social distrust due to possible fraudulent use of medical data. • Cost derived from technical and human resources associated with data processing techniques.
Strengths	**Opportunities**
• Genetics and Doctors Service in SNS-O services with the capacity to manage reference and specialized genomic results. • Well positioned private participation in the sector. • Solvent and consolidated SNS-O Health Information System. • Very active biomedical research ecosystem in Personalised Medicine (Navarrabiomed, CIMA). • Successful pilot experiences: supporting innovation in digital health (example InDemand); data integration tools (BARDENA); R&D&i Personalised Medicine (NAGEN Program, other projects).	• Social awareness and support from patients and professionals to develop Personalised Medicine. • New local infrastructures: High-capacity sequencing (public and private), Spanish Supercomputing Network in Navarra: RES (Nasertic); Navarra Digital Innovation Pole Campus (IRIS); Health Campus around Hospitals. • Forecast of great projection and development of Health associated with Personalised Medicine.

SPECIFIC OBJECTIVES OF THE HEALTHCARE AREA (H.SO)

H.SO1. Adaptation of the planning of the Health Strategy: modifying the planning of the Health system to accommodate personalised medicine.

H.SO2. Strengthening Genomic Medicine: Strengthening and coordinating the generation and management capacities of genomic services in the SNS-O.

H.SO3. Data integration and interoperability: Creation and maintenance of a system for the collection, integration and analysis of genomic and health data aimed at improving the health of each individual patient, and interoperable with other systems for secondary uses.

H.SO4. Knowledge Management and Sustainability: Lead and guarantee that innovative projects in Personalised Medicine reach the patient for real and that provide true added value to clinical activity.

ACTION PROPOSAL

According to the statement of objectives and the result of the SWOT analysis, this action plan is focused on the one hand, on strengthening the two main pillars that support the knowledge base of this proposal: **the strengthening of capacities** and **coordination to carry out genomic analyses** in an efficient and equitable way, and the **enhancement of the processes necessary for the integration and safe use of large biomedical data** with health objectives. In addition, it is intended to **provide new solutions for knowledge management** to overcome the existing gaps in the innovation and implementation process, as a way to strengthen the efficiency of the system and contribute to its sustainability. Some of the key elements of this action plan are:

Genomics Plan of the Health Service in Navarra

Genomics is a science capable of generating results with extraordinary potential to individualize the management of people's health and disease. Some of the most spectacular clinical applications of this science are now a reality, and have good examples, such as its proven ability to improve diagnosis and guide management of rare diseases; risk prediction that allows personalised prevention programs in healthy population; or the possibilities of optimizing the use of drugs based on the genetic profile, avoiding toxicities and adverse effects. But undoubtedly many other developments are yet to come, which also increases its value in the design of new health projects. Given the latest technological advances, based on adequate infrastructures for sequencing, bioinformatics analysis and supercomputing, it is now possible to propose health care based on the integration of genomics with other biomedical data.

Programs such as Kardiokompassi®, which integrates genetic predictors of cardiovascular risk, traditional clinical determinants, and lifestyle markers, through guiding algorithms developed

through data science and artificial intelligence tools, are already improving the prevention of cardiovascular diseases in countries like Finland.

Professionals from the Health Service in Navarra have been using genomic tests for different health services in recent decades, mostly centralised in the Genetics Service, although there are doctors in other Services who are specializing in the clinical management of some genomic results. However, unfortunately, there is no common census of benefits and services in the system, uniformity in the circuits, ordering of the profiles and roles of the professionals involved, protocols, standardized criteria for referral to external centres, or standardization and parameterization of results for its exploitation in EHR, which gives rise to duplication of actions, saturation of services, and deficiencies in the clinical management of results, which seriously affect the efficiency of the system and make it impossible to consider the development of a Personalised Medicine strategy in health in the coming years without undertaking an adaptation of this service. Therefore, the set of measures necessary for this **restructuring could be articulated in a single and coordinated plan**, which should address a series of priority tasks to build the basis of the strategy. These tasks include:

Elements for the SNS-O Genomics Plan:

- Service Portfolio Configuration.
- Organisation of professional profiles.
- Accreditation and training of professionals.
- Multidisciplinary resource management committee.
- Registry of protocols, circuits and clinical pathways.
- Integration and optimization of results and service management in HCE.
- Standardization of referral criteria.
- Assessment Tools.

Adaptation and Reinforcement of the SNS-O Results Evaluation Strategy

Advances in services based on data processing are transforming medical practice and will undoubtedly influence its development in the coming years. The **methodologies of data science**, articulated around big data, deep learning, or artificial intelligence, will be able to **provide tools to support medical decisions**, incorporating the interpretation of biomedical data of complexity and size unattainable for the human being to that of other health data of a different source and structure. This unstoppable process is determining that sciences such as genomics, with their enormous capacity to produce individualization data, are penetrating strongly into clinical practice. In this context, **electronic medical records (EHRs)** are becoming an essential tool that not only collects and records all the results and data of the process that can be later analysed, but can also provide decision support and online guidance to the professional through applications and support algorithms. The adaptation of the EHR to this new reality, of which interconnected elements such as medical monitors, personal devices that record biometric and lifestyle information, or movement trackers are also part, represents an unavoidable challenge

for all advanced health services. It also represents a never-ending source of material for research and acquisition of new knowledge.

For some years now, an analysis base has been developed in the SNS-O that can facilitate the integration of results in Personalised Medicine called **BARDENA (Base Analysis of Results of Navarra)**. The main objective of this base is to improve the work of professionals, assessing their performance, and facilitating work by processes, as well as collaborating in research and innovation. At the moment, this strategy is mainly oriented to actions and detection of problems, predictive analysis of trends, generation of indicators for the micro management of those responsible for Service, and for the macro-strategy of the senior management of the SNS-O. However, this approach is currently further away from the expectations of improving the practices of health professionals and researchers, surely conditioned by the saturation and shortage of qualified professionals, who are in high demand and with very high learning curves. At the moment BARDENA **integrates data from different health ecosystems** (primary care, hospital specialties, data on drug consumption, hospital admissions, emergency services, as well as data from diagnostic tests, inter consultations and pharmacological alerts since 2012), but it does not collect genomic or drug data or other omics, or data from external sources. In this context, it is necessary to establish a reinforcement and evolutionary reorientation plan of these results evaluation processes that includes accelerating the standardization of the coding and parameterization systems of biomedical data, facilitating the integration of omic results in EHR, generalizing access to data mining procedures and systematic evaluation of results, protocolize the development and implementation of AI tools to support clinical decisions. Also, the integration of data from diverse sources at different levels, as well as working together in the interoperability of the system to give support for secondary data use tasks described in other parts of this Strategy.

Delegated unit for acceleration of the implementation of innovation in Personalised Medicine in the SNS-O

Health systems need to incorporate those activities or innovative ideas diligently and safely with the capacity to improve health care, of which Personalised Medicine is a paradigm. However, this is a complex process that requires a meticulous and systematic approach, which must guarantee that clinical activity generates provide true added value. Furthermore, in areas where changes happen at such a dizzying speed as those in Personalised Medicine, this process must take place at a measured pace so as not to relegate the system to an outdated medical practice.

Health R&D&i occurs in a series of stages that lead from basic research and the preclinical prototype to its assessment, introduction, extension and use in the health system (market). In these stages, two large translational gaps are usually marked.

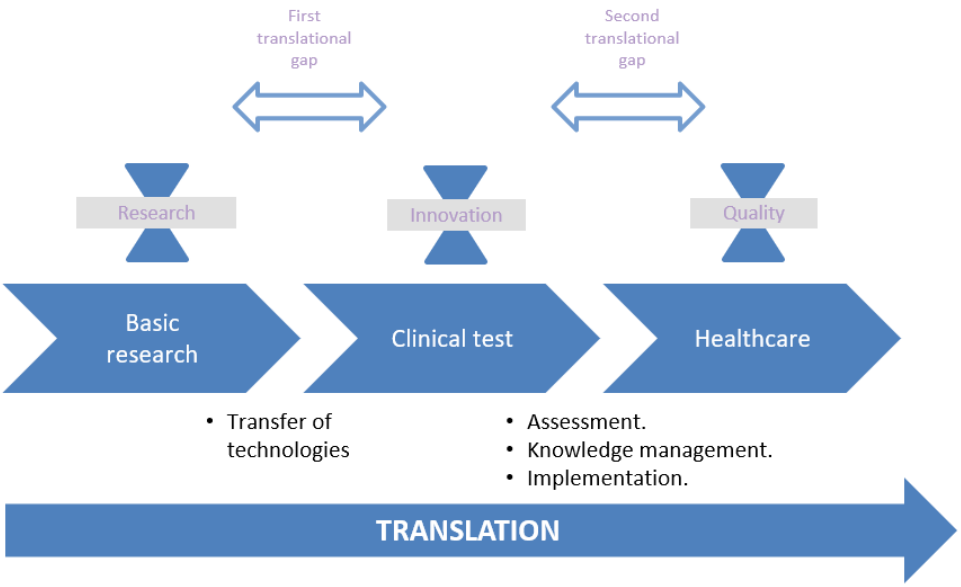


Figure 6. Translational process in Healthcare.

Although the gap between basic research and initial clinical results is usually supported by R&D technology transfer protocols that structure the path to overcome the second gap, the one that occurs between the first clinics test results and health care delivery, the innovative proposal can fail in a jungle of regulatory complexities, difficult access to data and systems, lack of knowledge and expert support, funding shortfalls, and lack of guidance through health assessment tools that guarantee the value of innovation (Health Needs Assessment (HNA); Health Technology Assessment (HTA); Health Impact Assessment (HIA)). To overcome these difficulties, some systems have provided specific Support Units for Knowledge Management and implementation. In Navarra, examples of proposals in this sense, such as that of the **inDemand** project, whose goal is to develop a new model in which health organisations and companies create digital health solutions, has been positively welcomed among the professionals of the Health System in Navarra.

For the final achievement of some of its objectives, the Personalised Medicine strategy of Navarra requires an accelerating entity, represented by a **reference Unit for integrated support for the implementation of Personalised Medicine**, which ensures that R&D projects, with good initial results in data and knowledge production are correctly assessed and introduced into our health system to improve the health care for which they were conceived, thus helping to improve the efficiency of the system and ensure its sustainability. This Unit should have the capacity to efficiently bring together the coordination of clinical implementation processes, being accessible to all professionals in the system that are potential generators of ideas, facilitating the administrative management of innovation projects, informing about the previous procedures and tools of access to data, advising on the identification of partners and facilitating technological solutions, adapting access to a test-bed environment (living-lab) for projects, guaranteeing follow-up through an effective health technology evaluation cycle, and providing an adequate support for final implementation by health information systems.

These three key actions are complemented by another series of specific measures in the health area, as summarized in the following table, and benefit from other action proposals that are mentioned in the transversal axes of the strategy.

Source:
Indemand. https://www.indemandhealth.eu/

Specific Objectives		Lines of Action		Actions	Suggested indicators
H.SO1	**Adapt the Healthcare Strategy Planning**	**H.LA1**	**Connection with the Healthcare Strategy Planning**	• Include specific PM objectives in Healthcare Strategies. • Coordinate and promote public-private cooperation in PM health actions.	• Number of PM objectives in the Healthcare Plan. • Number of PM objectives in the SNS Plan.
H.SO2	**Strengthen Genomic Medicine**	**H.LA2**	**Coordination and reinforcement of the genomic services capacities in SNS-O**	• Establishing a new genomics plan for the SNS-O o Define and coordinate the provision of genomic services in SNS-O. o Sort the Professional Profiles involved in SNS-O. o Protocolize genomic analysis in SNS-O. o Design the integratyion of genomic data in EHR. • Adapt HR policy to the reality of specialisation and new profiles in PM.	• Genomic plan: 1 • Specialisation and training: Consultant Clinical Geneticist; Genommic Laboratory Specialist; Operational Specialist with training. • New professional profiles: Genetic Counselor; BioIT.

TABLE 5. HEALTHCARE ACTION PLAN SUMMARY

Specific Objectives		Lines of Action		Actions	Suggested indicators

H.SO3	**Big data integration and interoperability**	**H.SO3**	**Enhanced healthcare based on big data integration into SNS-O**	• Reinforce and redirect the SNS-O Results Evaluation Strategy
				  ○ Standardise coding and parametrisation systems for biomedical data and integration of omic results in EHR.
				  ○ Generalise access to tools for the systematic assessment of clinical results.
				  ○ Implement AI clinical decision support tools available in EHR.
				  ○ Implement data interoperability systems from different sources: research repositories, portable devices, applications, social networks, questionnaires.
					• > 50% encoded entries.
					• Access to assessment tools granted to all doctors.
					• >50 New tools to support clinical decisions.
					• Health data interoperability environment; biosensors and trackers, portable devices; questionnaires; research repositories.

Specific Objectives		Lines of Action		Actions	Suggested indicators

H.SO4	**Knowledge Management and Sustainability**	**H.LA4**	**Knowledge Management and Sustainability**	• Appoint and equip a delegated unit to develop and accelerate PM.
				  ○ Administrative management of PM projects.
				  ○ Advice on procedures and data access.
				  ○ Identification of partners-technological solutions.
				  ○ Streamline the health technology assessment cycle (HTA, HNA, HIA).
				  ○ Implementation support in SIS.
				• Development of Living-lab environment and test bench for PM projects.
				• Reinforce agreements between academic research and clinical application.
				• Promote professional intensification programme in PM.
				• Assess cost-effectiveness and impact of PM procedures in SNS-O..
				• Guarantee availability of biomedical data for other secondary uses defined in the Strategy.
					• Delegated unit: 1
					• Living-lab: 1.
					• Sustainability and impact report: 1
					• Bilateral agreements: >2.
					• PM professional intensification: 2

R&D&I

ACTION PLAN

(RESEARCH, DEVELOPMENT & INNOVATION)

4.2.2. Research, Development & Innovation Action Plan (R&D&i)

FACT SHEET

R&D&i Area: Research, Development & Innovation for the Personalised Medicine of the Future

Position the Foral Region of Navarra as a research excellence region aimed at achieving results in terms of healthcare, social profitability, the attraction and retaining of talent, as well as cross-sectoral and interdisciplinary cooperation.

Specific Objectives		Lines of Action	
RDI.SO1	Promote R&D&i Projects	RDI.LA1	Stable R&D&i funding in the long run.
		RDI.LA2	Innovation as a driver of change.
RDI.SO2	Support the R&D&i Community	RDI.LA4	Creation of support and advisory units.
RDI.SO3	Assess and Monitor	RDI.LA2	Innovation as a driver of change.
		RDI.LA4	Creation of support and advisory units.
RDI.SO4	Enlarge the R&D&i Community	RDI.LA1	Stable R&D&i funding in the long run.
		RDI.LA2	Innovation as a driver of change.
		RDI.LA3	Attraction, return, and retaining of talent.
		RDI.LA4	Creation of support and advisory units.
RDI.SO5	Promote Multidisciplinary Profiles	RDI.LA3	Attraction, return, and retaining of talent.
		RDI.LA4	Creation of support and advisory units.
RDI.SO6	Give greater visibility to R&D&i in Navarra at an international level	RDI.LA5	Strategic alliances.
		RDI.LA6	Internationalisation.

Operational Lines of Action in R&D&i:

Transversal Axes	Lines of Action	
Infrastructures and Systems	IS.LA1	Infrastructures
	IS.LA2	Systems
	IS.LA3	Data Platforms
Regulations	R.LA1	Data Processing Plan (DPP)
	R.LA2	Regulatory Framework Revision
	R.LA3	Monitoring Committee
Education and Training	ET.LA1	Training Map
	ET.LA2	Undergraduate Education
	ET.LA4	Postgraduate Education
	ET.LA5	Continuing Education
	ET.LA6	Vocational Education
Communication and Participation	CP.LA1	Cohesion and Alignment of Expectations
	CP.LA3	Public Awareness

INTRODUCTION

R&D&i for Personalised Precision Medicine in the Foral Region of Navarra

For several decades now, the Foral Region of Navarra has considered **research and innovation to be essential drivers for growth** in the region. Investment in research, development, and innovation has increased over the years, thereby showing an unmistakably clear **commitment to society**, in order to achieve a significant improvement in well-being and quality of life.

Accumulated previous experience has made it possible to set the ground for current research and innovation in the region. More precisely, both the **Smart Specialization Strategy 2016-2030**, as well as the **Science Technology and Innovation Plan 2017-2020 for Navarra** have been defined, which point to the healthcare area as a strategic priority, and, **Personalised Medicine within it, as a fundamental line of development**.

As is the case in its peer European regions, Personalised Medicine is an emerging, continuously developing sector that is attracting a great deal of interest in the Foral Region due to its impact on citizens, not only with regard to the patient's health but also in terms of sustainability and improvement of healthcare systems. This is an **internationally oriented sector** that draws directly from **R&D&i**, and in which **public-private collaboration** becomes essential. In addition, it requires a **sound collaborative biomedical ecosystem** in order to empower its development, as well as the **cross-cutting nature of the support policies and tools** for its implementation.

In this regard, Navarra enjoys a privileged healthcare ecosystem, inasmuch as it is considered a landmark nationwide. A key integrating agent is the Institute for Healthcare Research of Navarra, **IdiSNA**, which is the only entity in Navarra that comprises all the public and private biomedical research institutions in the region. It is a **multidisciplinary and translational biomedical inquiry-oriented space in basic, clinical, epidemiological, and health services research**.

In addition, this ecosystem is brought to completion by the various executing agents of the **Navarra Innovation System** (SINAI) that are related to the health area, namely: the Centre for Applied Medical Research (CIMA), the Navarrabiomed Biomedical Research Centre, the University of Navarra (UNAV) and the Public University of Navarra (UPNA). Moreover, Navarra has two leading hospitals in health care, such as the Clínica Universidad de Navarra (CUN) and the Hospital Complex of Navarra (CHN), which facilitate the transference and implementation of findings in Personalised Medicine R&D&i into clinical practice. Finally, the ADItech Corporation, an entity aimed at fostering and invigorating the mutual relationship between science, technology, and business in Navarra, is in charge of the regional coordination of the aforementioned agents.

It should be noted that the main areas of research within SINAI include, among others, oncology and haematology, cardiovascular and kidney diseases, neurodegenerative diseases, or psychiatric diseases, with an eye toward developing new predictive biomarkers, be it diagnostic or prognostic, as well as developing innovative therapies.

R&D&i in Navarra has been advanced through various regional instruments, including **strategic R&D projects** linked to the **GEMA Challenge** (Genomics and Advanced Medicine) and several calls for proposals of **individual and collaborative projects**. As a result of these initiatives, sundry cases of international success came to light, such as the **NAGEN 1000** project (Genome 1000 Navarra Project), the **PharmaNAGEN** project (implementation of methodologies and procedures so that genomic information may be used as a clinical decision-making tool in the pharmacological prescription of the Health Service of Navarra) and the **DIANA** project (next-generation sequencing technology aimed at diagnosis and treatment efficiency optimisation in patients with high-mortality tumours).

With this background, the Foral Region of Navarra comes out as an innovative region and as a pioneer nationwide in the development of a Personalised Medicine Strategy with a clear commitment to an R&D&i-based drive.

R&D&i in Personalised Medicine in the national and international context

The current situation brought about by the COVID-19 pandemic has accelerated the design and launch of action plans and lines of investment in research, development, and innovation at the national and international level that have a direct impact on different aspects needed for the development of Personalised Medicine in Navarra. In this sense, on July 14, 2020, the Government of Spain passed the **Action Plan for Science and Innovation**, in which more than 77 million euros were allocated to the Spanish Strategy for Personalised Medicine.

The main goal of the Spanish Strategy for Personalised Medicine is to improve the capacities of the National Health System and, therefore, the health of the population, as well as to contribute to advancing the country's economic competitiveness, using scientific knowledge and innovation as a vector. Launched in the second semester of 2020, the strategy comprises actions between 2020 and 2021 that have been actualised in the following plans: **Big-Data Health Plan**; **Genomic Medicine Plan**; **Advanced and Personalised Therapies Plan**; **Predictive Medicine Plan**; **Precision Medicine Training Plan**; and Spain positioning in the Personalised Medicine European context.

More than a decade ago, Personalised Medicine was identified as one of the most promising areas of research and healthcare in Europe, in such a way that coordination of international efforts at different levels was considered key for its implementation. To this end, different European networks and partnerships were created, among which the **European Alliance for Personalised Medicine** (EAPM) and **ICPerMed** stand out. The main objective of both networks is to define the European priorities in Personalised Medicine, the policies that govern its development and the concrete actions to be implemented in order to position the European Union as an international benchmark in Personalised Medicine.

The objectives and lines of action described in the Integrated Personalised Medicine Strategy for Navarra 2020-2030 are aligned and cohere with what has been described above. All this shows an optimal moment for the development and promotion of Personalised Medicine in the Foral Region.

Source:

1. Smart Specialisation Strategy for Navarra 2016-2030
2. Science, Technology, and Innovation Plan 2017-2020
3. Action Plan for Science and Innovation

RESEARCH, DEVELOPMENT & INNOVATION (R&D&i) ACTION PLAN SWOT

Table 6. R&D&i Action Plan SWOT

Weaknesses	Threats
• Lack of knowledge about PM R&D&I actions and programmes already implemented in Navarra. • Unawareness of research and/or functions of other regional entities involved in PM. • Absence of specific PM actions (specialisation) instead of Health as a general area. • There is no visible single entity (one-stop-shop) in PM to contact. • Difficulty attracting talent with the current supply (short-term projects, lack of support for researchers, etc.)	• Potential duplication of actions and associated costs. • Broadening focus on general health might disperse implementation of R&D&I strategies. • Dispersed coordination and delays in start-up due to lack of clear leadership. • Short-term research tied to annual or biannual regional funding, rather than long-term robust research. • Postdoctoral brain drain due to incapacity of researchers to find project consolidation in the region after PhD and/or postdoc in Navarra.
Strengths	**Opportunities**
• Internationally recognised entities specialised in PM (CIMA, Navarrabiomed, CUN, UNAV). • Existence of IdiSNA, an umbrella entity for biomedical agents in the region; possible coordinating centre for PM. • Internationally recognised researchers in PM. • EU networks membership, which provides great visibility and successful networking. • Law of Science, Technology, and Innovation, S3 and different regulations that guide and foster the promotion of Personalised Medicine. • Regional funding for PM, as well as specific doctoral programmes. • Presence of leading ERC researchers in several health areas. • Existence of European Project Offices with long-term experienced professionals in the different biomedical centres. • Launch of the Massive Sequencing Centre in Navarra.	• Positioning opportunities as a European benchmark region in PM R&D&I. • Potential setting up of a unit fully adapted to regional PM R&D&I needs in IdiSNA. • Pioneering programmes and actions at the national/international level (solid positioning of Navarra as a leader in PM R&D&I). • Novel supply at a European level capable of attracting postdoctoral talent. • Coincidence with the launch of the new EU framework program, Horizon Europe 2021-2027, in which the budget for PM has been increased. • Creation and reorganisation of new European networks and partnerships in PM, which opens up the possibility for new regions to take part in Horizon Europe. • Launch of the National Personalised Medicine Plan, wherein different funding programmes for PM projects are established. • European Digital Innovation Hub Navarra as a boost tool for PM.

R&D&i SPECIFIC OBJECTIVES (RDI.SO)

RDI.SO1. Promote R&D&i Projects: Increase the number and participation of research and/or innovation projects (regional, national and international) related to Personalised Medicine.

RDI.SO2. Support the R&D&i Community: Enhance support received by the community of researchers and innovators specialized in Personalised Medicine, both at a methodological-technical level and at an administrative level.

RDI.SO3. Assess and Monitor: Develop evaluative and monitoring processes of research and innovation, adapted to each type of research/innovation and to the translational approach in Personalised Medicine, directed at the needs of the health system.

RDI.SO4. Enlarge the R&D&i Community: Increase the number of researchers and research groups specialized in Personalised Medicine carrying out their lines of research in Navarra.

RDI.SO5. Promote Multidisciplinary Profiles: Promote cross-disciplinary research profiles that integrate available experience in health, engineering, biomedical sciences, social and environmental sciences, and data science, within institutes and universities.

RDI.SO6. Give greater visibility to R&D&i in Navarra at an international level: Give greater visibility to R&D&i in Navarra at an international level to achieve an exchange of knowledge and talent that increases the quality of research and innovations carried out in the Foral Region.

ACTION PROPOSAL

Based on the specific objectives laid down and the strategic analysis carried out for the R&D&i area of the Integrated Personalised Medicine Strategy, six lines of action are thereby proposed as cornerstones for promoting research and innovation in the Foral Region of Navarra: stable and long-term funding; attraction, retention and return of specialized talent; strategic alliances; creation of support and advisory units; and internationalisation. They are detailed below:

<u>Stable R&D&i funding in the long run</u>

Excellence in research and innovation demands a process of ideation, development, validation and implementation in which all the value-chain actors play an essential role, from the main researchers of the project to the work team, research group and entities where the activity is carried out. By and large, in order to successfully complete one or more phases of this process, it is necessary to obtain funding that allows maintaining material and personal resources until the expected results are achieved.

Therefore, this Action Plan envisages the creation of programmes and actions aimed at stable and long-term funding, suggesting an optimal time horizon of 10 years. First and foremost, a selection of strategic lines in Personalised Medicine for Navarra should be taken into account and, once the funding is granted, an exhaustive assessment of the objectives and outcomes achieved on an annual basis would be carried out. In addition, several actions aimed at

expanding the budget, analysing and updating existing programmes focused on Personalised Medicine R&D&i are defined (eg, strategic R&D projects).

Innovation as a driver of change

Innovation is characterised by new or improved products or processes (or a combination of both) that differs significantly from former products or processes. In order for Personalised Medicine to innovate, it is imperative that thorough research processes have taken place beforehand.

Thus, in order to promote innovation in Personalised Medicine, two main types of actions are fundamentally contemplated. On the one hand, the creation of funding programmes and innovation support units, suited for the health area and, more specifically, for Personalised Medicine. On the other hand, actions directed at dissemination and encouragement for new innovators are necessary (innovation meetings and symposia, awards, etc.). Currently, the European Business and Innovation Centre of Navarra (CEIN) has different programmes and actions aimed at promoting innovation in the strategic areas of S3. With the development of this Action Plan, it is intended to expand this activity with the launch of actions focused on Personalised Medicine.

Attraction, return, and retaining of talent

One of the main obstacles that the Foral Region must face is the lack of research and innovation staff specifically trained in the different aspects related to Personalised Medicine (bio-IT specialists, geneticists, sequencing technicians, genomics-specialised doctors, etc.). International supply is more attractive for most Personalised Medicine professionals, what leads to a loss of research staff from Navarra, as well as a great difficulty in attracting talent from abroad. In this sense, an exhaustive analysis of regional needs should be carried out in order to achieve the objectives set out in this Strategy. Furthermore, an attractive and competitive offer, comparable to those proposed in the European counterpart regions, should be presented. To this end, three programmes are defined: attraction, return and retaining of talent.

Creation of support and advisory units

R&D&i activities require administrative support that facilitates the work of people involved in research and innovation. Furthermore, SINAI's needs are continually evolving and it is advisable to identify specific regional entities that can offer advice and support to the different agents concerned.

The creation of IdiSNA has made it possible to reorganize the biomedical research system in Navarra, thus offering a common ground for different professionals implied in medical research. To address the future needs of this strategy, it is necessary to **commission people in charge of R&D&i support and management**. For this purpose, the creation of advisory and support units within existing regional entities and the definition of the specific tasks to be addressed by each of them is proposed.

Strategic alliances

Strategic alliances —i.e., the establishment of **specific conventions and agreements with benchmark regions** in the area— are proposed in order to promote national and international collaborations in Personalised Medicine. These collaborations are thus intended to facilitate the exchange of knowledge, the flow of professionals, the attraction of talent, etc.

As a starting point, action will be intensified in those PM European networks and partnerships in which Navarra is already an active member (ICPerMed, ERRIN, EUREGHA, etc.). Likewise, new networks shall be defined according to the next European Union Framework Program, Horizon Europe.

Internationalisation

The Foral Law of Science and Technology envisages measures to favour **synergistic forces with other European research and innovation programmes**. In addition, it contemplates policies to promote openness and **collaboration for agents in Navarra with other agents of the European Union**, in order to enhance cooperation, as well as value-chain creation based on smart specialization strategies. It is essential for Navarra to actively participate in international R&D&i actions, projects and initiatives for several reasons; the priorities being to be informed and up-to-date on the most relevant policies and initiatives, establish contacts with relevant stakeholders and, above all, position Navarra in the international context.

In this sense, internationalisation in Personalised Medicine is addressed through the following actions: a programme to help internationalisation; the active participation of Navarra's agents in European Personalised Medicine networks and partnerships; the establishment of a Working Group composed by experts in Personalised Medicine international projects; the creation of its own Certificate in European Projects Management; the promotion of success stories in the internationalisation of Personalised Medicine R&D&I; and the organization of regional visits by expert committees and international delegations.

These lines of action are supplemented by a series of specific measures in the R&D&i area as summarized in the table below. They benefit from other action proposals that are cited in the transversal axes of the strategy:

Source:

1. Foral Law of Science and Technology (15/2018). https://www.boe.es/buscar/pdf/2018/BOE-A-2018-10582-consolidado.pdf
2. IC PerMed. https://www.icpermed.eu/
3. ERRIN. https://errin.eu/
4. EUREGHA. http://www.euregha.net/

TABLE 7. R&D&I ACTION PLAN SUMMARY

Specific Objectives		Lines of Action		Actions	Suggested indicators
RDI.SO1	**Promote R&D&i Projects**	**RDI.LA1**	**STABLE R&D&I FUNDING IN THE LONG RUN**	• Creation of a **new funding program for the development of long-term PM research lines** (10 years). For this, it is proposed: o Identification of 5-10 preferential specific lines of research in the field of PM for Navarra. A Working Group of experts will carry out the analysis and selection of these lines (for more details see Internationalisation - Creation of a Working Group). o Ongoing research progress will be reviewed on an annual basis to assess the achievement of expected results or, failing that, the fulfilment of previously developed contingency plans in order to warrant progress. o The program will encourage short-term stays in prestigious international entities (3-6 months), attendance to scientific conferences and first-rate scientific production.	• Number of applications submitted for approval in each line of research. • Number of scientific publications in high impact journals.
RDI.SO2	**Support the R&D&i Community**				
RDI.SO3	**Assess and monitor**				
RDI.SO4	**Enlarge the R&D&i Community**				
RDI.SO5	**Promote Multidisciplinary Profiles**				
RDI.SO6	**Give greater visibility to R&D&i in Navarra at an international level**			• Analysis and **updating of the call for grants for Strategic R&D Projects** to achieve stable financing for a 5-year period. As mentioned before, intermediate evaluations are proposed to assess progress according to expectations.. • **Increase existing funding** for R&D programs and initiatives for PM.	• Number of strategic projects submitted. • Number of additional projects. • Percentage of annual increase in funding allocated to programs and initiatives.

Specific Objectives		Lines of Action		Actions	Suggested indicators
RDI.SO1 **RDI.SO2** **RDI.SO3** **RDI.SO4** **RDI.SO5** **RDI.SO6**	**Promote R&D&i Projects** **Support the R&D&i Community** **Assess and monitor** **Enlarge the R&D&i Community** **Promote Multidisciplinary Profiles** **Give greater visibility to R&D&i in Navarra at an international level**	**RDI.LA2**	**INNOVATION AS A DRIVER OF CHANGE**	• Creation of a **funding programme for innovative R&D projects**. Through this action, groundbreaking projects focused on Genomics and Data Science for the development of PM will be financed. • Series of **Conferences on PM Innovation**, where internationally renowned speakers promoting R&D innovation (eg TED speakers, Google Innovators, South Summit, etc.) will meet and discuss applicable methodologies, good practices, opportunities for collaboration in innovation, etc. • Creation of the **Award for Innovation in PM**, which recognizes the work of people and/or entities from Navarra developing innovative projects and/or initiatives in the area (Navarra's Innovator of the year in PM). • Creation of an Innovation Promotion Unit (for more details, see Support and Advisory Units - Creation of an Innovation Promotion Unit).	• Number of projects submitted to the R&D projects funding programme. • Number of queries for participation in the programme. • Number of attendees to the sessions. • Attendee satisfaction surveys. • Number of innovative projects submitted. • Number of queries. • Unit users satisfaction surveys.

Specific Objectives		Lines of Action		Actions	Suggested indicators
RDI.SO1 **RDI.SO2** **RDI.SO3** **RDI.SO4** **RDI.SO5**	**Promote R&D&i Projects** **Support the R&D&i Community** **Assess and monitor** **Enlarge the R&D&i Community** **Promote Multidisciplinary Profiles**	**RDI.LA3**	**ATTRACTION, RETURN, AND RETAINING OF TALENT**	Creation of a **talent return programme for Navarra** aimed at promoting return to the Foral Region of researchers and/or innovators specialised in PM. For this, the following specific actions are proposed: o Definition of the desired or required profile for the attainment of the objectives set in this strategy by regional biomedical agents. o Tracking of researchers and innovators from Navarra working abroad through the NEXT programme and the IdiSNA network of researchers; and identification of the appropriate profiles resulting from the analysis carried out in the previous point. o Elaboration of a "welcome pack" with benefits for the returnee (eg advice in ERC submissions, assistance for accommodation, identification of bilingual schools, etc.). o Creation of a webpage containing useful information and main contact points for returned researchers/innovators.	• Number of returned researchers or innovators. • Number of queries made through the website/programme section.
RDI.SO6	**Give greater visibility to R&D&i in Navarra at an international level**			• Development of a **programme to attract national and international talent** so that researchers can choose among entities working in Navarra and, hence, settle and develop their lines of research there. o Needs analysis and definition of the desired profile to attract. o Preparation of a communication plan aimed at the promotion of Navarra and the benefits of the region for researchers. o Preparation of a "talent attraction pack" detailing benefits for the researchers/innovators who decide to develop their work in Navarra (eg. advice on ERC submissions, assistance for accommodation, identification of bilingual schools, etc.). o Creation of a webpage containing useful information and main contact points for researchers/innovators deciding to work in Navarra. • Creation of a **talent retaining programme** encouraging settlement in Navarra for researchers or innovators who are already developing their professional careers in the region. o Analysis of the desided profile in order to attain the objectives set in the PM strategy for Navarra 2020-2030. o New line of funding for the consolidation of profiles with a long profesional record in the region. o Creation of a webpage containing useful information and main contact points for researchers/innovators who wish to consolidate their activity in Navarra.	• Number of attracted researchers or innovators who were not originally working in Navarra. • Number of queries made through the website/programme section. • Number of researchers or innovators participating in the programme who were not originally from Navarra. • Number of queries made through the website/programme section.

Specific Objectives		Lines of Action		Actions	Suggested indicators
RDI.SO1 **RDI.SO2** **RDI.SO3** **RDI.SO4** **RDI.SO5** **RDI.SO6**	**Promote R&D&i Projects** **Support the R&D&i Community** **Assess and monitor** **Enlarge the R&D&i Community** **Promote Multidisciplinary Profiles** **Give greater visibility to R&D&i in Navarra at an international level**	**RDI.LA4**	**CREATION OF SUPPORT AND ADVISORY UNITS**	• Creation of a **researcher support unit** facilitating advancement in the different stages of the researcher's career, from the identification of calls for proposals and specific grants for each profile, to advice on the preparation of applications for European grants. The unit's main task will be to guide researchers in maximising regional, national and international resources to boost the development of their activity. • Creation of a **unit for the promotion of innovation** supporting, among others, PM, in order to provide advice for people and entities on innovation-based working methodologies, support in the different phases of development and implementation, and guidance in the exploitation and application of results. • Creation or identification of a **regional entity that acts as a "nerve centre"** (one-stop shop) for PM actions carried out in the region. This entity will pinpoint information on said area (calls, events, activities, etc.) through its website and social networks. Likewise, it will carry out informational events and promote collaboration between agents. • Creation of a **network of regional mentors** to advise junior researchers who wish to apply for European funding. Each mentor must have been a beneficiary of the grant/call on which they will subsequently carry out the counselling process (eg ERC starting and consolidator, MCSA IF, etc.). Likewise, mentors of the network will receive, in exchange for their participation, advice in the preparation of their own applications for international projects.	• Number of inquiries made and resolved. Rating of received assistance through satisfaction surveys. • Number of projects submitted by researchers as a result of the performance of the unit. • Number of researchers advised. • Number of inquiries made and resolved. • Rating of received assistance through satisfaction surveys. • Number of researchers advised. • Number of inquiries made and resolved. Rating of received assistance through satisfaction surveys. • Number of interactions through social networks. • Number of attendees at held events. • Number of researchers advised by the mentor network. • Number of projects submitted by researchers as a result of the mentoring process.

Specific Objectives		Lines of Action		Actions	Suggested indicators
RDI.SO1 **RDI.SO2** **RDI.SO3** **RDI.SO4** **RDI.SO5** **RDI.SO6**	**Promote R&D&i Projects** **Support the R&D&i Community** **Assess and monitor** **Enlarge the R&D&i Community** **Promote Multidisciplinary Profiles** **Give greater visibility to R&D&i in Navarra at an international level**	**RDI.LA5**	**STRATEGIC ALLIANCES**	• Establishment of **collaboration agreements** with benchmark European regions in PM (regions included in networks such as ICPerMed, Euroregion, EUREGHA, new European Partnership on Personalized Medicine, etc.). Likewise, potential alliances with non-European regions and/or entities providing a positive exchange of knowledge for Navarra will be analyzed. • Creation of specific agreements with European regions to attract international talent.	• Number of joint actions taken by Navarra and associated countries within the framework of the established agreement. • Number of joint actions taken by Navarra and associated countries within the framework of the established agreement.

Specific Objectives		Lines of Action		Actions	Suggested indicators
RDI.SO1 **RDI.SO2** **RDI.SO3** **RDI.SO4** **RDI.SO5** **RDI.SO6**	**Promote R&D&i Projects** **Support the R&D&i Community** **Assess and monitor** **Enlarge the R&D&i Community** **Promote Multidisciplinary Profiles** **Give greater visibility to R&D&i in Navarra at an international level**	**RDI.LA6**	**INTERNATIONALISATION**	• Creation of a program to support internationalisation of R&D&i in PM, including: o Helpline for hiring consultants/entities specialised in European projects development. o Bag of grants for mobility and attendance to international conferences, seminars, and events for technical and research staff. o Bag of grants for mobility and attendance to European networking events, brokerages/matchmakings for non-research personnel. o Helpline for conducting specialised courses in international project management, European policies, networks and partnerships management, preparing effective speeches and presentations in international contexts, etc. • Promotion of **Navarra's agents active participation in European networks and partnerships**, through: o Establishment of an "international dynamization node" of Navarra's agents for the PM area. An entity in Navarra for the centralisation of event identification, information sharing and specific support to agents who wish to participate in European networks and partnerships. o Signing of agreements and collaboration agreements with different regional entities (international dynamization node or nodes) capable of providing support to Navarra's agents with regard to European participation in networks and partnerships. o Registration in PM-specialised European networks and partnerships (S3 Health Platform, European Alliance for Personalised Medicine, EIT Health Spain, etc.). • Constitution of a **Working Group composed by experts in international PM projects**, located in Navarra. The main tasks of the Group would be: o Define the "vision-message-slogan" to be communicated by Navarra's agents in their international performances in PM. o Ongoing review of the international projection needs of Navarra's agents. o Review of future opportunities for the Foral Region of Navarra in PM and selection of the 5 lines of research to be financed in the long run by the region. o Selection of the main networks and partnerships in which to participate. o Establishment of annual objectives regarding international participation. o Collection of Navarra's success stories in international projects and definition of strategies for their dissemination. • Creation of its **own certificate of Specialization in European Project Management**. (As a complement to this action, a definition of competitive advantage(s) is proposed for those entities in Navarra prioritising recruitment of students who have completed the course). • **Promotion of successful stories** of PM R&D&I internationalisation (documentary filming, promotional collaborations with online science and technology communicators (youtubers), preparation of informative podcasts, organization of webinars, etc.). • Preparation of **study visits** by international organisations to the main PM entities in Navarra. o Organized visits for international committees, specialised companies, managers of innovative projects in the area, experts, etc. o Agendas constituted by representatives of the Government of Navarra and managers of benchmark PM entities in Navarra.	• Number of international projects presented, approved and awarded. • Number of attendees to conferences, events, symposia, etc. • Number of attendees from Navarra to international specialisation courses. • Number of queries for participation in European networks and partnerships. • Number of participants in European events. • Number of networks in which one or more agents from Navarra take part. • To be defined, based on the final tasks to be carried out by the Working Group. • Number of students registered per year. • Number of contracts carried out by Navarra's entities for students having the certificate. • Number of press appearances. • Number of participants in the webinars. Number of interactions in social networks. • Number of study visits. • Number of participants/organisations in the study visits.

EBD ACTION PLAN

(ECONOMIC AND BUSINESS DEVELOPMENT)

4.2.3. Economic and Business Action Plan (EBD)

FACT SHEET:

EBD Area: Leading the Personalised Medicine Sector

To be a leader in the advancement of Personalised Medicine thanks to the promotion and creation of a new industry in this sector, as well as in the different value chain sectors, in order to contribute to the wealth of the region and the well-being of its society.

Specific Objectives		Lines of Action	
EBD.SO1.	Companies	EBD.LA1.	Increase the participation of companies in the different sectors of the personalised medicine value chain.
EBD.SO2.	Competitiveness	EBD.LA2.	Public Procurement for Innovation (PPI).
EBD.SO3.	Investments	EBD.LA3.	Investment attraction.
EBD.SO4.	Startups	EBD.LA4a.	Ideation, validation, and market access for startups.
		EBD.LA4b.	Study and creation of validation units.
EBD.SO5.	Cooperation	EBD.LA5.	Launch of the Personalised Medicine Hub.

Operational Lines of Action in the EBD Area:

Transversal Axes	Lines of Action	
Infrastructures and Systems	IS.LA1	Infrastructures
	IS.LA2	Systems
	IS.LA3	Data Platforms
Regulations	R.LA1	Data Processing Plan (DPP)
	R.LA2	Regulatory Framework Revision
	R.LA3	Monitoring Committee
Education and Training	ET.LA1	Training Map
	ET.LA2	Undergraduate Education
	ET.LA4	Postgraduate Education
	ET.LA5	Continuing Education
	ET.LA6	Vocational Education
Communication and Participation	CP.LA1	Cohesion and Alignment of Expectations
	CP.LA2	Regional Positioning and European Collaborations
	CP.LA3	Public Awareness

INTRODUCTION

The **Integrated Personalised Medicine Strategy for Navarra** advances important changes in the areas of healthcare, research and economic development.

In order to warrant adequate development of the **interdepartmental strategy**, it is necessary to design and **implement an economic development strategy aimed at promoting the development of Personalised Medicine and to position Navarra as a benchmark region** in the advancement of Personalised Medicine.

Likewise, the joint vision of the **Government of Navarra** and the **public-private collaboration** of agents involved in the **Navarra Institute for Health Research (IdiSNA)** for an Integrated Personalised Medicine Strategy for Navarra, **paths the way of the future of the level of excellence** in medical care, research, entrepreneurship and the training of medical professionals in Navarra.

In the first place, this strategy is projected through the layout of economic lines of action aimed at boosting the **creation of new business lines** in order to grant an agile development of Personalised Medicine, as well as the strengthening of existing business lines with measures promoting investment.

Subsequently, a series of actions for an **optimal development of these lines of action** are presented with an eye to achieving a solid implantation of the new lines of business, as well as greater competitiveness of the existing ones.

Among the **strategic lines of the Economic and Business Development Department**, **innovation** is deemed one of the axes on which the competitive power of companies from Navarra revolves, under the appreciation that, since innovation and first-rank advanced industry go hand in hand, the greater the innovation, the higher-quality employment (which is one of the Government's priority objectives).

Navarra's Research and Innovation Strategy for Smart Specialisation (RIS3) is committed to a crash concentration system in those areas of development that might possibly spur the regional economy into the future and, within Health, the development of Personalised Medicine has been identified as one of the greatest challenges.

To achieve the **transformation of the industrial fabric of Navarra**, it is necessary to get it on track towards **Personalised Medicine specialisation** as an **industry of the future.** The goal is to **be at the forefront** by achieving a more competitive, more technological, more innovative, and more sustainable industry, but also with a much deeper commitment to social and environmental issues. All of this requires enhancing business competitiveness, attracting talent, growth, cohesion and dynamization policies between the four helixes: researchers, business, academia and hospitals, internationalisation and visibility policies, among others.

Furthermore, the **Foral Law of Science, Technology and Innovation** pleas for a future society in which well-being and quality of life improvement are prioritised. To this end, one of its priority objectives is to improve Navarra's competitive position in the market, with the **ambition of becoming a leader in the development of Personalised Medicine**. For this, it is necessary to

generate new business initiatives through development, knowledge-sharing and cooperation between the public sector, social entities and the productive sector, in which the generation and attraction of research and entrepreneurial talent will play a fundamental role in the emergent area of Personalised Medicine. Then, visibility and internationalisation will do the rest.

To promote **business attraction and entrepreneurship** in the field of Personalised Medicine, both the Government of Navarra and the regional development agency **Sodena**, together with the Public-Private Navarra Institute for Health Research, **IdiSNA**, have established a collaboration for the implementation of the **Initiative to Strengthen Competitiveness (IRC)** in the health sector, as well as the generation of **public-private working groups to promote technological economic development in medical equipment, well-being and nutrition**.

Source:

1. Smart Specialisation Strategy (RIS3). https://gobiernoabierto.navarra.es/sites/default/files/participacion/estrategia_de_especializacion_inteligente_de_navarra.pdf
2. Foral Law of Science and Technology (15/2018). https://www.boe.es/buscar/pdf/2018/BOE-A-2018-10582-consolidado.pdf

ECONOMIC AND BUSINESS DEVELOPMENT (EBD) SWOT

It can be said that, now that Navarra has launched the **Smart Specialization Strategy S3**, **in which the Healthcare area is established as a priority, and Personalised Medicine is fixed as one of its main challenges (Challenge 8)**, there are optimal conditions for the establishment of an economic development plan in the field of Personalised Medicine.

Furthermore, within the **Genomics and Advanced Medicine GEMA challenge**, strategic R&D projects are already bearing fruit in Navarra: 2016-2019: NAGEN 1000 genomes, 2016-2019: DIANA, 2017-2020: PharmaNAGEN, 2017-2020: MINERVA, 2017-2020: GENEURONA, among others.

Navarra is also a **member of international consortiums, such as ICPerMed and ERA PerMed, 2016**. Additionally, Navarra has the **Foral Law of Science and Technology** of June 27, 2018 and currently manages the **R&D Space**, presented in December 2018 by the S3 steering committee, which includes basic support infrastructures for Personalised Medicine: **supercomputing ICTS and sequencing infrastructure**.

Navarra's companies, as well as the region's entrepreneurial spirit, are driving forces for the attainment of the needed public and private infrastructures in order to become a landmark region in Personalised Medicine in Spain, with infrastructures for sequencing, supercomputing, talent, research centres, universities and first-rank hospitals. The weaknesses and threats to be dealt with are easily manageable, but they urge the joint collaboration of all the areas involved in the integrated strategy. The challenge is thus to fight these perceived weaknesses and threats, as well as capitalising on the strengths and opportunities to arise.

Navarra's commitment to Personalised Medicine gives it a small leeway over other neighbouring regions, which constitutes an excellent opportunity for the development and attraction of industries that can provide services beyond its borders.

Table 8. Economic and Business Development Action Plan (EBD) SWOT.

Weaknesses	Threats
• Small community with little business fabric dedicated to PM. • Lack of specialized startups in the PM sector. • Lack of professionals specialised in data, artificial intelligence and bioIT. • Lack of validation units (public clinical trials, prototyping, projects). • Need for greater support for business ideas generation. • Little knowledge of what others are doing (public-private).	• University projects flee to other regions where there is greater financial support (project validation and business plan). • Talent drain. • Creation of startups in other regions providing more incentives. • PM is a highly competitive global sector between regions and countries: a size barrier and a barrier to investment possibilities.
Strengths	**Opportunities**
• Society is receptive to new initiatives, such as access to anonymised medical records. There is a positive perception of the health system and citizens consider it reliable due to the high level of health. • Personalised medical records. • The SNS-O has a differential data repository at the international level due to its level of digitization, the number of parameters, which also includes genomic data. • Internationally awarded good health practices. • Excellence in the provision of medical services and the ability to attract clients. • Scientific excellence. • Strategic projects in Health. • Transference support. • Industry-academia collaboration through the PM Hub. • Being a small region facilitates contacts between public institutions and Navarra's economic agents. • Infrastructures that favour the development of companies (Digitization Hub, IRIS Hub).	• Small community with well-preserved family units: make it an ideal environment for the development of pilot projects in PM. • Possibility of managing the local demand to attract other agents and new working areas. • Technological players (Google, IBM, Microsoft). • Innovative public procurement (PPI). • Companies from other sectors (automobile industry) yearning for diversification. • New data infrastructures (data analysis, data mining), machine learning, artificial intelligence, omics technologies. • Creation of an accessible health Data Centre, complemented by historical data from the SNS, data from wearables, socio-economic data, etc. • Regulate to open the DATA CENTRE to both academia and industry would give leverage to companies, projects and talent in data science and artificial intelligence. • Creation of the PM Hub: working commissions, dynamization of meetings and generation of new opportunities between the quadruple helix: researcher, company, academy and hospital for the development of Navarra's economy in PM.

We must be aware that the commitment to the Integrated Strategy for Personalised Medicine in Navarra is a long-term strategy. It all comes down to creating a highly technological industry with solid foundations in the long run, as well as transferring the benefits of our genomics knowledge to healthcare. It is, nevertheless, true that everything takes time: research, professional training, transference to medical care and the creation of industry and economic growth.

EBD AREA SPECIFIC OBJECTIVES (EBD.SO)

EBD.SO1. Companies: Increase the participation of Navarra's companies in the Secondary Use of Genomic Data sector, mainly: development of methodologies, analysis and interpretation platforms and new personalised therapies, as well as encouraging the participation of companies in the different sectors of the Personalised Medicine value chain.

EBD.SO2. Competitiveness: Improve the competitiveness of Navarra's Health Sector focusing on Personalised Medicine and encourage market access to innovative solutions arising from research projects in Personalised Medicine.

EBD.SO3. Investments: Develop policies to attract investment from companies in the different sectors of the Personalised Medicine value chain, mainly: distribution and sale of genomic services; patient sampling and selection; sequencing, interpretation and implementation in the health system.

EBD.SO4. Startups: Promote the creation of new companies in the different sectors of the Personalised Medicine value chain.

EBD.SO5. Cooperation: Encourage intersectoral cooperation and the creation of platforms/Hubs, promote their connection and collaboration within the clinical care/research/business triangle and strengthen public-private collaboration in the area of Personalised Medicine.

ACTION PROPOSAL

The lines of action proposed below are set out in accordance with the priority objectives established in the economic development strategy for Personalised Medicine and other Personalised Medicine areas. Each main line of action is, in turn, broken down into a desirable set of actions for the achievement of the proposed objectives. In addition, a series of suggested indicators for each action will guide the assessment and progress of the strategy.

EBD.LA1. Increase the participation of companies in the Personalised Medicine sector and in the value chain sector.

This line of action is intended to promote the economic development of the sector, spur diversification and promote research and entrepreneurship.

The following actions are planned in order to contribute to the consolidation of the Personalised Medicine sector:

- **"Industry Discovery Forum**": targeted at local, national and international companies, hospitals, etc.
- Establishment of the **Personalised Medicine Hub** as a benchmark forum for meetings and participation.
- **Strategic diversification plans**: capitalise on the productive capacity of companies from other sectors (automotive, energy, etc.) for the production of medical devices, applications, etc. Help funding these strategic diversification plans.
- **Encourage Spinout creation:** transfer of new business ideas from companies not being interested in developing them to other companies (e.g., BioVentureHub).

EBD. LA2. Innovative public procurement

Through the offer of challenging projects launched by the public administration and its associated agents, innovation in technologies, such as data mining, artificial intelligence, artificial vision, etc. can be promoted. Within the framework of this strategy, bidding and public procurement processes will be analysed, so that attractive projects are generated for the private sector. This way Public Procurement becomes a potential channel for new business activities in Health Innovation.

For this Line of Action, the following actions are proposed:

- **Pre-commercial Public Procurement** aimed at companies and/or startups. Health challenge.
- **Innovative technology Public Procurement.**
- **Association** for innovation.

EBD. LA3. Investment attraction

In order to attract investment from companies coming from different sectors of the Personalised Medicine value chain, the following actions are proposed:

- SODENA (Navarra Development Society) **investment attraction programme**.
- Promotion of **the line of contacts with SODENA's public and private investors**.
- Complementing or enhancing **investments in Personalised Medicine programmes** in order to give greater visibility to projects and investors.
- Hub promotion to attract investment.
- Visibility of Personalised Medicine patents to attract investment.
- **Investors club**: meetings and detection of opportunities.

EBD.LA4a. Ideation, validation, and market access for startups

In order to boost the creation of new companies specialised in the area of Health innovation, the following actions are proposed:

- **Promotion of the Mentorship Programme** for business profile ideation, validation, assistance and advice.

- **Promotion of the MEDTECH Academy: Health entrepreneurship programme. Business idea.** Maturation and configuration of ideas for project development. Awards for the best project. Direct access to Entrepreneurial Drive.
- **Strengthening the Entrepreneurial Drive:** Acceleration and implementation of business initiatives. **New specific Health call. New business model accelerator.** "From your project to a scalable company in 4 months". It offers: mentors, funding, acceleration and workspace.
- **Promotion of innovation incubators for Startups** (generic theme, with high participation from the health sector). Strengthening competitiveness, consolidation and market scaling. It offers: tutoring, funding access support, contacts with large companies, premises, pilot plant.
- Entrepreneurial discovery itinerary for Health.
- Creation of an **open call** for startups and projects in order to grant access to capital and/or the incubation/acceleration process of the business project.
- **Promotion of the best startup award** (bioengineering, biomedicine, data science, AI, cybersecurity, etc.).
- **Promotion of startup-company agreements** (local, national or international) in the Personalised Medicine sector.
- **Promotion of the creation of an express validation unit for startups,** prototype validation unit: test beds.
- **Creation of a regulatory validation unit.**
- Establishment of a powerful and distinctive **funding programme - Business Plan**.

EBD.LA4b. Study and creation of validation units

For already consolidated companies:

- **Pre-feasibility study** for centralisation of public and private trial units: clinical trials (e.g., phases 1 and 2 of drug development; nutritional trials; e-health devices, genetic diagnosis, observational, population, epidemiological, etc., validation trials).
- Creation of the **validation unit** of technology, e-health monitoring computer applications for prevention and well-being.
- Study on the creation of the rapid **prototyping unit** for medical devices, e-health.

EBD.LA5. Launch of the Personalised Medicine Hub

The creation of a specific platform/Hub for Personalised Medicine can be of great help for knowledge transfer from research to companies, competitiveness reinforcement and value generation in both Navarra's business sector and regional healthcare.

To do this, the following actions are proposed:

- **Creation of the Personalised Medicine Hub for economic development**.
- The Hub as a **common ground for meetings dynamization and opportunity generation**.
- Promotion of **European funding search** through the Hub.
- **Contact making**.

TABLE 9. ECONOMIC AND BUSINESS DEVELOPMENT SUMMARY (EBD)

Specific Objectives		Lines of Action		Actions	Suggested indicators
EBD.SO1	**Companies**	**EBD.LA1.**	**Increase the participation of companies in the Personalised Medicine sector and in the value chain sector.**	• **"Industry Discovery Forum":** targeted at local, national and international companies, hospitals, etc. • Establishment of the **Personalised Medicine Hub** as a benchmark forum for meetings and participation. • **Strategic diversification plans**: capitalise on the productive capacity of companies from other sectors (automotive, energy, etc.) for the production of medical devices, applications, etc. Help funding these strategic diversification plans. • Encourage **Spinout creation**: transfer of new business ideas from companies not being interested in developing them to other companies (eg BioVentureHub).	• Annual hired staff increase. • Number of companies participating in the Hub. • Number of accesses to the Hub. • Percentage of company participation. • Number of created spinoffs or startups. • Percentage of funding for diversification. • Number of companies applying for diversification grants. • Number of spinouts.
EBD.SO2	**Competitiveness**	**EBD.LA2.**	**Innovative Public Procurement (PPI)**	• **Pre-commercial Public Procurement** aimed at companies and/or startups. Health challenge. • **Innovative technology Public Procurement**. • **Association** for innovation.	• Number of calls. • Number of applications to the call.
EBD.SO3	**Investments**	**EBD.LA3.**	**Investment attraction**	• **SODENA** (Navarra Development Society) **investment attraction programme**. • Promotion of the **line of contacts** with SODENA's public and private investors. • Complementing or enhancing **investments in Personalised Medicine programmes** in order to give greater visibility to projects and investors. • **Hub** promotion to attract investment. • Visibility of Personalised Medicine **patents** to attract investment. • **Investors club**: meetings and detection of opportunities.	• Number of calls. • Number of participants. • Number of contacts with investors. • Number of investments. • Number of appearances in different media of the innovative projects. • Number of hits on the web. • Number of meetings.

Specific Objectives		Lines of Action		Actions	Suggested indicators
EBD.SO4	**Startups**	**EBD.LA4a.**	**Ideation, validation, and market access for startups**	• Promotion of the **Mentorship Programme** for business profile ideation, validation, assistance and advice. • Promotion of the **MEDTECH Academy**: Health entrepreneurship programme. Business idea. Maturation and configuration of ideas for project development. Awards for the best project. Direct access to Entrepreneurial Drive. • Strengthening the **Entrepreneurial Drive**: Acceleration and implementation of business initiatives. New specific Health call. New business model accelerator. "From your project to a scalable company in 4 months". It offers: mentors, funding, acceleration and workspace. • Promotion of **innovation incubators** for Startups (generic theme, with high participation from the health sector). Strengthening competitiveness, consolidation and market scaling. It offers: tutoring, funding access support, contacts with large companies, premises, pilot plant. • Entrepreneurial discovery itinerary for Health. • Creation of an **open call for startups and projects** in order to grant access to capital and/or the incubation/acceleration process of the business project. • Promotion of the **best startup award** (bioengineering, biomedicine, data science, AI, cybersecurity, etc.). • Promotion of **startup-company agreements** (local, national or international) in the Personalised Medicine sector. • Promotion of the creation of an **express validation unit for startups**, prototype validation unit: test beds. • Creation of a **regulatory validation unit**. • Establishment of a distinctive **funding programme - Business Plan**.	• Number of calls • Number of applicants • Number of participants • Budget percentage • Number of startup-company agreements • Number of awarded prizes • Number of validated prototypes • Funding percentage
		EBD.LA4b.	**Study and creation of validation units**	• **Pre-feasibility study** for centralisation of public and private trial units: clinical trials (eg phases 1 and 2 of drug development; nutritional trials; e-health devices, genetic diagnosis, observational, population, epidemiological, etc., validation trials). • Creation of the **validation unit** of technology, e-health monitoring computer applications for prevention and well-being. • Study on the creation of the **rapid prototyping unit** for medical devices, e-health.	• Number of meetings • Number of participants

Specific Objectives		Lines of Action		Actions	Suggested indicators
EBD.SO5	**Cooperation**	**EBD.LA5.**	**Launch of the Personalised Medicine Hub**	• Creation of the Personalised Medicine Hub for economic development. • The Hub as a common ground for meetings dynamization and opportunity generation. • Promotion of European funding search through the Hub. • Contact making.	• Number of platform updates • Number of registrations in the platform • Number of platform hits • Number of Hub activities • Number of Hub initiatives • Number of collaborative projects • Number of meetings between IRC working groups • Number of international or national hits • Number of new generated initiatives

4.3. TRANSVERSAL AXES ACTION PLAN

INFRASTRUCTURES AND SYSTEMS ACTION PLAN

4.3.1. INFRASTRUCTURES AND SYSTEMS

FACT SHEET

INFRASTRUCTURES AND SYSTEMS

Operational Objectives		Lines of Action		STRATEGIC AREAS		
				Healthcare	R&D&i	EBD
IS.OPO1	Infrastructures	IS.LA1	Infrastructures	●	●	●
IS.OPO2	Systems	IS.LA2	Systems	●	●	●
IS.OPO3	Platforms	IS.LA3	Platforms	●	●	●

INTRODUCTION

Navarra is a leading region in health, with a very high-quality public and private health system, health being a priority sector in the **Smart Specialization Strategy (S3)**. Both the implementation of the Personalised Medicine Strategy and public-private collaboration are placing us at the forefront of medicine.

Navarra's industrial ecosystem is vigorous, so the point here is reinforcing it, improving its competitiveness to make Navarra a landmark region in the area from a shared public-private view on Personalised Medicine as a long-term strategic commitment for Navarra.

The implementation of Personalised Medicine in Navarra demands an **infrastructure for sequencing, storing and processing genomic data** in order to be able to meet the time and volume requirements of the development of the strategy, and promote education, training, R&D and economic development in this area.

SWOT

The Foral Region of Navarra is making a remarkable effort to **provide infrastructures and systems for the global development of Personalised Medicine** based on the wide experience already consolidated in digitization and development of **ICT Information and Communication Technologies in the Health Department**.

Besides, there are **specialised research groups capable of analysing and integrating genomic data**, as has been proven in several strategic projects encompassed within Challenge 8 (GEMA) of the recently launched Smart Specialization Strategy for Navarra, in which the most advanced technologies in telecommunications and information systems have been used, which in turn are being shared by the researchers of Navarra's R&D&i System through the **SIESS platform** (Scientific Infrastructure and Equipment Sharing System of Navarra).

The challenge now consists in the development of infrastructures and systems on a large scale, with **greater public-private integration**, abiding by required **regulations** and gaining **social trust**, as well as guaranteeing adequate specific professional profiles, so that the efforts of all the agents involved in Technological Personalised Medicine development and implementation are aligned.

It is time to take advantage of synergies, align with European and national strategies, evolve along with the infrastructures of **Navarra's IRIS Digital Innovation Pole** and the unravelling of the **2030 digital strategy for Navarra**.

Source:

1. Strategy for Smart Specialisation (S3). https://gobiernoabierto.navarra.es/sites/default/files/participacion/estrategia_de_especializacion_inteligente_de_navarra.pdf
2. IRIS. https://www.irisnavarra.com/
3. SIESS. https://www.siessnavarra.com/equipment/infraestructure

INFRASTRUCTURES AND SYSTEMS SWOT

Table 10. Infrastructures and Systems Action Plan SWOT

Weaknesses	Threats
• **Scant public-private integration.** • Lack of profiles specialised in bioIT and data science. • Distrust in the transfer of genomic and other health-related data due to lack of information and specific regulatory development.	• Business relocation to other regions due to lack of advanced ICT infrastructures, and talent drain. • Loss of Health systems effectiveness. • Misalignment of existing resources in the administration or non-prioritization of PM development. • Healthcare saturation due to the absence or little use of adequate infrastructures.
Strengths	**Opportunities**
• Nascent specialized research groups capable of analysing and integrating genomic data. • Experience of the Foral Region administration in digitization and ICT development in the Health Department. • SIESS: infrastructures sharing platform since 2017 (Scientific Infrastructure and Equipment Sharing System of Navarra).	• Technological research (bioIT engineering, biomedicine) in European strategic projects. • European PM strategy. • Spanish PM strategy. • Navarra Digital Strategy 2030. • Adherence to the Spanish Supercomputing Network. • IRIS - European Digital Innovation Pole.

INFRASTRUCTURES AND SYSTEMS OPERATIONAL OBJECTIVES (IS.OPO)

IS.OPO1. Infrastructures: Provide the necessary infrastructures to endow the strategy with technological independence, sustainability and support for development, in order to carry out the strategic objectives.

IS.OPO2. Systems: Develop specific systems for data management according to the objectives described in the strategy.

IS.OPO3. Platforms: Provide the strategy with the necessary platforms in order to manage obtained resources.

ACTION PROPOSAL

This action plan proposal is based on the convergence of three fundamental pillars:

On the one hand, the necessary **infrastructures** for the generation of genomic data, in particular high-capacity sequencing, with its storage, management, annotation and analysis capacities, for which high-capacity computing equipment (supercomputing) is required. These infrastructures will provide our region with the necessary technological independence to carry out the processes described.

On the other hand, **systems** aiming at integrating genomic data and other biomedical data, including data from electronic health records (EHR) and other related data sources, in order to generate the relevant interoperability layer.

And, finally, **digital platforms**, tools that will help manage access to resources to be used by the different agents related to Personalised Medicine.

LINES OF ACTION

1. IS.LA1. Infrastructures

The **General Directorate for Digital Transformation (GDTD)** has the mission, together with its suppliers (Tracasa, Nasertic, etc.), to carry out **ICT innovation** in this Strategy. This innovation is subject to corresponding organizational and healthcare innovation in the Health System.

As an approximation, and following patterns from other countries, it seems advisable to make use of a public company for the management of this type of infrastructure and, eventually, to meet the fixed objectives. There is already a public company in Navarra, Nasertic, which has experience and technical staff both in the field of ICT infrastructure management and genomic services. Most of the strategic projects developed in Navarra, **GEMA (Challenge 8, S3)**, have required the necessary support infrastructures to provide cutting-edge services, and to place the Foral Region at the forefront of advanced technologies. Nasertic has made some of these changes possible thanks to an integrated **telecommunications infrastructures** management

backed by an over-20-year experience in providing services for both self-provisioning services and favouring public-private collaboration models.

As a consequence, the Government of Navarra carried out a capital increase of the company in 2019 in order to expand its services and endow itself with the necessary infrastructures, so that **massive sequencing, storage and data processing services** were available to both the SNS-O and other research entities, whether internal or external to the Government of Navarra, public or private.

- **Massive Sequencing Centre**

One of the cornerstones of Personalised Medicine is the use of genomic data for better prevention, diagnosis and treatment of patients. The integration of this technology into the benefits of the health system in Navarra, which is already the first community in health services, will have a beneficial impact on the health of the population, the optimization of health system resources and will therefore place Navarra among leading international regions.

However, generating genomic results requires investment in increasingly powerful infrastructures. For this reason, the need for technological independence when it comes to sequencing genomes has been met by providing a **massive sequencing centre** with the capacity to carry out 9,000 whole human genome studies (WGS) per year. This centre, located in the same building as the HPC Cluster at Nasertic, already has, since the second half of 2020, specific infrastructure, such as:

- Illumina Novaseq 6000 sequencing system
- Hamilton NGS STAR 96MPH ODTC
- Agilent TapeStation 4200 System

This robust support infrastructure, necessary for the provision of sequencing services, will place Navarra at the forefront of advanced technologies and will lead to immediate benefits for patients, by reducing the need for partial studies and diagnostic times, as well as the adaptation of treatments, reducing side effects and increasing effectiveness.

- **Supercomputation and storage**

Thanks to **supercomputation (HPC, High-Performance Computing)** it is possible to perform billions of operations per second. This cutting-edge technology helps explain sundry biological processes through the use of algorithms and calculation programs, obtaining information of great impact on advances in research and, ultimately, on the patient's healthcare. This type of infrastructure provides an opportunity to interpret the more than 3,000 million data generated in a standard human sequencing process; for example, predicting the possibility of a person suffering from a disease, to carry out an accurate diagnosis, or to know the potential susceptibility of a patient to a specific drug.

Due to the needs that were generated within the **NAGEN 1000** strategic project, the **Supercomputing Cluster (Urederra)** has been functioning in Navarra since 2018. The **development of new infrastructures, storage systems and computational analysis for massive genomic data** in Navarra allow studying hundreds of genomes of patients participating in this

program thanks to the supercomputing cluster managed by Nasertic. In addition, this infrastructure was designed to be shared by all the Technology Centres of Navarra integrated in ADItech, SINAI agents, as well as those public companies (Navarrabiomed, Tracasa, CNTA, CENER, etc.) which might need to use it.

The supercomputing cluster has been specifically designed for **intensive artificial intelligence workloads** and is **four times more capable of improving the training times of Deep Learning frameworks** (from days to hours), allowing to build artificial intelligence applications in a faster way. Its **free software** serves both as a **tool** and a strategic move for the growth and development of supercomputing services, thereby using a hybrid model which uses technologies grounded on Intel, NVIDA and IBM Power9 processors. This free software is nowadays present in scientific solutions, as well as in the most visionary, innovative trends in today's cloud environments.

The Cluster is a **hybrid environment** merging several components from different manufacturers which may potentially become a single Supercomputer. The functional block diagram of the Supercomputing Cluster is as follows:

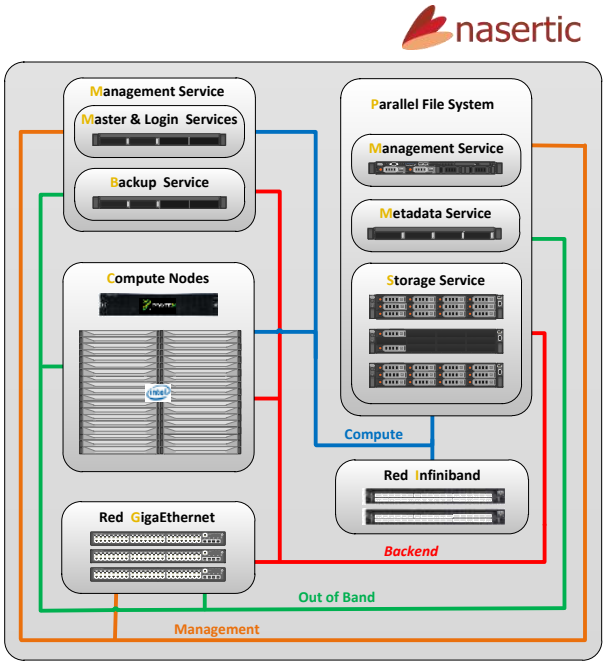


Figure 7. HPC Nasertic Cluster Diagram.

Until now, the cluster consisted of the following machines (BEFORE). After the approval of Nasertic's capital increase by the Government of Navarra, a series of extensions have been planned in order to meet the foreseeable needs that the Personalised Medicine Strategy is expected to bring about in the near future. This estimate has been made on the assumption that new acquisitions will be comparable to the ones being used now. Undoubtedly, new enhancements in future hardware versions will certainly offer higher performance. In the new context, these needs would translate into the following number of machines and features (AFTER):

BEFORE	AFTER
Computation: • 2 Management Nodes (coordination and priority management tasks) • **38 Intel computing nodes** **760 Cores** **5 Tb RAM Memory** **1 IBM Power 9 server & 2 Tesla V100** **32 CPU cores & 5000 CUDA Cores** **256 Gb RAM Memory** **Peak performance** **Intel: 29184 Gflop** **IBM Power 9: 320 Gflop** **GPU: 250 Tflops** **Storage:** • **110 Tb Scratch** • **179 Tb Local**	**Computation:** • 2 Management Nodes (coordination and priority management tasks) • 64 Intel computing nodes • 4 Intel servers with GPU • 4 Power 9 servers with 2 GPU 1280 Cores 8 Tb RAM Memory 4 Power 9 IBM servers & 2 Tesla V100 128 cores CPU & 20000 Cores CUDA 1 TB RAM Memory Peak Performance Intel: 44548 Gflop IBM Power 9: 1280 Gflop GPU: 100 Tflops **Storage:** • 220 Tb Scratch • Future expandability to 2 Pt

The supercomputing cluster in Navarra is kept in Nasertic's **Data Processing Centre (DPC)**. Nasertic is a public company specialising in **Data Centres** management, which is currently entrusted with the management of **two Data Processing Centres (DPC)** for the Government of Navarra. These mission-critical infrastructures are specifically designed for the **storage of telecommunications infrastructures, servers and storage subsystems** that are made available for the entire fabric of Navarra's Public Administration.

Last May 2020, Nasertic joined the **Spanish Supercomputing Network (RES) with its Urederra Cluster**. This incorporation as a RES node, which is expected to bring the European HPC strategy closer to Navarra, will involve participation in a networking group where the main national experts meet for the exchange of knowledge, good practices and collaboration.

In the next few years, during the development of the Integrated Strategy for Personalised Medicine, its **maintenance and preventive planning must be managed to preserve and sustain the availability of the infrastructure**. So far, this expanded supercomputing cluster is capable enough of taking on the work that will be generated during the development of this strategy. Nevertheless, in order to address future needs, its coordination with other development plans carried out by the Government of Navarra must, therefore, be taken into account.

- **Connections**

One of the challenges to be dealt with in this strategy is **to enable a connection that provides sufficient speed for data exchange**. In order for the areas of Health, Research, Development

and Innovation (R&D&i) and Economic Development to access the Urederra supercomputing cluster, a new network architecture that adds new connections to the cluster must be designed.

There is a network of different connections that makes it possible to share resources between entities, but there are no accesses enabled by default, due to very strict security policies. In this strategy, it is necessary to carefully study all the conditions that must be met to warrant a secure connection and authentication of several factors.

The **UPNA NETWORK**, connected through the Virtual Private Network service defined on the infrastructure of the Corporate Network of the Government of Navarra, uses MPLS (Multi Protocol Switching) technology for the isolation of that communication with the Supercomputing Centre (Nasertic). Access through this network, specifically from the **Digital Innovation Pole**, would favour data sending and receiving from the Supercomputing Centre in a safe and efficient way.

2. IS.LA2. Systems

The systems needed to implement the Personalised Medicine Strategy must be based on **biorepositories of genomic data files** (and other omics) generated from the actions promoted by the Strategy, as described in the Line of Action for the "Reinforcement of Genomic Medicine in Navarra's Health Service" (S.LA2), or other projects resulting from the R&D&i Action Plan. Ideally, these biorepositories will be federated with other similar national or international resources, such as the one being developed within the 1 million genomes (+1MG) EU project to allow **organized and distributed access of omics and genomic information**, and collaborate in the creation of novel knowledge for the overall progress of Personalised Medicine.

These files should be granted the necessary advanced security and data technology connections in order to advance **omics data integration with the clinical data from EHR and other sources**, following the standards proposed in other initiatives of the international community, such as the European Global Health Research Institutes Network. From this interconnection, it will be possible to develop interoperation systems based on the automatic generation of interrogations on minimal data sets that respond to specific questions posed by the objectives of the strategy, in the context of clinical questions, research questions, and other questions. The data policy and structure that is to be implemented will guarantee the **privacy of people** and their data, as well as the functioning of critical information systems based on the consideration of cybersecurity issues related to infrastructure and services.

In order to sustain the operational complexity of these systems, the full involvement of **IT solution providers**, both from the genomics sequencing centre and SNS-O, will be crucial. Regulations on data protection limit the distribution of biomedical data by health centres, which requires the development of federated systems for the organization of data within each jurisdiction, while the description of said data —in the format, for example, of its metadata— can be centrally synchronized in line with the "Data Processing Plan" (C.LA2) described in the Coordination Action Plan section, and within the framework of the "Data Processing Plan" (N.LA1) developed in the Regulations Action Plan. Centralised access to metadata allowed by

such a federation makes it possible to arrange studies between distributed sets (for example, cohort studies for research) with distributed data sets without revealing them, in compliance with current regulations. In addition, data federation is an essential ingredient for the implementation of learning technologies generated by artificial intelligence, capable of learning progressively more complex automated responses in order to ground useful clinical decision support systems projected for the development of Personalised Medicine. The adoption of software container technologies (e.g., docker, singularity) will pave the way for the optimization of computation at the very source, in such a way that initial analyses, e.g., anonymization or pseudonymisation of the data, can be carried out on each system *in lieu* of other capabilities offered by a secure environment.

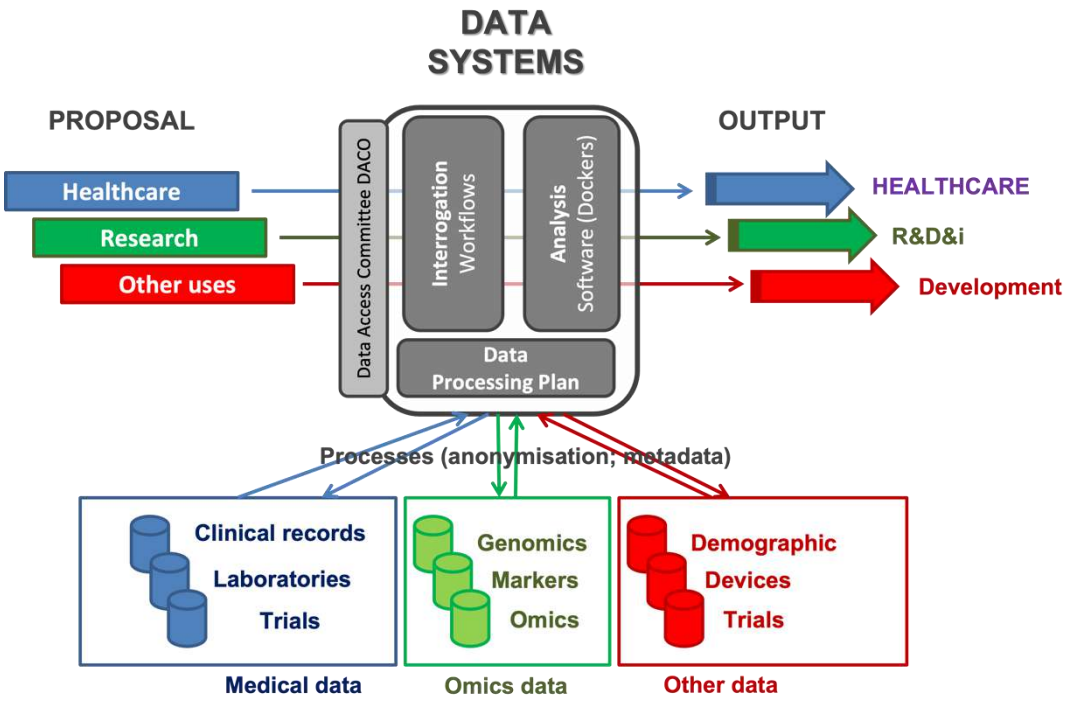


Figure 8. Systems Diagram.

3. IS.LA3. Platforms

To successfully develop this Personalised Medicine Strategy, it is necessary that there be **digital platforms** favouring **resources management** amid its different agents, as well as the possibility of **offering services** capable of boosting the economic fabric of the region.

The **Digital Innovation Pole** is expected to concentrate research and experimentation capacities, as well as to host a campus with supercomputing and sequencing facilities, laboratories, and meeting points to stimulate creativity and entrepreneurship. Its digital platform **IRIS (Artificial Intelligence and Robotics for Industry and Society)**, an innovation Hub whose function is to accelerate the digital transformation of companies, plays a fundamental role as a driver in this Personalised Medicine Strategy. This platform includes the Agents of the Innovation System in Navarra (SINAI); the SIESS platform for shared technological infrastructures; agents involved in economic development; companies that provide solutions and physical spaces; as well as the

IRIS Lab, with an eye to the development of technology and the provision of services related to digital transformation (e.g., management of genomic and omics data, etc.).

TABLE 11. INFRASTRUCTURES AND SYSTEMS ACTION PLAN SUMMARY

Operational Objectives		Lines of Action		Actions	Suggested indicators
IS.OPO1	**Infrastructures**	**IS.LA1**	**Infrastructures**	• Massive Sequencing Centre • Supercomputation Cluster • Connections	• Number of genomic studies. • Number of HPC services. • Number of new connections.
IS.OPO2	**Systems**	**IS.LA2**	**Systems**	• System	• New System.
IS.OPO3	**Platforms**	**IS.LA3**	**Platforms**	• IRIS Digital Platform • New Platforms	• Number of digital patform queries.

REGULATIONS ACTION PLAN

4.3.2. REGULATIONS

FACT SHEET

REGULATIONS

Operational Objectives		Lines of Action		STRATEGIC AREAS: Healthcare	R&D&i	EBD
R.OPO1	Legal-Ethical Framework	R.LA1	Data Processing Plan (DPP)	●	●	●
		R.LA2	Regulatory Framework Revision	●	●	●
		R.LA3	Monitoring Committee	●	●	●

INTRODUCTION

The Integrated Personalised Medicine Strategy for Navarra proposes a series of procedures in **biomedical data management for primary health purposes**, mainly focused on patient care, but also pursuing **secondary benefits, such as health service management and planning, research and knowledge enhancement, and sustainability and economic development**. This multifaceted vision, as well as the novelty of a technical field that incorporates cutting-edge elements, such as new genomic and multi-omics techniques, as well as the integration, interoperation and management of multiple source data through advanced artificial intelligence methodology, chart the main ethical coordinates and legal regulations against the backdrop of which the Strategy is set and developed, within the limit of the established knowledge and regulatory base.

When planning actions in this area, we must bear in mind the utmost relevance of the present-day milieu, as well as how the practice shall be adapted to the majority of the population's behaviour. Considering that in the future the vast majority of citizens will dispose of relevant genomic information for the benefit of the community, future users not willing to share this information will be —although, of course, not legally penalised— *de facto* disciplined by society, in the same way that, today, those who refuse to use the Internet are, even though not penalised, actually excluded from its many potential benefits for the community. In the future, people unwilling to share their genomic data will be left out of many public genomic-based health interventions. Therefore, **it is the duty of our Institutions to guarantee an adequate legal-ethical framework allowing for communitarian participation and benefit of all citizens in a fair and safe manner**.

For this reason, it is necessary to design a specific action plan to thoroughly appraise all the relevant details of the proposal, in order to **guarantee an adequate legal-ethical framework**. In this way, the aspiration is to avoid missing the potential benefits that the strategy is expected to bring to citizens, while scrupulously respecting ethical and legal principles alike in order to safeguard the rights of all involved users.

REGULATORY FRAMEWORK

The regulatory framework that grounds the design of the strategy, and, therefore, the basis on which our proposal is founded, is detailed below.

General Framework

The Integrated Personalised Medicine Strategy for the Foral Region of Navarra must be framed according to both scrupulous respect for the rights of the subjects in the bio-sanitary context, and the need to promote a high-quality health system driven by cutting-edge scientific and technological research. This integral approach finds its legal basis in a general regulatory framework, the basic pillars of which are listed below:

- Charter of Fundamental Rights of the European Union.
- Spanish Constitution.
- Organic Law 13/1982, of August 10, on the Reintegration and Improvement of the Foral Regime of Navarra.
- Law 14/1986, of April 25, General Health.
- Law 14/2011, of June 1, on Science, Technology and Innovation.
- Regional Foral Law 10/1990, of November 23, on Health in Navarra.
- Regional Foral Law 15/2018, of June 27, on Science and Technology.
- Resolution 1387/2017, of November 8, of the Managing Director of the Health Service-Osasunbidea of Navarra, which determines the Research Project Registry content and establishes the procedures for accessing clinical documentation for research purposes.

Health data protection regulations

- Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation). Being the most general regulation, it is important to underline that it is based on the so-called “privacy by design”, which requires, before carrying it out, the establishment of measures to guarantee the rights of the subjects and security in the data processing. It provides a flexible framework for the research-oriented use of health data, which must be developed according to the EU members’ regulations. Articles 9 and 89 are especially interesting in this regard.
- Organic Law 3/2018, of December 5, on Data Protection and Guarantee of Digital Rights (LOPDGDD). Cf., in particular, the 17th Additional Provision. It further develops the provisions of the GDPR. The description of the data pseudonymisation procedure in the context of research is particularly relevant.

- Law 14/1986, of April 25, General Health. Modified by the LOPDGDD, it refers to the former with regard to health data regulation.
- Law 41/2002, of November 14, on the basic regulation of patient autonomy and rights and obligations regarding clinical information and documentation. It regulates the use of clinical documentation. It has been modified by the Organic Law 3/2018, on Data Protection and Guarantee of Digital Rights. It is a basic law that has been developed by regional regulations.
- Foral Law 17/2010, of November 8, on the rights and duties of people regarding health matters in the Foral Region of Navarra. Chapter II, Title III establishes criteria for the processing of patient data, with references to the Organic Law 15/1999, of December 13, on the Protection of Personal Data, which must be replaced by the new regulation on data protection. In Chapter III (Rights related to scientific research and experimentation), Title V (Rights regarding party autonomy), a reference to the corresponding regulations for the conservation of samples for research purposes is included. Title VI regulates the rights regarding clinical documentation, in terms similar to those of the basic regulations (article 60 is of particular interest).
- Foral Decree 20/2019, of March 6, approving the data protection and information security policy of the administration of the Foral Region of Navarra and its public bodies. The organizational structure design for information security management is of the utmost importance in the context of data protection and information security policies of the Foral Region of Navarra and its public bodies. This structure is comprised of the following agents: the data controller, the information manager, the service manager, the information security manager, the system manager, the data protection officer, and the Data Protection and Information Security Committee.

Regulations on the carrying out of clinical genetic analyses

- Law 14/2007, on Biomedical Research. Chapter II, Title V regulates clinical genetic analyses and contains some guidelines on the use of genetic data. It partially contradicts some of the aforementioned legislation in regard to the use of health and genetic data for biomedical research (specifically, articles 5, 50.2 and 52.3), incongruities that ought to be fixed, considering that it is in the LOPDGDD where the general regime for the use of data for research purposes has subsequently been developed.

Regulations on biological samples research

- Law 14/2007, on Biomedical Research and Royal Decree 1716/2011, of November 18, which establishes the basic requirements for biobanks authorization and functioning for the purposes of biomedical research and regulates the treatment of human origin biological samples. The use of human samples regime for research purposes regulated in this law contravenes the use of data in research provided for in the LOPDGDD. The use of samples regime is characterized by establishing three options, which combine

greater flexibility in the breadth of consent and transfer possibilities, with the implementation of more demanding procedures for sample management (project, collection, biobank). Although this is not the system being followed in the LOPDGDD, it would be interesting to analyse possible practical confluences, for example, in data transfer procedures.

Regulations on clinical research

If the data are to be used in the framework of **clinical trials with medicines or clinical research with medical devices** (for example, software as an AI tool), the corresponding regulations that incorporate specific procedures must be applied.

- Royal Decree 1591/2009, of October 16, which regulates medical devices.
- Royal Decree 1616/2009, of October 26, which regulates medical devices implantable assets.
- Royal Legislative Decree 1/2015, of July 24, approving the revised text of the law on guarantees and rational use of medicines and medical devices (mainly in relation to advanced therapy drugs and genetic diagnostic products).
- Royal Decree 1090/2015, of December 4, which regulates clinical trials with medicines, Research Ethics Committees with medications and the Spanish Registry of Clinical Trials.
- Regulation (EU) 536/2014 of the European Parliament and of the Council, of April 16 2014 on clinical trials on medicinal products for human use, and repealing directive 2001/20/EC.

REGULATIONS SWOT

In the regulatory area, one of the weaknesses that immediately draws attention is that the legal basis for the development of the Personalised Medicine Strategy is **disjointed, incomplete, and possibly insufficient**. Other determining factors derive from the difficulty of **precisely defining the specific projects** that will be part of the long-term strategy, from the intervention of multiple agents with different objectives, and from the **general misinformation of legal services** in Personalised Medicine related matters.

On the other hand, among the favourable factors it is worth mentioning that there is a **good level of social trust in Navarra's public institutions**. In addition, **Navarra's small size and its level of regional autonomy** favour manageability, debate, and coordination between legal teams, cooperation and consensus among agents, as well as **public participation**.

According to the SWOT analysis, an element to which special attention should be paid is the **public perception of the use of medical data**. On the one hand, it cannot be denied that there is a certain general distrust towards the use of health data in an inappropriate or fraudulent way. Nevertheless, it is also evident that there is a **progressive change in the way society perceives** the possibility of —and even the public duty to— share health data for the benefit of the community, as long as the appropriate institutional warrants are in place.

Other arguments for the analysis are detailed in the following table:

Table 12. Regulations Action Plan SWOT.

Weaknesses	Threats
• Disjointed, incomplete and insufficient legal basis. • Disparity of data sources with different purposes in origin (health, research, sociodemographic). • Difficulties derived from the fact that the long-term PM strategy cannot currently be defined, and the threshold between research and assistance is not clear. • Lack of awareness on the part of researchers and other involved agents about the need to adopt data protection measures from the very design and execution of the treatment in a research project. • Shortage of lawyers with specific knowledge in health and data protection who can support decision-making. • There is no Data Protection Officer in Navarra's Health sector. • Need for ICT infrastructures that guarantee regulatory applicability.	• Citizen distrust towards inappropriate use of health data. • Difficulty keeping up with regulatory changes due to vertiginous evolution of the technical area. • Sensitive nature of some genomic data. • Different interests between agents on regulatory aspects (internal and external voracity for data). • Researchers' resistance to sharing data. • New technologies enable widespread dishonest dissemination of data. • Social pressure for rapid implementation of results. • Possible difficulty in aligning with future national and European regulations. • Use of genetic and non-genetic data of a predictive nature, which makes it difficult to foresee the risks and negative consequences of this use.
Strengths	**Opportunities**
• **Potent Health Sector.** • First-rate, trustworthy, and secure ICT infrastructures under development. • Citizen trust in public institutions. • **Institutional Support.** • Small size and regional autonomy favour manageability, debate, cooperation between agents and coordination between legal teams. • Background regulatory experience in data exploitation for research protocols. • Transparency and participation in the framework of the strategy, which can mitigate the distrust of citizens towards the use of their data.	• Potential pioneering regulation aligned ad-hoc in PM. • Regulation support by patients, researchers, and industry. • Change in public mindset regarding medical data sharing for the benefit of the community, generated by the recent health crisis. • Opportunity for consensus among agents and a forum for public participation. • EU regulation in evolution, linked to changes in PM (1 +MG European Project).

REGULATIONS OPERATIONAL OBJECTIVES (R.OPO)

R.OPO1. Legal-Ethical Framework: Guarantee that the actions carried out within the framework of the Personalised Medicine Strategy, particularly with regard to data processing for the primary and secondary uses described, respect the ethical and legal requirements in force at all times.

KEY ELEMENTS FOR THE ACTION PROPOSAL

A. GUIDELINES FOR THE IMPLEMENTATION OF THE GENERAL PRINCIPLES OF DATA PROTECTION

Article 5 of the GDPR includes a set of principles that represent the **foundation on which the entire regulatory framework** governing processing personal data management is developed. This is also relevant for the application and interpretation of the provisions in the Regulations and other development or sectoral regulations.

Some of these principles are also included in Title II of the LOPDGDD (articles 4 to 10). In addition, article 2 of the Foral Decree, 20/2019, of March 6, approving the data protection and information security policy of the administration of the Foral Region of Navarra and its public bodies, collects 25 principles, some of which are detailed here, while others are projected in other sections of this document (for example, attention to the rights of the people affected).

1. Principle of lawfulness of processing

A. Description and implications

The GDPR establishes that the data processing must be firmly grounded on a legitimate basis, as included in its article 6:

"(a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes; (b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract; (c) processing is necessary for compliance with a legal obligation to which the controller is subject; (d) processing is necessary in order to protect the vital interests of the data subject or of another natural person; (e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller; (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child (Art. 6)."

In addition, when the data being processed falls within special categories (personal data that reveals ethnic or racial origin; political opinions; religious and/or philosophical convictions, or union affiliation; and the processing of genetic data, biometric data targeted at identifying a

natural person, health-related data or information concerning the sexual life or sexual orientation of a natural person), the specific legal bases mentioned in article 9 must concur. In this case, **articles 5, 6 and 9, must be jointly taken into account**.

As mentioned before, health data management must proceed according to **article 9 of the GDPR**, some of whose bases require regulatory support in the corresponding law of the State members or the Union.

The first of the legal bases that should be taken into account is the consent of the interested party, which does not require regulatory development, beyond what is provided in the GDPR itself (article 9.2 a). Consent for the processing of health data must be "explicit" and granted for one or more "specified" purposes. Something relevant in this regard is the scope of consent, and the GDPR accepts "broad" consent: "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose (Recital 33)". Along these lines, the 17th additional provision, letter *a)* of the LOPDGDD determines that consent is granted for research in "general areas linked to a medical or research speciality". Let us also remember that the Law on Biomedical Research allows even broader consents when samples are managed through a biobank (Article 70.2).

On the other hand, letters *g)*, *h)*, and *i)* of Article 9.2 of the GDPR contemplate other legitimizing bases that may be tied to the purposes of the Personalised Medicine Strategy for Navarra. According to the GDPR, the purpose of data management should be of essential public interest (letter *g*); the management of health and social care systems and services, as well as guaranteeing high levels of quality and safety of health care, as well as medicines or health products (letters *h*, *i*). Article 9.2. of the LOPDGDD specifically establishes that the data processing contemplated in letters *g)*, *h)*, and *i)* of Article 9.2 of the GDPR based on Spanish law must abide by a norm with the force of law.

Finally, Article 9.2 *j)* GDPR also refers to the need of regulatory development in order to support data management for the purposes of scientific research, as a legitimate basis. This legal basis has been developed in the LOPDGDD itself (17th AP).

B. Projection towards the Personalised Medicine Strategy

The strategy should identify the legal basis on which data processing is based. If within the framework of the strategy, different treatments are to be carried out with different purposes, different legal bases could be provided for each of them, which should be expressly established.

In the first place, it does not seem appropriate to ground the different data processing included in the strategy on essential public interest reasons as a legal basis, in accordance with the content of **Art. 9.2 *g)* of the GDPR**, since a norm with the force of law endorsing this processing has not been identified. The AEPD referred to this provision in a recent report on the use of facial

recognition systems in online evaluation processes regarding the existence of essential public interest, in accordance with article 9.2.g) of the GDPR:

"(…) the processing of biometric data under article 9.2.g) requires that it be provided for in a standard of European or national law. In the latter case, it must have said norm, according to the constitutional doctrine cited and the provisions of article 9.2 of the LOPDGDD, rank of law. Said law must also specify the essential public interest that justifies the restriction of the right to the protection of personal data and in what circumstances can be limited, establishing the precise rules that make the interested party foreseeable imposition of such limitation and its consequences, without being sufficient, to these effects, the generic invocation of a public interest. And said law shall establish, in addition, the appropriate technical, organizational and procedural, preventing risks of varying probability and severity and mitigate its effects."

Regarding the legal basis included in art. 9.2 *i)*: "Processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy". The truth is that it could be adjusted for the processing that actually responds to said purpose. In our legal system, there is a regulatory provision that supports this legality: article 16.5 and 17.2 of Law 41/2002; Articles 6 and 7 of Royal Decree 1/2015, of July 24, approving the revised text of the law on guarantees and rational use of medicines and medical devices; Articles 18, 69.1 and 95.5 of Law 14/1986, of April 25, General Health; Article 59 of Law 16/2003, of May 28, on Cohesion And Quality Of The National Health System.

On the other hand, as noted before, scientific research as a basis for processing has been developed in the LOPDGDD itself in its further development of article 9.2 *j)* and 89 of the GDPR (AP 17th 2):

"d) The use of pseudonymised personal data for health and, in particular, biomedical research purposes is considered lawful. The use of pseudonymised personal data for public health and biomedical research purposes will require: 1. A technical and functional separation between the research team and those who carry out pseudonymization and keep the information that enables re-identification. 2. That the pseudonymised data are only accessible to the research team when: i) There is an express commitment to confidentiality and not to carry out any re-identification activity. ii) Specific security measures are adopted to prevent re-identification and access by unauthorized third parties. The data may be re-identified at its source, when, as a result of an investigation that uses pseudonymised data, the existence of a real and concrete danger to the safety or health of a person or group of people, or a serious threat to their rights is appreciated, or is considered necessary to guarantee adequate healthcare."

It is important to insist that pseudonymisation is a measure to guarantee data processing and not an operation on the assumption that these data are outside the scope of the GDPR and the LOPDGDD. The pseudonymised data remains linked to a subject that can be identified through a process of associating different data and codes, and, although anonymization is a data processing operation, this differentiates them from irreversibly dissociated or anonymous data, which do go outside the scope of this regulation.

The consent of the interested party can also operate as a legitimating basis for the treatment in a more effective way based on the GDPR, which adopts a more realistically research-oriented conception, in terms of the requirement of specificity, as indicated above. In this line, AP 17th 2, letter a of the LOPDGDD determines that consent is granted for research in "general areas linked to a medical or research speciality", and letter c considers the reuse of data for biomedical research lawful, when the purposes are related to the specific research that provided the basis for the initial specific consent: " In such cases, the controller must publish the information established by article 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, in an easily accessible manner on the corporate website of the centre where the research or clinical study is carried out, and, where appropriate, in the promoter's webpage, and notify the existence of this information by electronic means to those who are affected. When the means to access such information are lacking, they may request its referral in another format. For the treatments provided for in this letter, a prior favourable report from the research ethics committee will be required."

Let us also remember that the Law on Biomedical Research allows even broader consents when samples are managed through a biobank (article 70.2).

In addition, the sixth transitory provision of the LOPDGDD recognises the validity of the consent given prior to its entry into force, in the following terms:

"Sixth transitory provision. Reuse for health and biomedical research purposes of personal data collected prior to the entry into force of this organic law. The reuse of personal data lawfully collected prior to the entry into force of this organic law shall be considered lawful and compatible when any of the following circumstances concur: a) That said personal data is used for the specific purpose for which consent has been given. b) That, having obtained consent for a specific purpose, such data are used for purposes or research areas related to the medical or research speciality in which the initial study is scientifically integrated."

In terms of a strategy based on health and genetic data processing, in relation to this principle **the following questions should be answered**:

- Are different purposes in the data processing going to be considered within the framework of the strategy?
- How will they be differentiated?
- What legal basis will support the data processing?

2. Principle of minimization

A. Description and implications

The **principle of data minimization** is stated in article 5.1. *c)* of the GDPR, which states that personal data will be "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')".

This principle imposes **a first limitation**: before undertaking data processing, the purpose of that processing must be clear (if the purposes of the processing are unknown, it is impossible to know whether the data is adequate, relevant and limited to what is necessary).

Second, the principle requires that the data be **adequate and relevant, meaning that it must serve the purposes for which the processing was intended**. The concept of "limited to what is necessary in relation to the purposes for which they are processed" is a bit more complex. To begin with, it must be borne in mind that it refers to both the number of data and the amount of information it contains. Only the minimum information necessary for the purpose of the processing should be used. That is, it will be necessary to select the data, deleting superfluous information. Besides, it will be necessary to reduce the information they provide to the minimum necessary levels. For example, it will be preferable to create age categories ranging over 10 years rather than one. Likewise, data according to the person's residential neighbourhood will be preferable to classifications in terms of street. Finally, whenever possible, the data must be aggregated, so that the information they convey about a specific person is constrained.

Third, the principle includes a temporary element: **data can only be used for the time necessary to fulfil the purposes of the processing**. That is to say, they must be eliminated as soon as they are not necessary for that particular purpose (either due to being successful or because they have been disregarded). If achieving an end involves multiple stages, data that is not required for successive stages should be removed based on the principle of minimization. If, for example, the purpose of the processing is to develop an AI mechanism, the training data should be destroyed as soon as that stage is finished.

The principle of data minimization is closely related to the principle of "storage limitation", since it determines that the data be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed". It is also related to data protection by design and by default, since art. 25.2 of the GDPR establishes that "the controller shall implement appropriate technical and organisational measures for ensuring that, by default, only personal data which are necessary for each specific purpose of the processing are processed". In its turn, article 89.1 states that the secondary use of data for compatible purposes will always be done ensuring that "technical and organisational measures are in place, in particular, in order to ensure respect for the principle of data minimisation".

B. Projection towards the Personalised Medicine Strategy

In terms of a strategy based on health and genetic data processing, in relation to this principle **the following questions should be answered**:

- Is the data necessary for each processing going to be extracted from the databases that will feed the information system?
- How will it be determined what data is needed at each processing step and operation?
- How will the extraction be done?

- Will the data be processed while maintaining traceability with a specific subject? In all phases of processing? Why?
- Will the data be processed without identifying data? In all phases of processing? Why? How and who will carry out the pseudonymisation?
- How will the time limitation be established and justified at the various processing stages?

3. Principle of transparency

A. Description and implications

Article 5.1.a GDPR states that "personal data shall be processed lawfully, fairly and in a transparent manner in relation to the data subject".

The principle of transparency aims at guaranteeing that **all interested parties are aware of the existence of the processing, as well as of the essential information implied**. The importance of the principle is crystal clear if we bear in mind that, in the GDPR, the interested parties are empowered to be the main custodians of their own rights and freedoms. However, in order to protect themselves against any violation of these rights, it is necessary for the interested parties to be aware that such violation has occurred. In short, without transparency accountability cannot take place. Hence the importance of this principle.

The principle of transparency implies the need to inform interested parties of any processing of their data, whether or not it has been authorized by them. When processing is due to security violations, these incidents must be communicated to the interested parties in case they are known. In order to ensure that this principle is complied with, data controllers may appoint (in some cases it will be mandatory, see article 37 of the GDPR) a Data Protection Delegate, who acts as the single proxy between the data controller and the interested party.

The **Spanish Data Protection Agency** is in charge of supervising that the requirements of applicable regulations are met. In order to facilitate their task, data controllers must comply with requirements directly connected to the principle of transparency (although not only with this principle), such as documentation of the processing, or the preparation of impact evaluations, when applicable.

There are several articles in the **Regulation** that specify requirements connected to the principle of transparency:

- Articles 12 to 14 describe information that the controller of the processing must necessarily communicate to the interested parties.
- Articles 12 to 19 indicate the information that the controller must provide to the interested parties who are willing to exercise one of their rights.
- Article 34 obliges the controller to inform the interested parties of the security violations regarding the interested party's data and whether this implies a risk for them.

- Article 30 describes processing records, and so does Article 35 regarding data protection-related impact evaluations, as well as the information to be provided to the AEPD.
- Article 58.1 specifies how the controller must be transparent towards the AEPD.

It is important to mention that there may be exceptions to the right to information: " When the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, subject to the conditions and safeguards referred to in Article 89(1) or in so far as the obligation referred to in paragraph 1 of this Article is likely to render impossible or seriously impair the achievement of the objectives of that processing. In such cases the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available (GDPR art 14.5 b)". In particular, the LOPDGDD, in its 17th AP, includes a particular assumption, in which the subject is not informed, prior to their consent, of the concrete and specific purpose of the processing (section 2, letter c). In this case, the controller shall publish the information "in an easily accessible manner on the corporate website of the centre where the research or clinical study is carried out, and, where appropriate, on that of the promoter, and notify the existence of this information by electronic means to those who are affected. When they lack the means to access such information, they may request its remission in another format."

B. Projection towards the Personalised Medicine strategy

The information that a subject must be provided with in order to process their data must combine the provisions of the data protection regulations and the requirements of the sectoral regulations. Specifically, for the processing of data for research purposes, a model of an Information Document on the use of clinical records for biomedical research purposes in big data contexts has been proposed and published in the extraordinary issue of 2019 of La Revista de Derecho y Genoma Humano (file: /// C: /Users/bcpnijim/Downloads/numeros_Revista_Genoma_2019.pdf. Please note that this is just an indicative model to register the content of the information processed, and not a Form for signing consent. It is intended to be useful regardless of the basis that legitimizes the processing and, in this sense, it provides information on the exercise of the right to oppose).

In terms of a strategy based on health and genetic data processing, in relation to this principle **the following questions should be answered**:

- Have the necessary protocols been established to ensure that the interested parties are adequately informed about the processing of their data?
- Have they been informed about their rights and how to exercise them?
- Have they been provided with the contact details of the Data Protection Officer?
- Has the need to inform stakeholders of a security breach been adequately anticipated?

- Have treatment registers been set up, and have risk and impact evaluations of the treatments been carried out?
- Is it possible to know at all times who performs each data processing of the interested parties?

4. Principle of purpose limitation

A. Description and implications

Article 5.1.b of the GDPR determines that personal data shall be "collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation')".

The first part of this clause largely reiterates what was already said in letter *a)* of the same article. It is, therefore, the second part that states the aforementioned principle: **data must not be processed for purposes that are incompatible with those for which they were collected**. The fact that the article includes exceptions to this general rule due to research, statistical or archival purposes, should not be seen as an exception to the limitation of the original purpose, but, rather, as an *ex lege* definition of ends that are compatible with those for which the data were originally collected.

To find out whether such purposes are compatible with those expressed at the time the data were collected, it is necessary to refer to **article 6.4 of the GDPR**.

There are **two basic rules**.

- If the original legitimizing basis was consent, insofar as it must be specific. **Only those expressed in said consent will be compatible purposes**, broad consent (although not a "blank" consent); and there exists some leeway of interpretation on what falls within the original consent, though.
- If the original legitimizing basis was other than consent, it is necessary to comply with the provisions of article 6.4, which says that, "in order to ascertain whether processing for another purpose is compatible with the purpose for which the personal data are initially collected", the controller must take into account, *inter alia*:
    - any **link between the purposes** for which the personal data have been collected and the purposes of the intended further processing;
    - the **context** in which the personal data have been collected, in particular regarding the relationship between data subjects and the controller;
    - the **nature of the personal data**, in particular whether special categories of personal data are processed, pursuant to Article 9, or whether personal data related to criminal convictions and offences are processed, pursuant to Article 10;
    - the **possible consequences** of the intended further processing for data subjects;

- the **existence of appropriate safeguards**, which may include encryption or pseudonymisation.

The Working Party of **Article 29** offers further guidance, with examples for the application of these criteria (Article 29 Data Protection Working Party, 00569/13 / EN, WP203, Opinion 03/2013 on purpose limitation, <Adopted on April 2, 2013, https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2013/wp203_en.pdf.

As has been said, data processing for scientific research purposes will be considered compatible with the original purposes for which they were collected. Therefore, scientific research constitutes a legitimate basis for data processing (article 9.2 *j)* of the GDPR), as already explained (section 2.1).

B. Projection towards the Personalised Medicine Strategy

In terms of a strategy based on health and genetic data processing, in relation to this principle **the following questions should be answered**:

- Have sufficient measures been taken to ensure that the data will not be processed for purposes other than those envisaged?
- If data of different origin and with different legitimizing bases are mixed, has it been ensured that the principle of limitation of purposes is strictly complied with?
- In the event that the treatment is considered compatible with the initial purposes because it will be used for scientific research purposes,
- Has the data been pseudonymised?
- Have technical and organizational measures been adopted to guarantee the principle of minimization?
- Have exceptions been established to the rights contemplated in articles 15, 16, 18 and 21, subject to the conditions and guarantees indicated in section 1 of article 89?
- If so, has it been established that the exercise of these rights makes it impossible or if it seriously hinders the achievement of scientific ends, and that these exceptions are necessary to achieve those ends?

5. Principle of accuracy

A. Definition and implications

In accordance with **article 5.1.d of the GDPR**, the data must be "accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy')."

To ensure that this is so, the GDPR confers on the interested parties the **right to rectification** in its article 16, according to which they can claim inaccurate personal data concerning them, without undue delay from the controller. Furthermore, they shall have the right to have their incomplete data completed, even by means of an additional declaration.

The GDPR demands from controllers that the processed data are, in the first place, **accurate**. This, in turn, means that it must be possible **to verify the information** they contain. Therefore, checking data accuracy usually involves verifying the facts underlying the data. To this must be added that the controller must assess whether the data is **up to date** and, if it is not, proceed to update them.

Inaccurate data (including outdated data) must be either rectified or deleted by the controller without delay. In order to know when rectification is required, there are several mechanisms. In the most frequent one, it is the interested party him/herself who requests such modification in accordance with the right granted by the aforementioned article 16. However, two requirements must be first met:

- First, the interested party **must have been informed** of the processing (see articles 13 and 14 of the GDPR) and,
- Second, the interested party **must be granted access to their data** according to article 15 of the GDPR.

Therefore, the principle of accuracy demands that the requirements for the interested party to have accurate information and have access to their data are met.

If the data is collected from the interested party, a **presumption of accuracy** can be made unless the data benefits the interested party. If they come from another source, the controller should verify it, placing special emphasis on detecting inaccuracies when this could harm the interested party. Once the mechanism is activated, the data controller is obliged to check the accuracy of the data and, if they are inaccurate, to rectify them.

When the controller cannot act instantly on a request for rectification because he/she needs time to verify the accuracy of the data in question, it may be necessary to temporarily restrict his processing.

After verifying the accuracy and after proceeding to the pertinent rectification, the controller must inform the interested party in accordance with **Art. 12 (3) of the GDPR**. If the data controller verifies that the data is, indeed, accurate and does not need to be rectified, the interested party must be informed accordingly (**Art. 12 (4) GDPR**).

In the event that the data controller discloses the data to third parties, the recipients must also be informed of any possible inaccuracies (according to **Art. 19 GDPR**). Furthermore, the controllers are obliged to notify the recipients of any rectification, unless it is impossible or requires a disproportionate effort.

B. Projection towards the Personalised Medicine strategy

In terms of a strategy based on health and genetic data processing, in relation to this principle **the following questions must be answered**:

- Has the controller established minimum requirements of accuracy on the data to be used?
- Are measures to verify their accuracy in place when they come from sources other than the stakeholders?

- Has the controller established measures to prevent the interested parties from being harmed by the inaccuracy of the data?
- Have measures been established so that the right to rectification is applied efficiently?
- Have measures been established so that the obligation to notify the recipients in case of rectification is met in accordance with article 19 of the GDPR?
- Is the Data Protection Officer prepared to deal with requests for data rectification?

However, *prima facie*, the right to have inaccurate data rectified or completed does not seem to be of great significance in biomedical research (it may be more relevant, for example, in historical research). Neither is its limitation. Scientific methodology requires accuracy and reliability of information in order to draw sound conclusions, so it will be in the scientists' own interest to demand such accuracy. On the other hand, in terms of other data or conclusions being obtained precisely as a result of research, they may have an uncertain meaning (this is a matter concerning the field of research and not of the greatest certainty required in clinical practice). The inaccuracy of data in scientific research affects less the individual rights of the subject than the rigour of the scientific enterprise in itself.

6. Principle of storage limitation

A. Description and implications

Article 5.1 *e)* GDPR determines that the data shall be "kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed". It is added that "personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation')"; this second provision must be interpreted in accordance with the provisions of article 9 and article 89 GDPR. That is, the corresponding legal basis must be identified and the data processing should be guaranteed to have been carried out accordingly, since storage is a form of data processing. As long as the legal basis for the processing subsists, the data can be kept, unless the interested party requests, if deemed necessary, its elimination, through the corresponding exercise of their rights. There is no maximum storage period.

This principle must be applied in two ways. First, in relation to the databases within the strategy that were obtained for other purposes; second, in relation to the databases that are generated prospectively within the framework of the strategy.

It is important to point out that the data obtained for healthcare purposes should not be kept for purposes other than those that justified its gathering unless the corresponding legal basis for this secondary use exists and is identified.

It could be said that there is a general provision for the lawfulness of clinical data "storage" for purposes other than healthcare, since the law establishes other uses for this documentation, always protected from the exercise of the right of cancellation by the data owner.

According to **Law 41/2002**, the history data shall be kept "for the appropriate time for each case and, at least, five years from the date of discharge from each healthcare process" (article 17.1). In addition, "clinical documentation shall also be kept for judicial purposes in accordance with current legislation. It shall be kept as well when epidemiological, research or organizational and operational reasons regarding the National Health System ensue. Its treatment will be done in such a way as to avoid, as far as possible, the identification of the affected persons" (art. 17.2). In similar terms, article 61.3 of the **Regional Foral Law 17/2010**, of November 8, on the rights and duties of people regarding health matters in the Foral Region of Navarra, determines that "clinical documentation (...) will be kept, likewise, when there are epidemiological, research or organizational and operational reasons regarding the National Health System, in such a way that identification of the affected persons is avoided as much as possible".

However, **storage conditions should be adapted to the provisions of the AP 17th 2 of the LOPDGDD**, since archiving or maintenance (even without use) is a data processing operation.

The Law on Biomedical Research includes specific rules regarding the maintenance of genetic data in the following terms: "1. Personal genetic data will be kept for a minimum period of five years from the date they were obtained, after which the interested party may request their cancellation. 2. If no request is made by the interested party, the data will be kept for the period necessary to preserve the health of the person from whom they come or of third parties related to it. 3. Outside of these assumptions, the data may only be kept for research purposes in an anonymized form, without the identification of the source subject" (article 52). It is important to remember that, faced with this limitation, the development of the regime for the use of data for research in the LOPDGDD contains more flexible provisions that contemplate pseudonymisation, as an applicable guarantee instead of anonymization.

B. Projection towards the Personalised Medicine Strategy

In terms of a strategy based on health and genetic data processing, in relation to this principle **the following questions should be answered**:

- Is there a limited time horizon in the strategy?
- Is the lack of definition of the time horizon justified?
- How is the sustainability of the guarantees ensured?

7. Principles of integrity and confidentiality

A. Description and implications

According to article 5.1 f of the GDPR, data shall be "processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful

processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality')".

The **duty of confidentiality** that corresponds to those in charge of data processing, as well as all the people who intervene in any of its phases, is supplemented with the duties of professional secrecy in accordance with the applicable regulations (article 5 of the LOPDGDD).

In the health field, the professional duty of confidentiality has been developed according to the **Law 14/1986**, of April 25, General Health (LGS), the **Law 16/2003**, of April 28 May, on cohesion and quality of the National Health System (LCCSNS) and in **Law 44/2003**, of November 21, **management of the health professions** (LOPS). Article 10.3 of the LGS states that everyone has the right to "confidentiality of all information related to their treatment and their stay in public and private health institutions collaborating with the public system". The LCCSNS regulates in its Chapter V the health information system in order to guarantee patient information confidentiality (article 56). Article 5 of the LOPS establishes, as a general principle of the relationship between healthcare professionals and patients, the duty to respect their privacy.

In addition, numerous sectoral and specific provisions have been issued, in which the obligation of secrecy is established in specific areas or procedures or biomedical activity (in the management of clinical information, in the development of clinical trials or biomedical research, in the application of assisted reproductive techniques, in organ transplant interventions, in the practice of genetic analysis, etc.). Regarding clinical information, the duty of confidentiality stands out in article 16 of the Law 41/2002, of November 14, regulating patient autonomy and rights and obligations regarding clinical information, and article 60 of the Regional Foral Law 17/2010, of November 8, on the rights and duties of people in matters of health in the Foral Region of Navarra. These articles legitimise, as an instrument for adequate patient care, data access to healthcare professionals from the centre performing the diagnosis or treatment, as well as data access to the administration and management staff in cases related to their corresponding functions.

Data confidentiality implies the duty of reservation, but, as mentioned in the **principle of lawfulness of processing**, it also requires a legitimate basis for data use which, when a purpose other than that which justified the access obtains, this must be specifically identified. This means that access for healthcare purposes does not legitimise the use of data for research purposes. The possibility of accessing history for assistance purposes does not legitimise history access for research purposes either.

Bearing in mind that clinical information is confidential, it must be protected from unauthorized access. There is no mandatory catalogue of applicable security measures. The controller must justify those that are applied, depending on the risks of the processing. They must be technical and organizational.

B. Projection towards the Personalised Medicine strategy

In terms of a strategy based on health and genetic data processing, in relation to this principle **the following questions should be answered**:

- What measures to prevent illegitimate access to information are adopted?
- What measures are taken to ensure the integrity of the data?
- How will the identifiability of people be assessed in the different processing phases?
- What measures are taken to avoid people identifiability or to avoid the consequences of identification?
- Who will be granted access to the databases within the strategy?
- How are pseudonymization or anonymization procedures carried out?

8. Principle of accountability

Article 5.2 GDPR determines that "the controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 ('accountability'). This principle underpins the following obligations for the data controller: **analyse the risk of the processing, keep a record of processing activities, apply the appropriate security measures, notify "data security violations"**, carry out, where appropriate, **impact assessment on data protection, and appoint a Data Protection Delegate**.

It can be said that there are no specific provisions in relation to the development of this principle in the context of Personalised Medicine, although there are some measures that reinforce processing warrants, which originally come from non-binding rules applied to scientific research control. Article 89 of the GDPR determines that "processing for scientific purposes (…) shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner".

Although the principle of minimization and pseudonymisation are mentioned as specific guaranteeing measures in this context, it is important to add others, such as the research review by accredited Research Ethics Committees, as explained in AP 17th 2 of the LOPDGDD. Indeed, the adaptation of these organizational and technical measures to the context of research must take into account good research practices as well as, if applicable, criteria emanating from non-binding regulations. The creation of a committee that controls data access —the so-called Data Access Committee, DACO— (different from the CEI that evaluates projects) and a committee to monitor the ethical and legal aspects of the entire strategy, should be understood as a mechanism that springs from this principle. Due to its characteristics and more generic functions, it does not seem possible to assess whether the Committee for Data Protection and Information Security (attached to the Presidency Department, Public Function, Homeland and Justice) is the ideal body to be involved in these functions.

B. IDENTIFICATION OF THE AGENTS INVOLVED AND THE LEGAL ROLES OF EACH ONE TO ATTRIBUTE RIGHTS AND DUTIES

The processing of personal data implies the participation at some point of various natural or legal persons or other entities in the management of data and files, and in the processing of the data itself.

Internal regulations of the Foral Region of Navarra include within its data protection and security principles those of differentiated responsibility of the various agents that may be involved in the management and processing of files, in such a way that the different responsibilities and roles are demarcated (FD 2019/11, art. 2.11).

Consequently, it will be necessary **to identify the agents involved** in the management of files and data and in the processing of the latter, whose creation and maintenance is considered necessary or mandatory, in order to establish the rights and/or duties that correspond to them in accordance with current regulations, thus being able to determine the measures to be adopted to ensure its fulfilment and observance.

1. The data owner. Exercise of rights

The **data owner** is legally known as the interested party: **the natural person from whom the data are obtained, be them either identified or identifiable**.

Therefore:

i. He/she is a **natural person**.
ii. He/she is an **individual holder** (or several individualizable people): they do not belong to a collective or social group (family or ethnic group), although information may be shared (e.g., of a genetic nature), which implies that we are facing a right of a personal and individual nature. Family members and members of the same ethnic group do not have rights to the data of another family member or member of the group, although they may have legitimate expectations and interests over them, provided that they have been recognized by law.
iii. The **rights of autonomy** (granting consent in the processing of data, in particular, the transfer of data to third parties) and information on the data obtained (e.g., on the development of the research project or its extension; on unexpected findings related to the holder who has given a biological sample; on the most relevant results of the project) can be exercised exclusively by the data owners.
iv. The **development of the rights** of the data owners must be carried out in accordance with current regulations (LOPDGDD, arts. 11 and 12, on general aspects; and on specific rights, arts. 13 to 18). The obliged subject is the controller or, in some matters, the person in charge on behalf of the former.

Special situations

- Regarding **underage people (up to a certain age) and people with limited legal capacities**, the established rules on representation will apply, if their data were to be used for research purposes (LOPDGDD, art. 7, on consent). It is important to define how these people are involved in making decisions about the processing of their data and to

determine how it will be guaranteed that they can exercise their rights once full capacity has been reached or recovered.

- Regarding the **data of the deceased**, although they are excluded from the data protection regulations, (GDPR, cndo. 27 and article 2.2 b of the LOPDGDD), they must be deleted at the request of the next of kin because of family, domestic, or hereditary reasons. In addition, regulations on biomedical research regulate the use of samples from deceased people (article 26 of Royal Decree 1716/2011, of November 18, which establishes the basic requirements for authorization and operation of biobanks for biomedical research purposes and the processing of biological samples of human origin, and the functioning and organization of the National Registry of Biobanks for biomedical research is regulated) and provides for what could be called a "presumption of donation". There is no regulation on the use of deceased people's data for research purposes beyond these provisions.

2. Controller

It is the "natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data" (GDPR, art.4.7; FD arts. 2.11, a and 8).

Regulations do not explicitly clarify whether one or more people can be responsible, but it seems acceptable that there are several ("alone or jointly with others").

It must be publicly identified, with due regard to the communication duties of the AEPD.

It is ultimately responsible for the file, its keeping and guaranteeing respect for the rights of the owners, by itself or by third parties (normally: the controller).

Therefore, it is an inalienable position of legal existence.

3. Processor

i. It is the natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller (GDPR, art. 4.8; FD 2019/11, art. 2.11, b).

ii. It acts on behalf of the controller, without prejudice to his own responsibilities within the scope of his own or delegated powers.

iii. As the immediate person in charge of managing the file, it must be publicly identified.

v. It must comply with the obligations assigned by the law (LOPDGDD, art. 33).

4. Data protection officer

It is the person who informs and advises the controller of the obligations in terms of compliance with the GDPR (FD 20/2019, arts. 2.11 c and 12).

It will be appointed by the controller(s) and its existence is mandatory, among others, in relation to the following activities:

i. **Health centres legally obliged to keep the medical records of their patients**. Health professionals who, despite being legally obliged to maintain the medical records of patients, exercise their activity on an individual basis, are excluded (LOPDGDD, art. 34.1, l).
ii. **Research Ethics Committees (Clinical or with Medicines)** must have a data protection officer or, failing that, an expert with sufficient knowledge regarding Regulation (EU) 2016/679 when they deal with research activities involving the processing of personal data or pseudonymized or anonymized data (LOPDGDD, AP 17th).

5. Authorized user

These users process the data under the direct authority of the controller or processor (ex GDPR, article 4.10).

6. Recipient

A natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not.

However, public authorities which may receive personal data in the framework of a particular inquiry in accordance with Union or Member State law shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing (GDPR, art. 4.9).

7. Third party

A natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data (GDPR, art. 4.10).

The legal concept of third party is not very precise, since it is obtained by exclusion: any person other than one of those listed in the definition of third party.

In conclusion, we can deduce that a third party is any natural person, but also any legal person, or other bodies that do not enjoy this condition (public authority, service or body) that is not the interested party or data owner or is not involved under any legitimate title in the processing of personal data. It is thus alien to the data in question.

8. Other subjects involved in data management or processing in accordance with the regional regime of Navarra

Navarra's regional regulations distinguish other subjects that are not explicitly or accurately defined in the corresponding state or European regulations, but which it is important to take into account, given that said regulations assign them certain specific functions in relation to the management or the processing of the data and the corresponding responsibilities (FD 2019/11, art. 2.11):

i. Person in charge of information: the person who determines the security requirements of the information processed (FD 2019/11, arts. 2.11, d and 8).
ii. Person in charge of the service: the person who determines the functional and security requirements of the services provided based on the information (DF 2019/11, arts. 2.11, e and 9).
iii. Person in charge of information security: the person who determines decisions to satisfy the security requirements (DF 2019/11, arts. 2.11, f and 10).
iv. Person in charge of the system: the person who is responsible for the non-functional requirements and design, construction, operation and support of the information systems used in the provision of services (DF 2019/11, arts. 2.11, g and 11).
v. The Data Protection and Information Security Committee (attached to the Department of the Presidency, Public Function, Homeland and Justice) shall manage and coordinate all activities related to data protection policies and information systems security. (DF 2019/11, art. 13.1)

C. ECONOMIC EXPLOITATION

Several important questions need to be analysed when considering the analysis of the economic exploitation of the data.

1. Types of data

It is of the utmost importance to **distinguish between personal and non-personal data**. Non-personal data is marketable. Regulations on this type of data are based on Regulation (EU) 2018/1807, regarding a framework for the free circulation of non-personal data in the European Union ("Regulation on the free circulation of non-personal data") and the civil or commercial law regulations which are applicable to the sale of goods susceptible to trade. The European Regulation, in fact, not only does not prohibit limitations on the processing of personal data, including its commercial use, but also prevents its restriction by governments.

However, **this clause should not be understood in a broad sense**. It does not seem to cover, for example, the sale of anonymized personal data if its commercialization was not foreseen in the purposes of the processing that gave rise to that anonymization. The principle of **loyalty of processing** should be considered particularly relevant in these cases.

As a matter of fact, **personal data cannot be marketed**, for the simple reason that they are not property objects and the paradigm of economic law does not fit adequately with the GDPR,

which is based on the rights of the interested parties. As is well known, these cannot renounce such rights in exchange for a price. In any case, it would be possible to think of **data transfer agreements** in exchange for a price, which would introduce **figures of co-responsibility and problems of processing supervision**.

Again, however, it is doubtful that transfer for a price of personal data of an interested party who had consented to the transfer without knowing that it would be done in exchange for a price would comply with the principle of legality, loyalty and transparency (Article 5.1.a GDPR).

There are, in any case, intermediate terms, such as the transfer of data in exchange for compensation for the efforts made for the creation, ordering, conservation, etc. of those databases. This issue will be further developed when we discuss sui generis rights in the following sections.

In the event that personal and non-personal data coexist in the databases, it is advisable to consult the **Communication from the Commission to the European Parliament and the Council**, **Guidance on the Regulation** on a framework for the free circulation of non-personal data in the European Union, of 29.5.2019 (COM (2019) 250 final). Prima facie, the applicable regulations in such cases will be the GDPR. For this reason, it is advisable, whenever possible and when it is desired to commercialize non-personal data, to establish a strict separation between them. This should ideally be done the moment they are collected, as the costs of the process can be considerably higher than the potential benefits later on.

2. Sui generis rights

Regardless of whether databases are of one type or another, it is advisable in any case to **protect the rights** corresponding to controllers who wish to obtain some type of economic compensation for their effort through sui generis rights on databases, which can be supplemented with copyright on specific content.

These rights are based on **Directive 96/9 / EC of the European Parliament and of the Council**, of March 11, 1996, on the legal protection of databases (OJ L 77 of 27.3.1996, pp. 20-28). In Spain they are regulated in title VIII of BOOK II. On other intellectual property rights and "sui generis" protection of the databases, see the **Royal Legislative Decree 1/1996**, of April 12, which approves the revised text of the Intellectual Property Law, regularizing, clarifying and harmonizing current legal provisions on the matter. This title was introduced precisely in Article 6 of the **Law 5/1998**, March 6, **incorporating Directive 96/9 / EC, of the European Parliament and of the Council, of March 11, 1996, into Spanish law**, on the legal protection of databases (BOE March 7), in order to properly implement the aforementioned directive.

The sui generis rights of the databases are **rights that protect the substantial investment, assessed qualitatively or quantitatively, made by whoever creates, modifies, maintains**, etc., them, whether through financial means, use of time, effort, energy or other, to obtain, verify or present its content.

By virtue of this right, **the database manufacturer** (*ergo*, the natural or legal person who takes the initiative and assumes the risk of making substantial investments aimed at obtaining, verifying or presenting its content) **may prohibit the extraction and/or reuse of all or one**

substantial part of the content of the database. Since this right can be transferred, assigned or given in contractual license, it is perfectly possible to obtain financial compensation for the effort made.

These rights act independently of the rights that may relate to the data contained in the databases in question. Therefore, **they are compatible with those that correspond to the interested parties**. It is important to remember that the data owners (who, as such, are not subject to economic rights in Europe) are the subjects from whom they were obtained, and they continue to hold the rights recognized in the GDPR and the LOPDGDD.

In any case, it seems necessary to underline that **the mentality of this regulation and that of the GDPR do not seem very compatible**. In fact, it seems as if the GDPR was developed as if the Directive did not exist. Spanish regulations say verbatim (art. 137) that "the provisions of this Title shall be understood without prejudice to any other legal provisions that affect the structure or content of a database such as those relating to copyright or other intellectual property rights, industrial property law, competition law, contract law, secrets, protection of personal data, protection of national treasures or access to public documents".

The use of this figure is, in any case, very useful to ensure the protection of generated databases, which would last in principle fifteen years. However, this term could be extended for successive periods of fifteen years if it is guaranteed that any substantial modification has been made, especially the accumulation of additions, deletions or successive changes that lead to consider that it is a new substantial investment, evaluated from a quantitative or qualitative point of view.

3. Use of the data to solve specific queries

A promising alternative model for using databases may be the **provision of specific services for a fee**. In these cases, **the data are not transferred**, nor is it allowed to access the databases to third parties, but are simply **used to transmit information, solve specific questions, support technological developments**, etc. To give a few examples, the aggregate bases can be used to determine efficiency statistics for the use of combined drugs, the reduction in hospital stay days due to the use of a specific resource, the efficacy of certain genetic markers to diagnose certain pathologies, etc.

They could also, for example, be used to fine-tune artificial intelligence tools, through the use of databases for training. In such cases, the tool should be provided to the Health Service of Navarra, which would be in charge of training or validating it, depending on the service required. In some cases, this could pose some problems, in that some algorithms need to store personal data for their proper functioning. In any case, it would be necessary to exclude this possibility in the contracts drawn up for this purpose, or to be aware that we would be talking about a transfer of personal data to third parties.

ACTION PROPOSAL

The **actions proposed** to cover the operational objectives described for the Regulations strategic axis of the Strategy are based on **3 initiatives**: a **data processing plan**; a **monitoring committee**; and **impact assessment**.

Data Processing Plan (DPP)

A Data Processing Plan (DPP) must be designed so that a series of questions are answered. This information is essential to lay out the legal requirements for a specific processing, depending on the decisions made.

The Data Processing Plan must be a framework developed within the strategy itself during its deployment phase based on a detailed analysis of the answers to a series of key questions about the data management pursued by the strategy:

- Are different purposes in the data processing going to be considered within the framework of the strategy?
- How will they be differentiated?
- What legal basis will support the data processing?
- Is the necessary data for each processing going to be extracted from the databases that will feed the information system?
- How will it be determined what data is needed at each processing step and operation?
- How will the extraction be done?
- Will the data be processed while maintaining traceability with a specific subject? In all phases of processing? Why?
- Will the data be processed without identifying data? In all phases of processing? Why? How and who will carry out the pseudonymisation?
- How will the time limitation be established and justified at the various stages of processing?
- Have the necessary protocols been established to ensure that stakeholders are adequately informed about the processing of their data?
- Have they been informed about their rights and how to exercise them?
- Have they been provided with the contact details of the Data Protection Officer?
- Has the need to inform stakeholders of a security breach been adequately anticipated?
- Have treatment registers been established and have risk and impact assessment of the processing been carried out?
- Is it possible to know at all times who performs each data processing of the interested parties?
- Have sufficient measures been taken to ensure that the data will not be processed for purposes other than those envisaged?
- If data of different origin and with different legitimising bases are mixed, has it been ensured that the principle of limitation of purposes is strictly complied with?
- In the event that the processing is considered compatible with the initial purposes because it will be used for scientific research purposes, has the data been pseudonymised?

- Have technical and organizational measures been taken to guarantee the principle of minimization?
- Have exceptions to the rights contemplated in articles 15, 16, 18 and 21, subject to the conditions and guarantees indicated in section 1 of article 89 been established?
- If so, has it been established that the exercise of these rights makes it impossible or seriously hinders the achievement of scientific ends and that exceptions are necessary to achieve those ends?
- Has the data controller established minimum requirements for accuracy on the data to be used?
- Are measures in place to verify their accuracy when they come from sources other than the stakeholders?
- Has the controller established measures to prevent interested parties from being harmed by the inaccuracy of the data?
- Have measures been established so that the right to rectification can be applied efficiently?
- Have measures so that the efficient application of the obligation to notify the recipients of the rectification of data in accordance with article 19 GDPR been established?
- Is the Data Protection Officer prepared to deal effectively with requests for data rectification?
- Is there a limited time horizon in the strategy?
- Is the lack of definition of the time horizon justified?
- How is the sustainability of the guarantees ensured?
- What measures are adopted to prevent illegitimate access to information?
- What measures are taken to ensure the integrity of the data?
- How will the identifiability of people be assessed in the different phases of processing?
- What measures are taken to avoid the identifiability of persons or to avoid the consequences of their identification?
- Who will access the databases within the strategy?
- How are pseudonymization or anonymization procedures carried out?

The **essential questions to be answered by the DPP** are shown in the diagram below (green shapes).

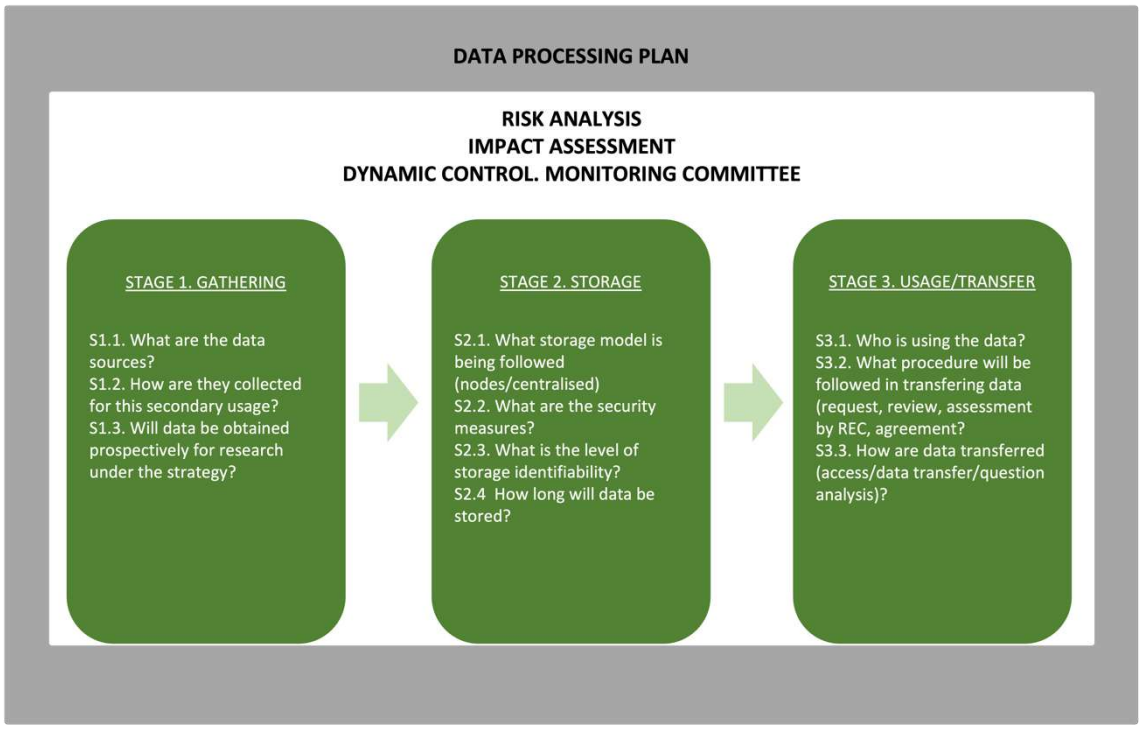


Figure 9. Data Processing Action Plan Diagram.

This DPP may be the basis for preparing the impact assessment provided for in **article 35** of the GDPR.

On the other hand, the DPP must be an **open and dynamic document**, and must therefore be periodically reviewed, so that changes in the strategy are incorporated. An advisory entity should be identified for updating and review, a function that could correspond to a Monitoring Committee (SC of the DPP).

This diagram must be integrated into a **data circuit**. It has a return required by the regulations relating to biomedical research, beyond the right to data protection: the right to know the results of the research that are relevant to health (articles 4.5 and 26 of the Law on Biomedical Research) and the right to know the overall results of the investigation (article 27 of the LBR).

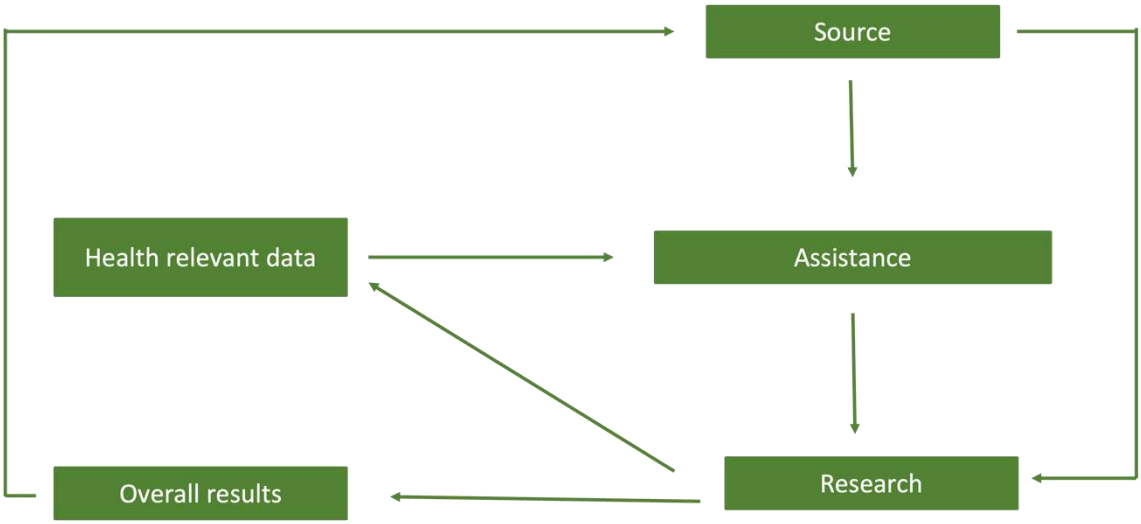


Figure 10. Data Circuit Diagram.

This plan exceeds the provisions made in the **Resolution 1387/2017**, of November 8, of the Managing Director of the Health Service-Osasunbidea of Navarra, which determines the content of the Research Projects Registry and establishes the procedures for access to clinical documentation for research purposes. Indeed, this resolution regulates, on the one hand, the registration of projects and, on the other, the use of data for research purposes. This activity is contemplated either from an "individual" or by a project perspective (not as a global strategy), thus establishing procedures that concern the researcher in all the processing stages, as well as in the data collection, in the duty to inform the data owner if this were the legal basis. In sum, the Resolution should be reviewed.

On the other hand, the **Data Protection Officer** is a key figure in the design and application of the DPP. It should be assured that the person who performs this function knows the legal system applicable to this sector (data processing in the framework of health care and research). According to the objectives and the key elements identified in the previous sections of this chapter, the Action Proposal for the Personalised Medicine Strategy of Navarra must be articulated around a Data Processing Plan.

TABLE 13. REGULATIONS ACTION PLAN SUMMARY

Operational Objectives		Lines of Action		Actions	Suggested indicators
R.OPO1	**Legal-Ethical Framework**	**R.LA1**	**Data Processing Plan (DPP)**	Develop a Data Processing Plan with the following components: • **Data processing lawfulness** - Identify the data sources and the legal ground(s) for management in the context of the strategy. - Identify those people in charge and other subjects involved in data management. • **Minimization** - Determine the amount of data to be kept for the purposes of the strategy. - Prepare a model request form to access databases and a model agreement form for the data transfer by researchers. - Establish the application, review, approval and access protocol. • **Transparence** - Prepare documentation to inform citizens in general and patients in particular about data management in the strategy. - Provide a protocol for deceased people's data management. - Provide a protocol for underage people's data management. - Provide mechanisms to ensure transparency and exercise of rights by citizens. - Prepare documentation models for exercise of rights. • **Purpose limitation** - Identify the strategy's and data management's purpose(s). • **Accuracy** - Verify data accuracy. • **Limitation of the conservation period** - Establish a relationship between terms and purpose. • **Integrity and confidentiality** -Identify or establish security measures for data mining, filing and flow. • **Proactive accountability** - Prepare an impact evaluation of data processing. - Appoint a Health Data Protection Delegate. - Prepare agreements for data flow between institutions including, where appropriate, the person in charge of the data management.	• Data Processing Plan
		R.LA2	**Regulatory Frameworks Revision**	• Regional Regulation Adaptation	• Proposal
		R.LA3	**Monitoring Committe**	• Monitoring Committee	• Monitoring Committee

EDUCATION & TRAINING

ACTION PLAN

4.3.3. EDUCATION & TRAINING

FACT SHEET

EDUCATION & TRAINING

Operational Objectives		Lines of Action		STRATEGIC AREAS		
				Healthcare	R&D&I	EBD
ET.OPO1	Education & Training Map	ET.LA1	Education & Training Map	●	●	●
ET.OPO2	Degree Education	ET.LA2	Degree Education	●	●	●
ET.OPO3	Healthcare Science Specialists	ET.LA3	Healthcare Science Specialists	●		
ET.OPO4	Postgraduate Education	ET.LA4	Postgraduate Education	●	●	●
ET.OPO5	Lifelong Training	ET.LA5a	Lifelong Training of Healthcare Professionals	●		
		ET.LA5b	Lifelong Training of Other Professionals	●	●	●
ET.OPO6	Vocational Training	ET.LA6	Vocational Training	●	●	●

INTRODUCTION

The Integrated Personalised Medicine Strategy for Navarra proposes important changes in the fields of healthcare, research and economic development that **will require adaptations of professional profiles** and curricula in order to bring about **a new generation of healthcare providers who are informed, skilled, committed and responsible**.

Some of the professional profiles required to advance the Strategy are either already in place or are evolving within the system and must be encouraged and consolidated for the development of the project. Other existing profiles, however, need to be reoriented in terms of education and training in order to cover the needs of the strategy, while there is a definite lack of some profiles in our region. Despite this, with a time horizon of up to 2030, a brilliant opportunity is opening up to introduce an educational continuum at different levels, aimed at covering the training and educational needs in the area for the performance of professional practice and the promotion of research projection.

Framework for Personalised Medicine Education & Training

The *European Higher Education Area* (EHEA) is a project promoted by almost all the countries of the Union, which is the ideal framework for the acquisition of the necessary skills for this Personalised Medicine Strategy. Its main purpose of **developing a process of convergence and reinforcement of higher education in Europe** is in line with various initiatives that the European Commission and the member countries of the Union are carrying out to build a Europe of knowledge. In this sense, the European institutions are working on what is known as a European

Research Area, which will enable Europe to become a continent where research and development are its pillars. In Spain, the Royal Decree 1393/2007 of 29 October on the *Planning of Official University Education* establishes a new three-level degree structure (bachelor's, master's and doctorate) in accordance with the EHEA model, and allows universities to create and propose, in accordance with the established regulations, the courses and degrees to be taught and issued. Furthermore, this decree makes the organisation of university education more flexible, promotes curricular diversification and allows universities to make the most of their capacity for innovation, their strengths and opportunities.

The **training of Health Science Specialists** is regulated in Spain by Law 44/2003, of 21 November, on *Regulation of health professions*, and Royal Decree 183/2008, of 8 February, which *determines and classifies specialities in Health Sciences*. It grants the *Directorate-General for Vocational Management of the Ministry of Health and Consumer Affairs* the power to make proposals for the organisation of health professions, management of specialised training in health sciences and professional relations, supporting the plenary session of the *National Health System's Human Resources Commission* in this area. This Commission is currently working on the draft of a new royal decree that will develop the areas of specific training and regulate the procedure for new specialist qualifications based on the population's increasing demand for healthcare or the evolution of scientific knowledge and techniques. It should consequently reflect the changes introduced in the healthcare practice by new developments such as Personalised Medicine. On the other hand, the *Mandatory Common Transversal Training Programme for Specialised Healthcare Training* is the training organised by the territorial education commissions to complement the specific programmes of each speciality, allowing for the standardisation of transversal healthcare training in Navarra, and is therefore an agile and versatile tool for including specific training content for residents in the region, as are the Lifelong Learning activities accredited by the *Commission on Continuing Education of Health Professions in Navarra*.

Vocational Education and Training is regulated by *RD 1147/2011*, of 29 July, which establishes the *general organisation of vocational education* and training in the education system and *DF 54/2008*, of 26 May, which *regulates the organisation and development of vocational education and training in the education system of the region of Navarra*. Vocational Education and Training provides training for the qualified performance of different jobs and access to employment. It also represents an excellent opportunity to train specific support roles for the development of Personalised Medicine.

Sources:

1. RD 1393/2007 Planning of Official University Education. *https://www.boe.es/buscar/pdf/2007/BOE-A-2007-18770-consolidado.pdf*
2. Ley 44/2003, on the Regulation of health professions. https://www.boe.es/eli/es/l/2003/11/21/44/dof/spa/pdf
3. RD 183/2008, classification of specialities in Health Sciences. https://www.boe.es/boe/dias/2008/02/21/pdfs/A10020-10035.pdf
4. DF 54/2008 Vocational education and Training in Navarra. http://www.lexnavarra.navarra.es/detalle.asp?r=29651

EDUCATION & TRAINING ACTION PLAN SWOT

There are several factors that determine the action plan for education and training in order to develop Personalised Medicine in our Community. The **general lack of information** among healthcare professionals in areas related to **Personalised Medicine, Digital Health and data protection regulations** is noteworthy, linked to the accumulated lack of training at undergraduate, postgraduate and lifelong training levels. However, these limitations are also undoubtedly **affected by overworked Health Care staff and the lack of consideration of these skills in the official curricula of both Specialised Health Training and postgraduate programmes**, to which must be added the absence of **training and professional itineraries oriented towards Personalised Medicine, and the deficient inclusion of professional training profiles in some tasks**.

However, on the other hand, it is particularly favourable to have **strong educational offerings in health sciences and technical degrees** in our region, some of them having programmes in development phase that facilitate the introduction of new contents; the **adaptability of the Mandatory Common Transversal Training Programme for Residents** (Medical Intern *MIR*, Pharmacology Intern *FIR*, Biology Intern *BIR*, Nursing Intern *EIR*, Radiophysics Intern *RIR*, Clinical Psychology Intern *PIR*, and Chemistry Intern *QIR*) and **mentors in Specialised Healthcare Training**; as well as the existence of **qualified providers** and coordination elements such as the **Teaching Plan and the Training Plan coordinated by all centres**, which make the design of lifelong training aligned with the Strategy viable.

On a more general level, the opportunities offered by elements such as the **Spanish Government's Action Plan for Science and Innovation**, presented in July 2020, are attractive, which, specifically as measure 3 of its key axis 1 "Research and Innovation in Health" proposes "Launching a Spanish Strategy for Personalised Medicine", with a specific section and budget for an **Education and Training Plan in Precision Medicine**; the plan to amend the Royal Decree whereby "transversal" training in health science specialities, the areas of **specific training** and the procedure for creating specialist degrees are regulated; instruments such as **specialisation diplomas, master's degrees and non-official degrees** that have a place within the new European Higher Education Area; and **internationalisation and specialisation programmes in vocational training**.

Table 14. Education & Training Action Plan SWOT.

Weaknesses	Threats
• Lack of knowledge, lack of training and saturation of healthcare professionals (in clinical PM/ e-health/ MP research/ entrepreneurship). • Lack of professional organisation in PM related subjects. • Lack of training itineraries linked to PM and e-health. • Scarcity of MP content in current undergraduate and postgraduate curricula. • Atomised and unfocused continuing training in MP subjects. • Insufficient inclusion of vocational training in MP and e-health support tasks.	• Lack of the Speciality on Clinical Genetics in the Specialised Healthcare Training programme. • Absence of MP content, e-health and regulations in speciality curricula. • Scarce offer of related university and higher vocational training degrees. • Postgraduate training on offer not specific for PM. • Lack of suitable training profiles for PM. • "Brain drain".
Strengths	**Opportunities**
• Strong training offer in university degrees and vocational training in Health Sciences and Technical. • Related university degrees under development or newly created. • Transversal Training Programme for residents and Specialised Healthcare Training mentors. • Postgraduate maps UPNA and UNAV under review. • A system for the planning, evaluation and knowledge management, Teaching Plan and coordinated Education & Training plan. • Institutions and providers of Continuing Learning: FUS, CIMA, NBM, IdisNA, associations, professional associations. • ESTNA, Integrated Vocational Training Centre of Navarra.	• Royal Decree on new specialities in Health Sciences under review. • National Health System (*SNS*) HR Commission and Interterritorial Health Board. • Undergraduate teaching instruments: optional subjects, specialisation diplomas, mentions. • Postgraduate teaching instruments: official master's degrees, doctoral programmes, non-official degrees. • Internationalisation programmes. • Vocational Training specialisation programmes.

EDUCATION & TRAINING OPERATIONAL OBJECTIVES (ET.OPO)

ET.OPO1. Training and Development map: Organise the training of professionals in Personalised Medicine.

ET.OPO2. Undergraduate training: To train graduates with solid competencies, capable of undertaking the complementary training and professional tasks necessary for Personalised Medicine.

ET.OPO3. Specialists in Health Sciences: To train specialists in Health Sciences with advanced health competencies specialised in Personalised Medicine.

ET.OPO4. Postgraduate training: To train professionals with advanced technical competencies, orientated towards the complementary and multiprofessional environment in Personalised Medicine.

ET.OPO5. Lifelong Learning: To update and improve the knowledge, skills and attitudes of healthcare and non-healthcare professionals towards the scientific and technological evolution of Personalised Medicine.

ET.OPO6. Vocational Training: To train higher-level professionals capable of undertaking complementary tasks for Personalised Medicine.

PROPOSED ACTIONS

Subjects

A strong **need for complementary training** in subjects such as e-health and the skills to correctly integrate, interpret and communicate complex biological information is foreseeable in healthcare professionals. In addition, there is a need to incorporate new areas of knowledge such as **bioinformatics and data science** for the integrated analysis of the vast amounts of multi-source biomedical data generated, which are available during the provision of medical care and analysis results, as well as other areas such as the **use of ICT, or the regulatory issues and ethical principles** governing the appropriate access and use of all available information for the benefit of the community. A solid basic training in the critical appraisal of scientific evidence and research methodology shall be a must too.

Highlights in Education & training for Personalised Medicine:

- Genomics and multiomics.
- ICTs and e-health.
- Bioinformatics.
- Data Science
- Ethical/legal regulations and data protection
- Assessment of scientific evidence.
- Research Methodology

Organising professional profiles and responsibilities

In most places, the challenges posed by genomics and big data clinical interpretation are transforming medicine. As a result, health systems need to develop Human Resources plans and strategies that are adapted to the new healthcare models. Many initiatives have identified the need for an audit or assessment of the roles and skills that will be needed in the future, as well as the outline of current training resources. This is usually followed by the **development of new education and training programmes and resources** at different levels, from experts to users, and aimed at different groups. In this context, the value of complementarity and multidisciplinarity in the practice and decision-making in healthcare, incorporating professionals from different backgrounds, will undoubtedly be greatly promoted.

Table 3. Professional profiles and responsibilities.

Profiles	Responsibilities
Genetic Counsellor	Pre- and post-test genetic counselling.
Consultant Clinical Geneticist	Organisation and clinical interpretation of genomic tests.
Genomic Lab Specialist	Designing omics techniques and result analysis.
Trained Specialist Physician	Clinical management of results.
Bioinformatics Engineer	Programming/adaptation of bioinformatics pipelines.
e-health Specialist	Designing health information systems projects.
Computer/Telecoms/biomedical Engineer	Implementing projects for adapting infrastructures and systems.
Data Scientist	Data strategy design.
Health Data Protection Lawyer	Multi-omics and integrated data protection.
Lab Technician (genomic profile)	Lab techniques.
Bioinformatics Technician Specialist	Maintenance of bioinformatics pipelines.
Data Management Technician	Maintenance and management of biomedical data.

Training and Development map

A wide variety of approaches have been suggested for the origin and training pathway of the future Personalised Medicine professionals. These may come from different university degrees or vocational training; through official training programmes in the health professions, master's degrees, specialisation courses, doctorates and refresher courses; and starting from established programmes, under development, under revision, or even new proposals, guaranteeing, as far as possible, a training continuum from the end of schooling to training and specialisation in personalised medicine. A **possible Training and Development map with the origin and pathway** is shown below:

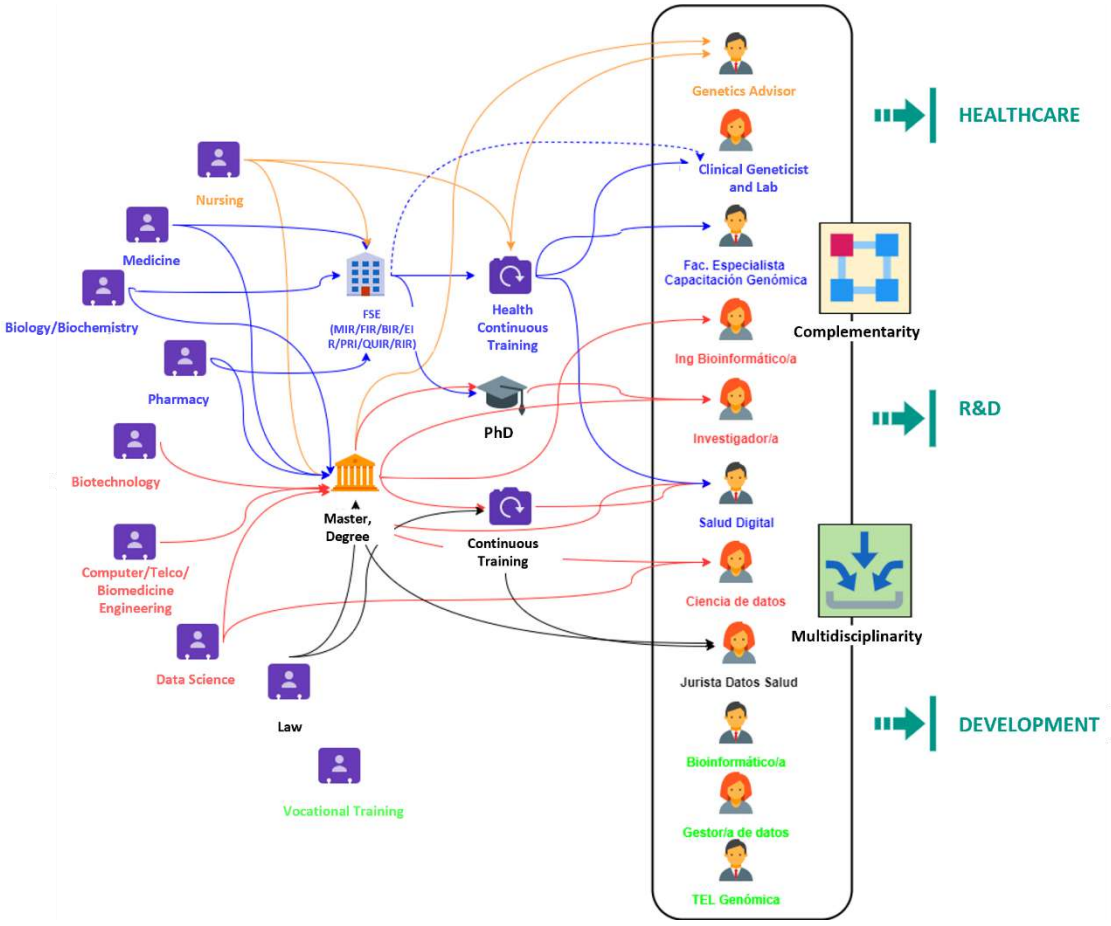


Figure 11. Training & Development map.

Given the rapid turnover of technologies and their potential impact on healthcare, **continuous and Lifelong learning** related to this area will also be essential for all healthcare professionals. Moreover, digitally experienced professionals will have a better understanding of health personalisation alternatives and clinical problems from different approaches, making clinical interactions and integration in professional teams with different backgrounds easier. Finally, this new approach will need to extend to managers and health policy makers, and not leave out legal departments and data protection officers, so that the potential benefits can be quickly and fully passed on to the patient.

Lines of action

There are different **levels of education and training** that will contribute to consolidating capable professionals in the Personalised Medicine of the future. Thus, the actions proposed to achieve the objectives described in this strategy should be divided into different lines of action. Regarding **undergraduate training**, it is recommended to reinforce the contents of related studies by means of optional subjects, cross-cutting subjects, specialisation diplomas or mentions, and proposing new degrees. With regard to **official, specialised health training programmes**, it should be pointed out that Spain is the only country in the European Union where the speciality of clinical genetics has no official recognition, so actions have been submitted in order to address this deficit by supporting the creation of this speciality, reinforcing

general competencies in Personalised Medicine for all residents, and in particular for some specific specialities, by the competent bodies, and introducing new specific content in the Common Compulsory Cross-curricular Training Programme at the accredited teaching centres in Navarra. Another notable shortcoming in this area is the **lack of training pathways for e-health and health information systems**, where qualified professionals are scarce and in great demand. This is the reason why proposals have been put forward to reinforce this area of education and training from different perspectives. Regarding postgraduate training, some projects on new master's programmes and non-official degrees are planned to be launched. These suitably complement the educational profile and enable professional practice, as well as encourage doctoral thesis. There are also plans to reinforce regulated and non-regulated Lifelong learning for health and non-health professionals through courses, activities, workshops, seminars, scientific meetings, clinical sessions, etc. Finally, it is evident there is a **need to train support professionals** for the main tasks described in the strategy through the specialisation of advanced vocational education and training on health and technical vocational training.

TABLE 15. EDUCATION & TRAINING ACTION PLAN

Operational objectives		Lines of Action		Actions	Suggested indicators
ET.OPO1	**Education & Training map**	**ET.LA1**	**Education & Training map**	• To establish a training and development map of professional profiles in PM.	• Map
ET.OPO2	**Undergraduate Education**	**ET.LA2**	**Undergraduate Education**	**Established degrees** • Reinforce PM contents in Medicine, UNAV. • Reinforce PM contents in Nursing, UPNA/UNAV. • Reinforce PM contents in Biochemistry, UNAV. • Reinforce PM contents in Biology, UNAV. • Reinforce PM contents in Pharmacology, UNAV. • Reinforce PM contents in Nutrition and Dietetics, UNAV. • Reinforce Computer Engineering and Telecoms. • Reinforce PM contents in Law, UPNA/UNAV. **Degrees being developed** • Reinforce PM contents in Medicine, UPNA. • Reinforce PM contents in Biotechnology, UPNA. • Reinforce PM contents in Biomedical Engineering, UPNA/UNAV • Reinforce PM contents in Data Sciences, UPNA. **New degrees** • Explore new (innovative) degree in Genomics and PM. • Explore new dual degrees. • Explore open degrees in PM.	• Optational subjects. • Specialisation Diplomas. • Specific credits on PM. • New degrees.

Operational objectives		Lines of Action		Actions	Suggested indicators
ET.OPO3	**Specialists in Health Science**	**ET.LA3**	**Specialists in Health Science**	• Propose new PM content for specific Official Specialised Healthcare Training Programmes. • Propose new and specific transversal PM content in all Specialised Healthcare Training Programmes. • Support the creation of the Speciality in Clinical Genetics. • Introduce new specific transversal PM content in Specialised Healthcare Training Programmes at accredited centres in Navarra. • Propose an Internationalisation programme (Erasmus-MIR) with specific transversal PM content in Specialised Health Care Training Programmes in accredited centres in Navarra.	• Proposal to the Spanish National Health System HR Commission, via the DG for Professional Organisation via the Interterritorial Health Council. • Proposal for a new Royal Decree on Specialised training, via the Interterritorial Health Council. • Modification of the Transversal Training Programme. • Grants from the Dept. of Health for Internationalisation Programmes in PM.
ET.OPO4	**Postgraduate Education**	**ET.LA4**	**Postgraduate Education**	• Increase the offer of non-official degrees related to PM (Bioinformatics, genetic counselling, Big Data Health, Regulations and Data Protection, etc.). • Propose a specific Doctorate Programme on PM. • Promote the development of doctorates related to PM.	• New master's degree. • New non-official degrees. • New doctoral programmes. • Doctoral thesis on PM.

Operational objectives		Lines of Action		Actions	Suggested indicators
ET.OPO5	**Continuous Learning**	**ET.LA5a**	**Continuous Learning for Healthcare professionals**	• Include PM as part of the Preferential subjects in Continuing Education. • Incorporate PM into the Health and Health Centres Teaching Plan. • Incorporate PM into the Health Plan. • Subsidise the provision of PM courses. • Promote PM training agreements. • Promote figure vectors from PM training in Medical Services.	• Proposal to the Spanish National Health System HR Commission, via the DG for Professional Organisation, via the Interterritorial Health Council. • Proposal for a new Royal Decree on Specialised training, via the Interterritorial Health Council. • Modification of the Transversal Training Programme. • Grants from the Dept. of Health for Internationalisation Programmes in PM.
		ET.LA5b	**Continuous Learning for other professionals**	• Promote PM Continuing Learning Activities.	• PM Continuing Learning Activities: courses/workshops/ seminars/scientific meetings.
ET.OPO6	**Vocational education and training**	**ET.LA6**	**Vocational education and training**	**Especialización advanced vocational education and training** • Specialisation in genomic laboratory and PM (in Clinical and Biomedical Laboratory; in Pathological Anatomy and Cytology). • Bioinformatics (in Computer Systems Administration). **New advanced vocational education and training** • Health Documentation and Administration. • Radiotherapy and Dosimetry. • Production of Pharmaceutical, Biotechnological and related Products.	• Speclialisation Programmes. • Offer Dual advanced vocational education and training courses.

COMMUNICATION & PARTICIPATION

ACTION PLAN

4.3.4. COMMUNICATION AND PARTICIPATION

FACT SHEET

COMMUNICATION AND PARTICIPATION

Operational Objectives		Lines of Action		STRATEGIC AREAS		
				Healthcare	R&D&I	EBD
CP.OPO1.	Consistency and alignment of expectations	CP.LA1.	Consistency and alignment of expectations	●	●	●
CP.OPO2.	Positioning	CP.LA2.	Regional positioning and European collaborations	●	●	●
CP.OPO3.	Public awareness	CP.LA3.	Public awareness	●	●	●

INTRODUCTION

The Government of Navarra is committed to promoting an **Integrated Personalised Medicine Strategy** in order to position Navarra at the forefront of Innovation in Healthcare. To ensure its correct development, it is necessary to design a **Communication and Participation Plan** which, as well as providing and disseminating information, will spark the public interest, making them feel involved in the process and, in short, proud that this type of initiative is being implemented in Navarra.

Communication is a key tool for the promotion of this strategic plan by publicising and demonstrating the benefits of integrating Personalised Medicine into the Navarra Health System, an opportunity for **more efficient, high-quality Medicine**. Raising public awareness regarding the importance of being at the forefront of innovation through the integration of Personalised Medicine in the field of healthcare is a complex task. It involves a series of critical steps such as the concept perception, process transparency and the involvement of different agents through their unconditional commitment to this **unique, stable and transversal public strategy**.

The **participation** by all in political, economic, cultural and social life is an essential principle that is necessary to guarantee real and effective **freedom and equality**. On a strictly political level, this leads to the need to complement representative democracy with forms and modes of government in which **transparency and participation** are key instruments.

In Navarra there are two laws that reflect the principles of Open Government (transparency, participation and citizen collaboration) and they are the **"Foral Law 5/2018, of 17 May, on**

Transparency, access to public information and good governance" and the **"Foral Law 12/2019, of 22 March, on Democratic Participation in Navarra"**.

Greater participation is the ideal path to achieve the goal of making citizens feel heard by their Government and Administration, resulting in effective and quality collective decision-making in terms of current and future public policies and services. That is why increasing the involvement of citizens in administrative and governmental decisions and actions is necessary in order to reach solutions to solve society's complex problems.

In this chapter, the **aim** of this strategy is to publicize the actions carried out in the Integrated Personalised Medicine Strategy in Navarra, focusing especially on informing the public about the activities supported by the Government of Navarra.

For this reason, it is necessary to organise and systematise a series of communication and participation actions that address the different points that make up the strategic plan over the coming years.

The different parts of this chapter are described below:

- ✓ Definition of the Target Audience Map
- ✓ Planning of the strategy: Operational objectives, Lines of Action and Actions
- ✓ Impact assessment: Indicators
- ✓ Summarising Chart

COMMUNICATION & PARTICIPATION ACTION PLAN SWOT

Table 16. Communication & Participation Action Plan SWOT.

Weaknesses	Threats
• Lack of knowledge of the PM Plan in Navarra. • Non-existence of a single entity or person in charge to be addressed. • Absence of specific actions for Citizen Participation. • Lack of coordination between the different departments involved in the PM Plan. • Non-existence of an agenda of specific PM events and communications.	• Risk of duplication of actions and spending. • Lack of knowledge in PM. • Dispersion in coordination and delay in planning and monitoring due to a lack of clear leadership. • Changes in the environment. • Duplicated activities. • Latent social conflicts.
Strengths	**Opportunities**
• Qualified, multidisciplinary team. • Good relationship with regional and national media. • Low, initial investment required. • Members of several functioning EU networks providing high visibility and networking. • Support from GN (political commitment).	• Wide acceptance of ICT and social media, a great space that provides the possibility of raising the visibility of the PM Plan. • Raising public awareness regarding the importance of science/health for improving their quality of life. • To promote Navarra as a region specialising in PM. • Untapped potential in the media and social media.

TARGET AUDIENCE MAP

TARGET AUDIENCE MAP

One of the first steps to be taken is to determine the different groups that make up the target audience.

Figure 12. Target audience map.

COMMUNICATION & PARTICIPATION GOALS (CP.OPO)

CP.OPO1. Consistency and Alignment of Expectations

To guarantee the exchange of information and communication between professionals, who will perceive Personalised Medicine as a professional aspect (healthcare professionals, researchers, teachers, entrepreneurs, etc.), and those who are responsible for the execution of the Personalised Medicine strategy in order to consolidate and integrate Personalised Medicine in Navarra from different perspectives.

CP.OPO2. Positioning

To turn Navarra into a benchmark in Personalised Medicine at a European and international level, to increase its capacity for international relations and its resources obtained outside the region.

CP.OPO3. Public awareness

To integrate the wishes, detected needs and risks declared by the non-professional public that could hinder the implementation of Personalised Medicine. To open a conversation with people who are not familiar with it by delivering a clear message that allows this strategy to be perceived as a public strategy promoted by the Government of Navarra.

LINE OF ACTION

This section sets out the following 3 lines of action, based on the target audiences they are aimed at:

- **CP.LA1**. Consistency and alignment of expectations
- **CP.LA2**. Regional positioning and European collaborations
- **CP.LA3**. Public awareness

ACTIONS

Different actions have been defined, specific to Communication and Participation, grouped in the suggested three Lines of Action in order to contribute to consolidate this integration of Personalised Medicine as a stable and transversal strategy, allowing to fulfil the objectives established.

1. CP.LA1. Consistency and alignment of expectations

The actions to be taken in this line of action consist of two types:

- **Structural Actions**
  - Creation of a specific website for the Personalised Medicine strategy.
  - Map of people in charge (coordination and supervision)
  - Register of services, units/departments, labs, professionals involved in Personalised Medicine.

- **Operational Actions**
  - Organisation of activities designed to bring the importance and benefits of Personalised Medicine in Navarra closer to professionals from the areas of Health, R&D&I, Education and training, etc.

Healthcare professionals (different services at CHN; Reina Sofía de Tudela Hospital, García de Orcoyen Hospital, CUN)	**PM Professional presentations, PM seminars, case study videos: testimonial patient/family**
Professionals R&D&i (Navarrabiomed, CIMA, UPNA, UNAV, businesses, *startups*)	PM Professional presentations
Education and Training professionals (UPNA, UNAV, Colleges)	PM seminars, talks with Healthcare/R&D&I professionals
Politicians, institutional representatives (GN, parliamentary groups)	PM professional presentations (Health, R&D&I). Training for spokespersons in order to give a clear and unique PM message.

- Organisation of events on Personalised Medicine where professionals from Navarra from different fields share and exchange their progress (scientific, clinical, business), good practices, expectations, and B2B meetings that encourage interaction. Participation of politicians (openings/closings) as a reflection of their political commitment.

- To transfer content to different communication platforms (newsletters, social media, impact on local press, both specialised and general).
- To set up virtual communication spaces where information can be shared among the different internal target audiences (intranet within the Personalised Medicine website).

2. CP.LA2. Regional positioning and European collaborations

a. Structural Actions

i. Creation of a brand for the Personalised Medicine strategy, as well as a single interlocutor that can capture and reallocate resources.

ii. Mapping of International Agents and strategic markets. Search for international target audiences in order to identify actors to impact/partner with, as well as best practices.

iii. Translation and interpretation of the activities carried out into English, and ensuring their publicity (news, mailing, RRSS, impacts on media outside Navarra).

b. Operational Actions

"To be seen"

i. Active participation of Navarra in European Networks (ICPerMed, ERRIN, EUREGHA, etc.).

ii. To raise awareness of the advances in Personalised Medicine in Navarra, as well as the organisation of events, through the Permanent Forums portal (Health Section).

iii. Event organisation and participation at an international level (symposia, presentations at congresses, spaces at trade fairs, invitation

of KOLs to B2B events organised in Navarra, etc.), search for alliances with other participating regions or organisers.

iv. To promote the expansion of the international collaborative network through trips to regions identified in the agents map, exchange meetings, European projects.

"To be found"

v. Assistance to the delegation/consultation of professionals. Putting in contact with the appropriate agent.

vi. Manage international delegations and Soft landing of professionals/entities interested in being part of Navarra's Personalised Medicine network.

vii. Organise additional tours the days before or after a related fair.

viii. Record keeping of entities and research groups from Navarra to potentially collaborate with.

"To provide resources to Agents from Navarra"

ix. To provide resources to researchers, assistants, entrepreneurs, teachers, etc. such as grants/assistance for work trips/travel, training, advice, access to contacts, international mentoring, speaking opportunities.

x. To channel public and private resources, securing them through European projects (Interreg/Cosme/HEU calls), or generate them through agreements with other regions (e.g., access to contacts).

3. <u>CP.LA3. Public awareness</u>

a. Actions aimed at discussing and incorporating

i. Open Participation Days (opening ceremony by institutional representation).

ii. Informative talks given by the professionals responsible for the Personalised Medicine strategy to the different groups that compose the general public.

iii. Living Lab: co-creation with interested parties to detect needs.

b. Actions aimed at dissemination

i. Preparation of educational material to disseminate and communicate the importance and benefits of Personalised Medicine in Navarra for the general public (different groups: adult centres, community workshops, etc.).

ii. A simple, visual guide integrating the Personalised Medicine strategy.

iii. Mass mailing of personalised letters to all households with information from the Citizen Participation Delegation on the specific participation process in Personalised Medicine.

iv. Open days at the Personalised Medicine key centres (Nasertic: Sequencing and HPC Centre; Navarrabiomed, CIMA, UPNA, UNAV, etc.).

v. Advertising campaigns at key locations in the region (posters, banners, etc.).

c. Actions aimed at influencing

i. STEM: Scientific talks to educational centres to direct towards bioinformatics, genomics.
ii. Drawing competitions: "what is DNA for you", followed by an exhibition at the Planetarium: To direct towards bioinformatics.
iii. Annual meeting for patients benefiting from Personalised Medicine: "annual DNA party" with real testimonies.
iv. Talks at the Summer University.

COMMUNICATION CHANNELS

Identifying the communication channels to be used is key to be able to inform effectively and reach the different agents that make up the Plan's target audience map:

- ✓ Specific Personalised Medicine **website**, to showcase the strategy, informs, shares information, positions.
- ✓ **Social networks** (Twitter, LinkedIn, Facebook, etc.), to strengthen the feeling of belonging, active listening and dialogue between the different agents.
- ✓ **Audiovisual resources** (testimonial videos, corporate video, videoconferences, etc.) to reinforcee the effectiveness of the message, informs, influences, builds loyalty.
- ✓ **Images** (Personalised Medicine brand image, advertising campaigns), to position, inspire and inform.
- ✓ **Intranet,** to communication between the Personalised Medicine different professionals, generating value by helping with day-to-day work.

TABLE 17. COMMUNICATION & PARTICIPATION ACTION PLAN SUMMARY

Operational objectives		Lines of Action		Actions	Suggested indicators
CP.OPO1	**Consistency and alignment of expectations**	**CP.LA1**	**Consistency and alignment of expectations**	**Structural Actions:** • Creation of a **specific website** for the Personalised Medicine strategy. • **Map of people in charge** (coordination and supervision) • **Register** of services, units/departments, labs, professionals involved in Personalised Medicine. **Operational Actions:** • Organisation of **activities** designed to bring the importance and benefits of Personalised Medicine in Navarra closer to professionals from the areas of Health, R&D&I, Education and training, etc. • Organisation of **events** on Personalised Medicine where professionals from different fields from Navarra share and exchange their progress (scientific, clinical, business). • Transfer content to different **communication platforms** (newsletters, social media, impact on local press, both specialised and general). • Set up **virtual communication spaces** where information can be shared among the different internal target audiences (intranet within the Personalised Medicine website).	• Number of individual projects (e.g. startups founded, submitted projects at regional/national/international level). • Size of investment (public and private). • Number of collaborative projects per year. • Number of physicians prescribing genomic tests. • Number of genomic tests ordered per quarter. • Number of interactions: B2B, communications via the PM website. • Number of attendees throughout the year and average rating (per survey). • Number of subscribers to the PM Newsletter (open rate, number of readings). • Inverse: prescribed commercial tests (e.g. oncotype dx).

Operational objectives		Lines of Action		Actions	Suggested indicators
CP.OPO2	**Positioning**	**CP.LA2**	**Regional positioning and European collaborations**	**Structural Actions:** • Creation of a PM strategy **brand**, as well as a single interlocutor that can capture and redistribute resources. • **Mapping of international actors** and strategic markets. International Target Audience research to be able to identify actors to impact/partner with, as well as good practices. • **Translation and interpretation** of activities into English, and ensuring their dissemination (news, mailing, Social Media, extra-foral media impacts). **Operational Actions:** **"To be seen"** • Active participation of Navarra in European Networks (ICPerMed, ERRIN, EUREGHA, etc.). Visibilisation of PM advances in Navarra through the Permanent Meeting Forums portal (Health Section) and organisation of events through it. • Organising and participating in events at international level (symposia, appearances at congresses, stands at trade fairs, inviting KOLs to B2B events organised in Navarra, etc.), seeking alliances with other participating regions or organisers. • Encourage the expansion of the international collaborative network through missions to regions identified in the map of agents, exchange meetings, European projects.	• Number of international collaborations. • Number of projects with European funding. • Amount raised in the form of non-refundable grants from Europe. • Amount invested from outside in start-ups. • Amount invoiced to non-European entities for services. • Number of delegations attracted. • Number of interactions (sum of B2B at fairs/meetings throughout the year). • Media impact (RRSS, newspapers, TV, radio, etc.).

Operational objectives		Lines of action		Actions	Indicators
CP.OPO2	**Positioning**	**CP.LA2**	**Regional positioning and European collaborations**	**Operational Actions:** **"To be found"** • **Assistance to the delegation/consultation of professionals.** Putting in contact with the appropriate agent. • **Manage international delegations** and Soft landing of professionals/entities interested in being part of Navarra's Personalised Medicine network**.** • Organise additional **tours** the days before or after a related fair. • **Record keeping** of entities and research groups from Navarra to potentially collaborate with**.** **"To provide resources to Agents from Navarra"** • To **provide resources** to researchers, assistants, entrepreneurs, teachers, etc. such as grants/assistance for work trips/travel, training, advice, access to contacts, international mentoring, speaking opportunities. • To **channel public and private resources**, securing them through European projects (Interreg/Cosme/HEU calls), or generate them through agreements with other regions (e.g., access to contacts).	• Number of international collaborations. • Number of projects receiving European funding. • Amount raised from European non-refundable grants. • Amount invested from outside in start-ups. • Amount invoiced to entities from outside Navarra for services. • Number of attracted delegations. • Number of interactions (sum of B2B at fairs/meetings throughout the year). • Impact in the media (Social Media, newspapers, TV, radio, etc.).

Operational objectives		Lines of action		Actions	Indicators
CP.OPO3	**Public awareness**	**CP.LA3**	**Public awareness**	**PUBLIC AWARENESS:** **"Actions aimed at discussing and incorporating"** • **Open Participation Days** (opening ceremony by institutional representation). • **Informative talks** given by the professionals responsible for the Personalised Medicine strategy to the different groups that compose the general public. • ***Living Lab***: co-creation with interested parties to detect needs **"Actions aimed at dissemination"** • Preparation of **educational material** to disseminate and communicate the importance and benefits of Personalised Medicine in Navarra for the general public (different groups: adult centres, community workshops, etc.). • A **simple, visual guide** integrating the Personalised Medicine strategy. • Mass mailing of **personalised letters** to all households with information from the Citizen Participation Delegation on the specific participation process in Personalised Medicine. • **Open days** at the Personalised Medicine key centres (Nasertic: Sequencing and HPC Centre; Navarrabiomed, CIMA, UPNA, UNAV, etc.). • **Advertising campaigns** at key locations in the region (posters, banners, etc.).	• Number of attendees at talks, PM events. • Number of people enrolled in PM-related degrees. • Number of enquiries (degree of participation by segments). • Number of contributions made (degree of opinion). • Number of contributions accepted. • Number of contributions not included and reasons why. • Satisfaction surveys.

MODULE ON COORDINATION

4.4. MODULE ON COORDINATION

FACT SHEET

COORDINATION

Objective		Lines of Action	Actions
C.O1	Coordination	C.LA1.Coordination	Create a Technical Coordination Unit
			Define Integrated Data Management Plan
			Design of a Schedule for overall benefits and sustainability

INTRODUCTION

A strategy of this nature, which brings together the efforts of many professional areas, involves multiple internal and external agents, and seeks to achieve diverse objectives. It is therefore essential to dedicate a section to planning how to **suitably coordinate the collaborative processes** in which the entire system participates.

In this regard, on the one hand, it seems important to have an instrument that **centralise and coordinate the development of the lines of action** proposed in each of the areas and in each of the strategic axes (**horizontal coordination**), and the degree of implementation of said lines **(vertical coordination**). This process also involves identifying and solving problems, and effectively harmonising and synchronising actions to avoid the duplication and delays a compartmentalised approach may cause.

On the other hand, a particularly relevant section of this Strategy is the **data management proposal** to further health, research and economic development. Given the complexity of this design, which strives to manage data from multiple origins and processed in different ways, to serve different clients and for different purposes, it is deemed necessary to structure a specific plan that encompasses a global design of **integrated data management**, capable of facing those challenges from the perspective of rights safeguarding and proactive citizen participation. In this sense, data management coordination is configured as a unique added value for the entire Strategic Plan and emerges as one of the **most relevant distinctive aspects and hallmarks of this proposal**.

Finally, the guidelines from the main experts and agendas in Personalised Medicine recommend incorporating the perspective of **sustainability** from the earliest stages in the design of the initiative, seeking to shape the planning and execution of the whole system from its initial stages, in order to guarantee the necessary consistency in this regard, which is particularly critical in the medium and long-term success plans in this area.

ACTION PROPOSAL

According to the objectives within this coordination section, the present action plan is focused, firstly, on the **constitution of a permanent coordination instrument integrated in the Strategy general governance structure**; secondly, on the design of an **integrated data management plan** and, lastly, on the consideration of an **agenda of global benefits and sustainability**.

Technical Coordination Unit

In order to achieve the involvement and smooth participation of all the parties involved in the project, it is essential to have a **Technical unit** that manages and boosts the line of actions in a coordinated manner.

The main role of this Unit is to **coordinate all proposed actions**, by identifying the needs for implementing the Strategy and by facilitating **conflicts resolution**. The Unit also aims to create collaborative spaces between the different Administration departments while combining efforts with other Governmental Strategic Plans. Other additional tasks of this Unit will be to carry out **periodic monitoring and results evaluation** according to the indicators and targets set during the deployment phase.

Given the Strategy's cross-departmental design, it will be necessary for this Unit to have an **appropriate affiliation** to facilitate its cross-departmental work within the Government of Navarra's structure.

Key elements of the Integrated data management plan:

- Coordination functions:
    - Overall management of the Strategy.
    - Coordination and synchronisation of actions.
    - Facilitating collaborative spaces.
    - Problem solving.
    - Identification of needs.
    - Coordination of the Data Management Plan.
    - Coordination of the Global Benefits and Sustainability Agenda.
    - Monitoring, evaluation and reporting.
    - Coordination with other of the Government of Navarra's strategies and plans.
- Framework within the Strategy's Governance.
- Appropriate allocation within the structure of the Government of Navarra.

Integrated Data Management Plan

One of this Strategy's major and differentiating actions is the **integrated, centralised data management**. This design is oriented towards the possibility of integrating information from multiple source data which, suitably processed and in accordance with the Regulatory Action Plan's guidelines, allows for **exploitation for primary purposes** (the purposes for which these data were initially collected), but also for the **licit secondary purposes** described in this strategy: health management and planning, research and economic development. For this reason, three key points must be considered when defining the Integrated Data Management Plan: the **definition of uses and services**, **adaptation to regulations** and consideration of **transparency** and **participation**.

1. Definition of uses and services.

To enable adequate management within the strategy's framework, it is necessary to define in detail the uses and services that data management and processing shall be intended to. This can be defined as follows:

- **Use of data for medical purposes:** Data processing for medical purposes is protected by Law 14/1986, of 25 April 1986, on General Health and by the Foral Law 10/1990, of 23 November 1990, on Health in Navarra, and regulated by Law 41/2002, of 14 November 2002, on patient autonomy and on rights and obligations regarding clinical information and documentation, which has been developed by Foral Law 17/2010 of 8 November 2010 on the rights and duties of persons with regard to health in Navarra. Furthermore, the Foral Decree 20/2019, of 6 March, which approves the data protection and information security policy of Navarra's Administration and its public bodies, describes the organisational structure design for the management of information security within the scope of the data protection and information security policy of the Navarra's Administration and its public bodies. In Navarra, the SNS-O has generated a data analysis database called BARDENA, (Analysis of Results database of Navarra), which is fundamentally oriented towards the management of the Services, and the macro-strategy of the SNS-O's senior management. However, this initiative has currently fallen far short of expectations for health services based on the integration of genomic and other omics data and external sources pursued by this Strategy. This is why the lines of action that have been defined in the Health Action Plan aim at reinforcing and adapting this initiative.

- **Use of data for health management and planning purposes**: According to constitutional doctrine and in accordance with Article 9.2 of the *LOPDGDD* (Organic Law on Protection of Personal Data and Guarantee of Digital Rights), the processing that effectively responds to this purpose could be adjusted, and therefore the management of medical data, research data and data from other sources for this purpose could be considered.

- **Use of data for research purposes**: Law 14/2007, on Biomedical Research, regulates clinical genetic analyses and includes some references to the use of genetic data; Organic Law 3/2018, of 5 December, on Organic Law on Protection of Personal Data and

Guarantee of Digital Rights (*LOPDGDD, Spanish acronym*), in the 17th Additional Provision. It provides an interesting description of the procedure of data pseudonymisation when used for research. In Navarra, Resolution 1387/2017, of 8 November, from the Managing Director of the Health System of Navarra, which determines the content of the Register of Research Projects and establishes the procedures to access clinical documentation for research purposes. One legal basis that should be taken into account is the consent of the data subject, which does not require further regulatory development beyond the provisions of the RGPD itself (article 9.2 a). A relevant aspect in this regard is the scope that consent is able to cover, and the RGPD accepts consent in its "broad" sense. Accordingly, data subjects should be allowed to give consent for certain areas of scientific research that respect the recognised ethical standards for scientific research. Along these lines, DA17th.2, letter A of the LOPDGDD stipulates that consent may be given for research in "general areas linked to a medical or research speciality". It is also worth noting that the LOPDGDD even admits a broader consent when samples are managed through a biobank (Article 70.2). On the other hand, the LOPDGDD itself, in development of article 9.2 j and 89 of the RGPD (DA 17ª 2) d), considers the use of pseudonymised personal data for health and, in particular, biomedical research purposes, to be lawful. Therefore, key elements to be reviewed regarding this term are the type of consent given, anonymisation and pseudonymisation processes, security guarantees and the involvement of accredited Research Ethics Committees, as contemplated in DA 17a 2 of the LOPDGDD.

- **Use of data for other purposes**: Letters g), h) and i) of Article 9.2 of the GDPR address other legitimate grounds which may be linked to the Strategy for Personalised Medicine in the Foral Region of Navarra. These are that the purpose of the processing is an essential public interest (letter g); the management of health and social care systems and services, as well as ensuring high standards of quality and safety in healthcare and medicines or healthcare products (letters h, i). Article 9(2) of the LOPDGDD specifically establishes that data processing, as referred to in Article 9(2)(g), (h) and (i) of the RGDP based on the Spanish law, must be covered by a norm equivalent to a Law.

2. Regulatory Framework.

As described in the Regulatory Action Plan, a Data Management Plan must be designed so that it adequately responds to the Strategy's data management objectives. This Data Management Plan should collect the necessary information for translating the legal requirements to a specific treatment, depending on the choices made.

The Data Management Plan should be a framework that has been developed within the strategy itself during its deployment phase, based on the detailed analysis and answers to the number of key questions about the data management addressed in this strategy. The key features of this regulatory framework are described in the Regulatory Action Plan chapter of this document and a summary outline is shown below:

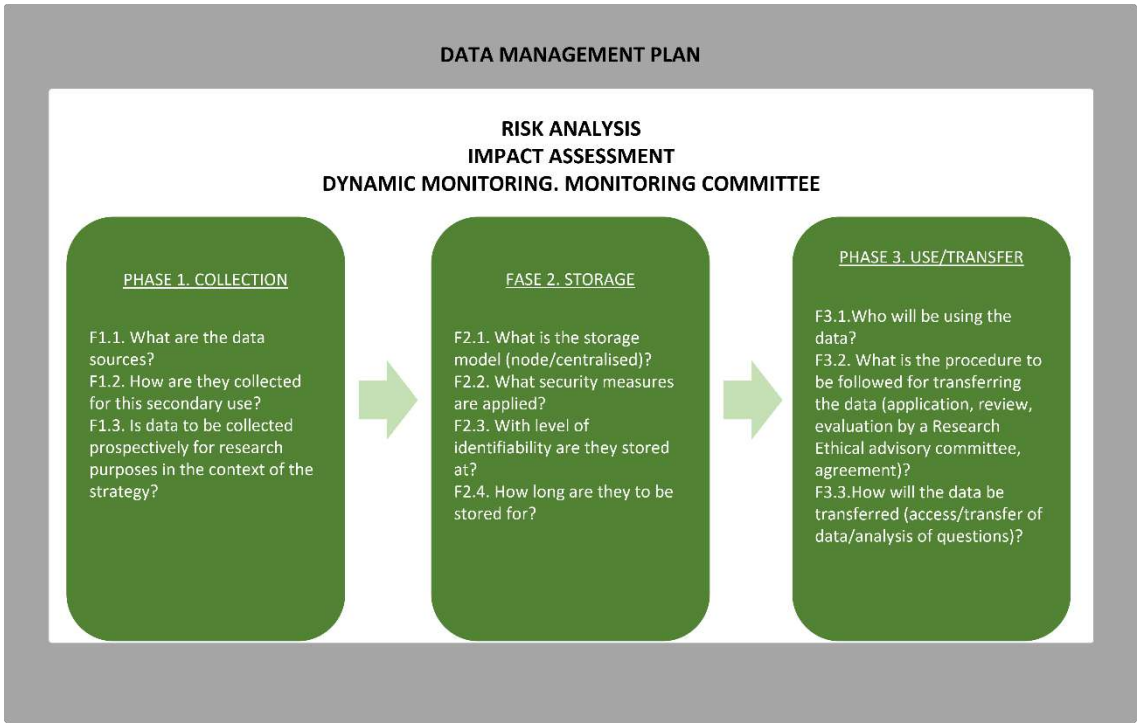


Figure 13. Outline Data Management Plan.

On the other hand, the Data Management Plan should be an open and dynamic document that is revised periodically and incorporates changes in the strategy. An advisory body should be identified for its updating and revision, a function that could correspond to a Monitoring Committee (*CS, Spanish acronym*).

The creation of a multidisciplinary committee to define data uses and services in detail and in accordance with all perspectives envisaged in the Strategy should be regarded as a suitable mechanism to manage this process. This committee shall establish the protocol for the evaluation of data access requests - the so-called **Data Access Committee** (DACO), in close collaboration with the committee in charge of monitoring ethical and legal aspects, separate from the Research Ethics Committee, who evaluates projects.

The infrastructures and systems required to **develop the Data Management Plan** are detailed in more depth in the corresponding chapter of this document, but can be summarised as follows:

- **Infrastructures**: It will be necessary to guarantee infrastructures with the capacity to store large volumes of enough data and the necessary computing operations, and to enable networked resource connections with the necessary speed and level of cybersecurity to enable efficient and secure sharing of resources between entities.
- **Systems**: A federated, and interoperable data structure should be in place to allow for the composition of studies across distributed sets, without disclosing them when necessary. It shall also allow for the implementation of artificial intelligence-generated learning technologies, supporting the specific questions posed by the strategy

objectives; medical and research questions; and other questions. All of them in strict compliance with current regulations.

- **Digital Platforms**: it will be necessary to set up appropriate Digital Platforms to facilitate the resource management between the different agents that are part of the Strategy.

3. Transparency, participation and citizen collaboration.

The **participation** of everyone in the political, economic, cultural and social life is an essential principle, necessary to guarantee real and effective freedom and equality. On a strictly political level, this leads us to the need to complement representative democracy with forms and modes of government in which **transparency** and **participation** are key instruments. Therefore, making further progress in the involvement of citizens in administrative and governmental decisions and actions is not a whim or a trend. It is a necessity, a demand to which the Administrations must respond to in order to provide solutions to the complex problems of our society, where exclusively technical responses won't suffice.

When considering an integrated management of biomedical data, the key, central part of this process should not be forgotten: **the citizen**. Without this fundamental element no action in this sense may be considered.

All successful initiatives that have proposed centralised data management for the benefit of the community have actively engaged the knowledge and participation of citizens from the beginning, so transparency must be seen as an essential and central part that permeates throughout this Strategy.

In Navarre there are two laws that include the principles of Open Government (transparency, participation and citizen collaboration). These are the "**Foral Law 5/2018, of 17 May, on Transparency, access to public information and good governance**" and the "**Foral Law 12/2019, of 22 March, Democratic Participation in Navarra**".

In terms of **transparency** in the Personalised Medicine Strategy, it is necessary to integrate this concept from the very moment of its planning in order not to lose the traceability of its development. It should therefore be reflected in Open Government throughout all its design, development, presentation, debate, approval, and implementation phases. Similarly, it is necessary to maintain a commitment to transparency throughout the process through Open Government to facilitate access to data files and their subsequent re-use. These measures will include the preparation of specific documentation that is easy to read and to understand on the Personalised Medicine strategy for the Open Government space, and the necessary **accountability** through information and justification on the development of the strategy (efficiency, effectiveness, transparency and legality criteria).

These measures are also complemented by the lines of action targeting the public. These are reflected more precisely in the Chapter on the Communication and Participation Plan, and the public representation in the Strategy's Governance system could be considered very opportune.

The citizens of Navarra will be able to trust in the correct use of data by the administration to improve their well-being and quality of life thanks to a regulatory framework and protocols based on ethics and transparency. They will also be able to enjoy a new healthcare model centred on people: prevention, effective management, personalised medicine and telemedicine.

Global benefits and sustainability agenda

Despite being a major issue in any strategic plan, sustainability remains an abstract principle when it comes to its practical application in the process of designing Personalised Medicine strategies. Unlike other organisational units that measure sustainability and value creation along their value stream, Personalised Medicine must consider its sustainability based on the **value and sustainability of products, processes and services in a global ecosystem**, throughout their entire life cycle.

The Patient

By definition, the main recipients of the benefit of the service within the healthcare environment must be the **patients and their families** so, in any decision on the investment of resources in this area, this must be considered the capital factor. In this sense, a study carried out in our setting within the NAGEN pilot project with a complete human genome study in patients with rare diseases, revealed a high satisfaction of the participants, with 97.4% expressing a satisfaction level of 7/10 or higher, regardless of the project identifying the cause of their family's genetic disease or not. Furthermore, in more than two thirds of the cases, participants placed a monetary value on the service equal to or higher than the investment made to deliver it. 66% of them stated that they would be willing to pay this amount themselves to obtain the service if necessary. This shows the importance that patients give to tests aimed at obtaining a diagnosis of the disease affecting them.

Some of the possible benefits for the patient are:

- More accurate diagnoses.
- Faster diagnoses with the possibility of early intervention and better prognosis.
- Personalised treatments.
- More accurate prognoses.
- Greater understanding of the disease and the ability to collaborate and become involved in management decisions.

Global benefits Agenda

Beyond the benefits to the patient, there are other agents who can perceive the **return of value from the services provided** by a personalised medicine strategy and who can contribute to its sustainability.

1. **The Health Service:** A simplistic approach to assessing the economic impact of new health technologies is cost-effectiveness analysis (CEA), which compares the advantages of two methodologies using indicators such as numbers of years of life saved, or cases or mutations detected with respect to the cost of the process. The most common type of CEA is cost-utility analysis (CUA, a special form of CEA), which assesses both survival in number of years and quality of life years lived. The aforementioned NAGEN study showed that the healthcare cost of genetically screening 1,000 patients with rare diseases in order to identify their diagnosis by the standard route would be 4 times higher than study based on the whole genome study protocol proposed in the project. It also showed that, firstly, the waiting time for diagnosis was reduced from almost 15 years to as little as 6 months in one third of the participants. Secondly, that there is an additional potential benefit in terms of disease prevention and toxicity and pharmacological expenditure from the required clinical management after identifying secondary findings of predisposition to severe genetic disease in 7.8% of participants, risk of transmitting severe genetic disease to offspring in 6. 8% and pharmacogenetic findings in 100% of the participants. All these findings should be considered of very high interest in the study of the health care system sustainability.

Some of the **possible gained benefits for the Health Service** are:

- Cost-effectiveness of diagnostic tests.
- Lower treatment costs for preventive measures or early treatment.
- Reduction of non-elective admissions due to adverse drug responses.
- Abundant data that will optimise management and enable R&D.

2. **Government planning**: The alignment of the agenda with economic development policies is a return value that should also be analysed within the Strategy's macro-benefits agenda (see also Economic Development Action Plan).

Some of the **possible benefits for the Government Agenda** are:

- A healthier population, with lower health expenditure and higher productivity.
- Contribution to job creation.
- Return on tax contributions.
- Opportunity for cross-development and cooperation.
- Identification and positioning.
- Increased social responsibility and social awareness.

3. **Research**: The alignment of the agenda with R&D&I policies is a return value that should also be analysed within the overall benefits agenda of the Strategy (see also R&D&I Action Plan).

Some of the **possible benefits for Research are**:

- Increased capacity to attract R&D funding.
- Greater diversity in research.
- Technological independence and attracting talent.
- Platform for collaboration and contribution to global knowledge.

4. **Commercial development:** From a legal point of view, there is a number of important issues to be considered when analysing the possible economic exploitation of data.

Types of data

It is essential to distinguish between **non-personal data and personal data**. Non-personal data is marketable. The regulation on this kind of data is based on Regulation (EU) 2018/1807 on a framework for the free flow of non-personal data in the European Union (the "**Free Flow of Non-Personal Data Regulation**" and the rules of **civil or business law** applicable to the sale of goods that can be traded.

However, this clause should not be understood in a broad sense. It does not seem to cover, for instance, selling anonymised personal data if this sale was not foreseen in the purposes of the processing that led to such anonymisation. The principle of fair processing should be considered particularly relevant in such cases.

As a matter of fact, **personal data cannot be marketed**, for the simple reason that they are not objects of property, and the property law paradigm does not adequately fit with the GDPR, which is based on the rights of data subjects. Data subjects, as is well known, cannot waive such rights in exchange for a price. In any case, it would be possible to think of **agreements for the transfer of data in exchange for a price**, which would introduce figures of co-responsibility and problems of processing supervision.

Again, however, it is questionable whether transferring personal data from data subject who had consented to the transfer without knowing that it would be made for a price would comply with the principle of lawfulness, fairness and transparency (Article 5.1.a GDPR).

There are, in any case, intermediate terms, such as data transferring in exchange for compensation for the efforts made for the database creation, organisation, storage, etc. This issue will be developed further when sui generis rights are discussed in the following sections.

In cases where databases include both personal and non-personal data, it is advisable to refer to the **Communication from the Commission to the European Parliament** and the **Council on Guidelines for a Regulation** on a framework for the free flow of non-personal data in the European Union of 29.5.2019 (COM(2019) 250 final). In principle, the regulation to apply in such cases will be the GDPR. For this reason, where possible and where it is intended to market non-personal data, a strict separation should be made between these two. This should ideally be done at the time of collection, as the costs of the process may be considerably greater than the subsequent potential benefits.

Payment for service

An alternative and promising model for the use of databases may be the **provision of specific services in exchange for a fee.** In these cases, data is not transferred or made accessible to third parties, but is simply **used to transmit information, solve specific questions, support technological developments**, etc. To give some examples, aggregated data may be used to calculate statistics on the efficiency of the use of combined medicines, shortening a hospital stay by using a specific resource, the efficacy of certain genetic markers for diagnosing certain pathologies, etc.

They could also be used, for example, to develop artificial intelligence tools, by using databases for training. In such cases, the tool should be provided to the Navarra Health System, which would be responsible for training or approving its use, depending on the service required. In some cases, this could present problems since some algorithms need to store personal data in order to work properly. In any case, this possibility should be excluded in the contracts drawn up for this purpose, or we should be aware that we would be dealing with personal data being transferred to third parties.

Use of sui generis rights

Irrespective of whether databases are of one type or the other, it is in any case advisable to **protect the rights of the data controller** who wishes to obtain some kind of financial compensation for his effort through sui generis database rights, which can be complemented by copyright on the use of the specific content of the database.

These rights are based on Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (OJ L 77, 27.3.1996, pp. 20-28). In Spain they are regulated in Title VIII of Book II. On other intellectual property rights and "sui generis" protection of databases of the Royal Legislative Decree 1/1996, of 12 April, which approves the revised text of the Intellectual Property Law, regularising, clarifying, and standardising the current, legal provisions on the matter. This title was precisely introduced by Article 6 of Law 5/1998, 6 March, on the transposition into Spanish law of Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (Official State Bulletin, "*B.O.E.*" 7 March), to properly implement the aforementioned directive.

Sui generis databases rights are rights that protect the substantial investment, qualitatively or quantitatively evaluated, made by whoever creates, modifies, maintains, etc. them, either of financial means, time invested, effort, energy, or others of a similar nature, for the collection, verification or presentation of their content.

By virtue of that right, the maker of the database (i.e. the natural or legal person who takes the initiative and bears the risk of making the substantial investment in obtaining, verifying or presenting its contents) may prohibit the extraction and/or re-utilisation of all or a substantial part of the database contents. Since this right may be transferred, assigned or licensed contractually, it is perfectly feasible to obtain financial compensation for the job made.

These rights operate entirely independently of any rights that may relate to the data contained in the databases in question. They are therefore compatible with those of the data subjects. It

is important to remember that the data owners (which as such, in Europe, are not the subject of economic rights) are the subjects from whom they were obtained, who continue to hold the rights granted by the GDPR (General Data Protection Regulation) and the Organic Law on Protection of Personal Data and Guarantee of Digital Rights (*LOPDGDD, Spanish acronym*).

In any case, it seems necessary to underline that this **regulation's approach and that of the GDPR do not seem quite compatible**. In fact, it seems as if the GDPR has been developed as if the Directive did not exist. The Spanish regulation states verbatim (art. 137) that " the provisions of this Title shall be without prejudice to any other legal provisions affecting the structure or the content of a database such as those relating to copyright or other rights of intellectual property, industrial property right, competition law, contract law, secrets, protection of personal data, protection of national treasures or access to public documents".

The application of this figure is, in any case, very useful to ensure the protection of the databases generated, which would, in principle, last for fifteen years. However, this term could be extended for successive periods of fifteen years, provided that any substantial modification has been made, in particular regarding the accumulation of additions, deletions or successive changes leading to a substantial new investment, being evaluated from a quantitative or qualitative point of view.

Consequently, compensation through a fee for consultation service could help defray the costs of a centralised database management, generation, processing and management of the data directory under the above-mentioned use of sui generis rights.

Figure 14. Outline of the Global Benefits Management Agenda.

There are, therefore, different considerations surrounding the Strategy that determine the **models capable of assessing the ecosystem of internal and external factors** to configure a global benefits agenda that will enable the system's sustainability to be successfully addressed. This should be a route to be incorporated into the design of the strategy from the beginning.

The **development of the agenda** should be carefully planned **in line with the development of the Strategy** and in collaboration with all parties involved in the initiative in several steps: definition and planning; building a case-based model; evaluation of the model; extension to other cases; monitoring and monitoring.

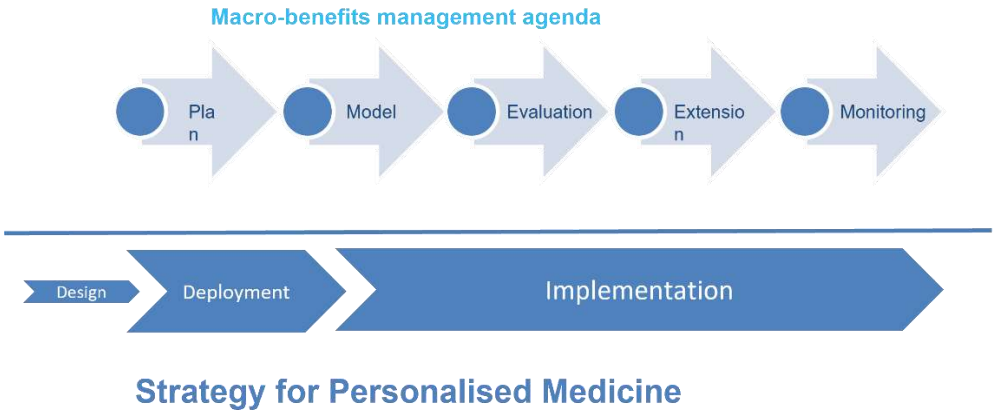


Figure 15. Outline of the incorporation of the Global Benefits Agenda in the phases of the Personalised Medicine Strategy in Navarra 2020-2030.

Proper management of the global benefits scenario from the beginning of the strategy will determine the outcome of the long-term sustainability of the whole process.

5

IMPLEMENTATION AGREEMENT

5.1. PRESENTATION

Based on the previous description developed throughout this document, and by means of conclusion, it is important to define an implementation agreement that establishes the lines of action, phases of the strategy, timeframe and budget that will make the outlined objectives achievable.

5.2. STRATEGY PHASES

In a strategy with a time horizon to 2030, it is very important to define a series of phases that will enable the smooth development of the whole process. These phases are design phase, deployment phase and implementation phase.

Design Phase (2020-2021)

During this phase all the required tasks for the **drafting and approval of the document** which describes the Strategy planning and development shall be completed. A more detailed review of the tasks included in this phase can also be found in the Methodology section within this document. An outline of the summary of this process is shown below:

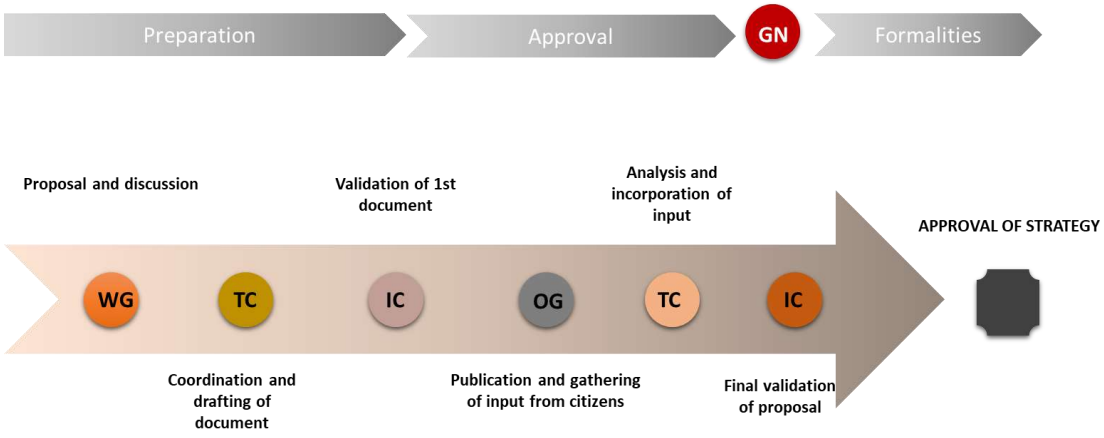


Figure 16. Workflow in the elaboration and consensus of Navarra's PM Strategy. (WG) Working Groups; (TC) Technical Committee; (IC) Cross-departmental Commission; (GA) Open Government; (GN) Government of Navarra.

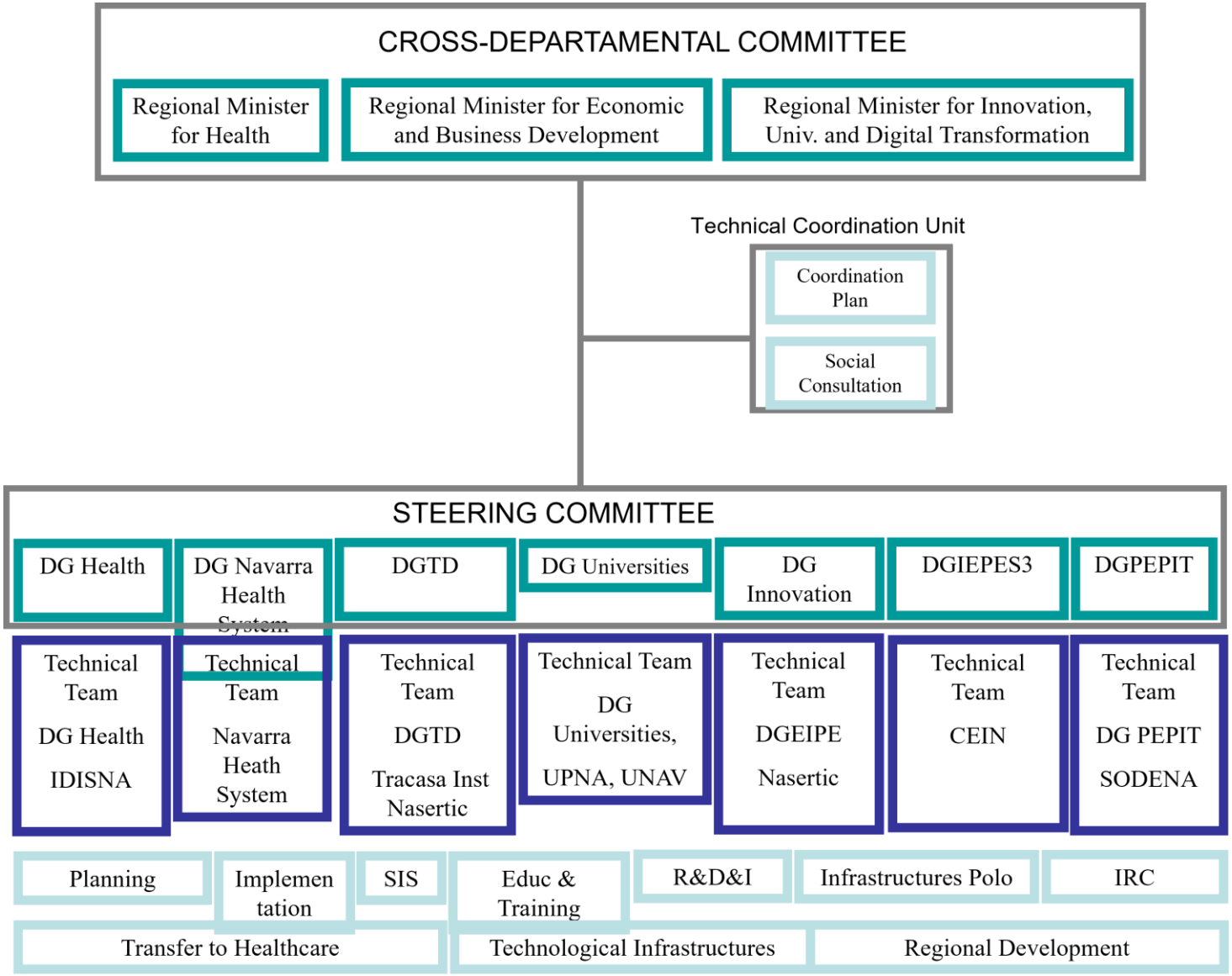
Deployment Phase (2021-2022)

During this deployment phase all the required tasks for the **implementation of all lines of action** shall be completed effectively.

Important milestones that are to be achieved during this phase are:

1. Establishing the **Governance** model.
2. Description of the **map of those in charge** with the assignment of **tasks and lines of action** to the different agents.
3. **Prioritising** Lines of Action.
4. Establishing the project's **timetable, indicators and goals**.
5. **Budget allocation**.

Below are several summary tables which include templates for these milestones, in accordance with this Personalised Medicine Strategy:


CROSS-DEPARTAMENTAL COMMITTEE
Regional Minister for Health
Regional Minister for Economic and Business Development
Regional Minister for Innovation, Univ. and Digital Transformation
Technical Coordination Unit
Coordination Plan
Social Consultation
STEERING COMMITTEE
DG Health
DG Navarra Health System
DGTD
DG Universities
DG Innovation
DGIEPES3
DGPEPIT
Technical Team DG Health IDISNA
Technical Team Navarra Heath System
Technical Team DGTD Tracasa Inst Nasertic
Technical Team DG Universities, UPNA, UNAV
Technical Team DGEIPE Nasertic
Technical Team CEIN
Technical Team DG PEPIT SODENA
Planning
Implementation
SIS
Educ & Training
R&D&I
Infrastructures Polo
IRC
Transfer to Healthcare
Technological Infrastructures
Regional Development

PARTICIPATING AGENTS

- ADItech Technological Corporation.
- CEIN, European Business and Innovation Centre of Navarra.
- CIMA Research Centre for Applied Medicine of the Clínica de Navarra.
- Directorate General for External Action.
- Directorate General for Vocational Training.
- Directorate General for Industry, Energy and Strategic Projects S3.
- Directorate General for Innovation.
- Directorate General for Business Policy, International Projection and Employment.
- Directorate General for the Presidency and Open Government.
- Directorate General for Health.
- Directorate General for Telecommunications and Digitalisation.
- Directorate General for Universities.
- Miguel Servet-Navarrabiomed Foundation.
- IdiSNA, Healthcare Research Institute of Navarra.
- Nasertic, Navarre Services and Technologies.
- Navarra Health System.
- SIESS, Scientific Infrastructure & Equipment Sharing of Navarra.
- SODENA, Navarra Development Society.
- Tracasa.
- UNAV, University of Navarre.
- UPNA, Public University of Navarra.

TABLE 18. TIMEFRAME

			PHASE									
		LINES OF ACTION	LAUNCH	EXECUTION 2022-2030								
HEALTHCARE	H.LA1	Adapt the Health System										
	H.LA2	Strengthen Genomic services capacity in Navarra Health System										
	H.LA3	Integration of big data in Navarra Health System										
	H.LA4	Management of Knowledge and Sustainability										
R&D&I	RDI.LA1.	Stable and long-term R&D funding										
	RDI.LA2.	Innovation as a driver for change										
	RDI.LA3.	Attraction, return and retention of talent										
	RDI.LA4.	Creation of support and advisory units										
	RDI.LA5.	Strategic Alliances										
	RDI.LA6.	Internationalisation										
ECONOMIC AND BUSINESS DEVELOPMENT	EED.LA1	Increasing business participation										
	EED.LA2	Innovative public procurement (*CPI*)										
	EED.LA3	Attracting investment										
	EED.LA4a	Ideation, validation, and market access for startups										
	DEE.LA4b	Study and creation of validation units										
INFRASTRUCTURES & SYSTEMS	IS.LA1	Infrastructures										
	IS.LA2	Systems										
	IS.LA3	Platforms										
REGULATIONS	R.LA1.	Data Processing Plan (DPP)										
	R.LA2.	Regulatory Framework Review										
	R.LA3.	Monitoring Committee										
EDUCATION & TRAINING	ET.LA1.	Education and Training map										
	ET.LA2.	Undergraduate Education										
	ET.LA3.	Specialists in Health Care										
	F.LA4.	Postgraduate Education										
	ET.LA5a.	Continuous Learning for Healthcare professionals										
	ET.LA5b.	Continuous Learning for other professionals										
	ET.LA6.	Vocational education and training										
COMMUNICATION & PARTICIPATION	CP.LA1.	Consistency and alignment of expectations										
	CP.LA2.	Regional positioning and European collaborations										
	CP.LA3.	Public awareness										
COORDINATION	C.LA1.	Coordination										
	C.LA2.	Data Management Plan										

TABLE 19. BUDGET HEADING

	BUDGET HEADING		BUDGET
1	**HEALTHCARE SERVICES & PRODUCTS**		**€**
	H.LA1	Adapting the Health System	
	H.LA2	Coordination and reinforcement of genomic services capacity in Navarra Health System	
	H.LA3	Integration of big data in Navarra Health System	
	H.LA4	Knowledge Management and Sustainability.	
	EED.LA4a	Creation, validation and market launch of start-ups.	
2	**TOOLS, RESOURCES (IMPULSE)**		**€**
	RDI.LA1.	Stable and long-term R&D funding	
	RDI.LA2.	Innovation as a driver for change	
	RDI.LA3.	Attraction, return and retention of talent	
	RDI.LA4.	Creation of support and advisory units	
	RDI.LA5.	Strategic Alliances	
	RDI.LA6.	Internationalisation	
	EED.LA1	Increasing business participation	
	EED.LA2	Innovative public procurement (*CPI*)	
	EED.LA3	Attracting investment	
	EED.LA4b	Study and creation of validation units	
	EED.LA5	Promotion, management and transfer of innovation in Navarra Health System	
	R.LA1.	Data Processing Plan	
	R.LA2.	Regulatory Framework Review	
	R.LA3.	Monitoring Committee	
	CP.LA1.	Consistency and alignment of expectations	
	CP.LA2.	Regional positioning and European collaborations	
	CP.LA3.	Public awareness	
	C.LA1.	Coordination	
	C.LA2.	Data Management Plan	
3	**INFRASTRUCTURES**		**€**
	IS.LA1	Infrastructures	
	IS.LA2	Systems	
	IS.LA3	Platforms	
4	**COMPETENCIES & KNOWLEDGE**		**€**
	ET.LA1.	Education & Training map	
	ET.LA2.	Degree education	
	ET.LA3.	Specialists in Health Sciences	
	ET.LA4.	Postgraduate education	
	ET.LA5a.	Lifelong Learning for Healthcare professionals	
	ET.LA5b.	Lifelong Learning for other professionals	
	ET.LA6.	Vocational training	

Implementation Phase (2022-2030)

The implementation phase will involve all the actions described in the Strategy until the final achievement of its objectives. During this period, **periodic monitoring and result evaluation** must be conducted according to the indicators and targets set during the deployment phase.

1. Implementation of the Lines of Action.
2. Monitoring.
3. Result evaluation.

6

GLOSSARY

6.1. GLOSSARY

***1+MG*:** The 1+ Million Genomes Initiative *(Declaración Europea 1 Millón de Genomas)*
ADItech: Coordinator of Agents of the Innovation System in Navarra (*Coordinador de Agentes del Sistema Navarro de Innovación)*
ADN: DNA, Deoxyribonucleic acid (*Ácido desoxirribonucleico)*
AEPD: Spanish Data Protection Agency (*Agencia Española de Protección de Datos)*
AIN: Industry Association of Navarra (*Asociación de la Industria Navarra)*
BARDENA: Analysis of Results database of Navarra (*Base Análisis de Resultados De Navarra)*
BIR: Specialization programme for Medical Biologists *(Biólogo Interno Residente)*
CAD: Data Analysis Centre (*Centro de Análisis de Datos*)
CCAA: Spanish Autonomous regions *(Comunidad Autónoma)*
CEA: Cost-effective Analysis
CEI: Research Ethics Committee (*Comité Ético de Investigación)*
CEIN: European Business and Innovation Centre of Navarra (*Centro Europeo de Empresas e Innovación de Navarra)*
CENER: National Renewable Energy Centre of Spain (*Centro Nacional de Energías Renovables)*
CHN: Hospital Network of Navarra *(Complejo Hospitalario de Navarra)*
CI: Interdepartamental Commission (*Comisión Interdepartamental)*
CIMA: Research Centre for Applied Medicine of the Clínica de Navarra (*Centro de Investigación de Medicina Aplicada)*
CNAG: CNAG-CRG, National Centre for Genomic Analysis and Centre for Genomic Regulation *(Centro Nacional de Análisis Genómico)*
COVID-19: Coronavirus disease 2019
CPD: DPC, Data Processing Centre (*Centro de Proceso de Datos)*
CPI: IPP, Innovative public purchase (*Compra Pública Innovadora)*
CRefIX: *Centre de Référence, d'Innovation, d'eXpertise, et de transfert*
CS: Monitoring Committee (Comité de Seguimiento)
CT: Technical Committee (*Comité Técnico)*
CUN: University Clinic of Navarra Clínica (*Universidad de Navarra)*
DACO: Data Access Committee
DAFO: SWOT: Strengths, Weaknesses, Opportunities, Threats
DEE: Economic and Business Development (*Desarrollo Económico y Empresarial)*
DG: Directorate General *(Dirección General)*
DGTD: Directorate General for Digital Transformation (*Dirección General de Transformación Digital)*
DIANA: Next-generation sequencing technology project to optimize the efficiency of diagnosis and treatment in patients with high-mortality tumors *(Proyecto de tecnología de secuenciación de nueva generación para optimizar la eficacia del diagnóstico y tratamiento en pacientes con tumores de alta mortalidad)*
EAPM: European Alliance for Personalised Medicine *(Alianza Europea para la Medicina Personalizada)*
EECTI: Spanish Science, Technology and Innovation Strategy 2021 -2027 (*Estrategia Española de Ciencia, Tecnología e Innovación 2021-2027)*
EEES: EHEA, European Higher Education Area (*Espacio Europeo de Educación Superior)*
EERR: Rare Diseases *(Enfermedades Raras)*
EIR: Nursing Specialization programme (*Enfermero Interno Residente)*
EEUU: USA, United States of America (*Estados Unidos)*
ELSI: Ethical, Legal and Social Issues
ERC: European Research Council
ERRIN: European Regions Research and Innovation Network

ESTNA: Integrated Vocational Training Centre of Navarra *(Escuela Sanitaria Técnico Profesional de Navarra)*
EUREGHA: European Regional and Local Health Authorities
FIR: Farmacology Specialization programme (*Farmacéutico Interno Residente)*
FP: Vocational education and training (*Formación Profesional*)
FSE: Specialised Healthcare Training *(Formación Sanitaria Especializada)*
GA: Open Government (*Gobierno Abierto*)
GEMA: Genomics and Advanced Medicine *(Genómica y Medicina Avanzada)*
GN: Government of Navarra
GS: Advanced vocational education and training *(Grado Superior, Formación Profesional)*
GT: Working Group (*Grupo de Trabajo*)
HCE: Electronic Medical Record (EMR) or Electronic Health record (HER) (*Historia Clínica Electrónica)*
HEU: Horizon Europe
HGP: Human Genome Project
HPC: High Performance Computing
IA: AI, Artificial Intelligence (*Inteligencia Artificial)*
ICPerMed: International Consortium for Personalised Medicine
ICT: Information and Communication Technologies
ICTS: Unique Scientific and Technical Infrastructures *(Infraestructuras Científico-Tecnológicas Singulares)*
I+D+i: R&D&I, Research, Development and Innovation (*Investigación, Desarrollo e Innovación*)
IdiSNA: Healthcare Research Institute of Navarra (*Instituto de Investigación Sanitaria de Navarra)*
IRIS: Artificial Intelligence and Robotics for the Industry and Society (*Inteligencia artificial y Robótica para la Industria y la Sociedad)*
IRC: Initiative to Strenthen Competitiveness *(Iniciativa de Refuerzo de la Competitividad)*
IT: Information Technology
LCCSNS: Cohesion and Quality in the National Health System (*Ley de cohesión y calidad del Sistema Nacional de Salud)*
LGS: Health Care General Act (*Ley General de Sanidad*)
LIB: Law on Basic Research (*Ley de Investigación Básica*)
LOPDGDD: Organic Law on Protection of Personal Data and Guarantee of Digital Rights (*Ley Orgánica de Protección de Datos y de Garantía de Derechos Digitales)*
LOPS: Law on health professions (*Ley de ordenación de las profesiones sanitarias)*
MINERVA: Personalised Cardiorenal Medicine In Navarra (*Medicina cardIoreNal pERsonalizada en NaVArra)*
MIR: Medical resident interns programme (*Médico Interno Residente)*
MP: PM, Personalised Medicine *(Medicina Personalizada)*
NAGEN: Project Genome 1000 Navarra *(Proyecto Genoma 1000 Navarra)*
NAGENCOL: Navarre strategy in genomic medicine applied to hypercholesterolemia (*proyecto dedicado a implementar el análisis del genoma completo para el diagnóstico y tratamiento individualizado de los pacientes con hipercolesterolemia)*
NAITEC: Technology Centre specialised in mobility and mechatronics in Navarre *(Centro Tecnológico de Automoción y Mecatrónica)*
NASERTIC: Navarre Services and Technologies (*Navarra de Servicios y Tecnologías S.A.)*
Navarrabiomed: Biomedical Research Centre (*Centro de Investigación Biomédica)*
NHS: United Kingdom National Health Service
P4: Approach to make medicine more Predictive, Preventive, Personalised and Participatory *(Medicina predictiva, preventiva, personalizada y participative)*
PAIDI 2020: Andalusian Plan for Research, Development and Innovation (*Plan Andaluz de Investigación, Desarrollo e Innovación 2020)*

PharmaNAGEN: Project to implement the methodology and procedures that allow the use of genomic information in the pharmacological prescription of the Navarra Health Service as a tool for clinical decision-making.
PMC: Personalised Medicine Coalition
PMI: The Precision Medicine Initiative
PN: Parliament of Navarra
PTD: Data Processing Plan (DPP) (*Plan de Tratamiento de Datos)*
QIR: Chemistry Specialization programme (Químico Interno Residente)
RES: Spanish Supercomputing Network (*Red Española de Supercomputación)*
Reto GEMA: R&D strategic projects. Challenge of Genomics and Advanced Medicine *(Proyectos estratégicos I+D. Reto Genómica y Medicina Avanzada)*
RGPD: GDPR, General Data Protection Regulation (*Reglamento General de Protección de* datos)
RIR: Radiophysics Specialization programme (*Radiofísico Interno Residente)*
RIS3: Research and Innovation Strategies for Smart Specialisation
RRSS: Social Media (*Redes Sociales*)
S3: Smart Strategy Specialization
SIESS: Scientific Infrastructure and Equipmet Sharing System *(Sistema de Infraestructuras Científico Técnicas Compartidas de Navarra)*
SGP: Scottish Genomes Partnership
SINAI: Research & Development and innovation System in Navarra *(Sistema Navarro de Innovación)*
SMS-I: Stratified Medicine Scotland Innovation
SNS: Spanish National Health System (*Sistema Nacional de Salud*)
SNS-O: Navarra Health System (*Sistema Navarro de Salud-Osasunbidea)*
SODENA: Navarra Development Society (*Sociedad de Desarrollo de Navarra)*
STEM: Science, Technology, Engineering and Mathematics
TIC: ICT, Information and Communications Technology (*Tecnologías de la Información y la Comunicación)*
UE: EU, European Union (*Unión Europea*)
UNAV: University of Navarra (*Universidad de Navarra)*
UPNA: Public University of Navarra (*Universidad Pública de Navarra)*
WGS: Whole Genome Sequencing

7

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