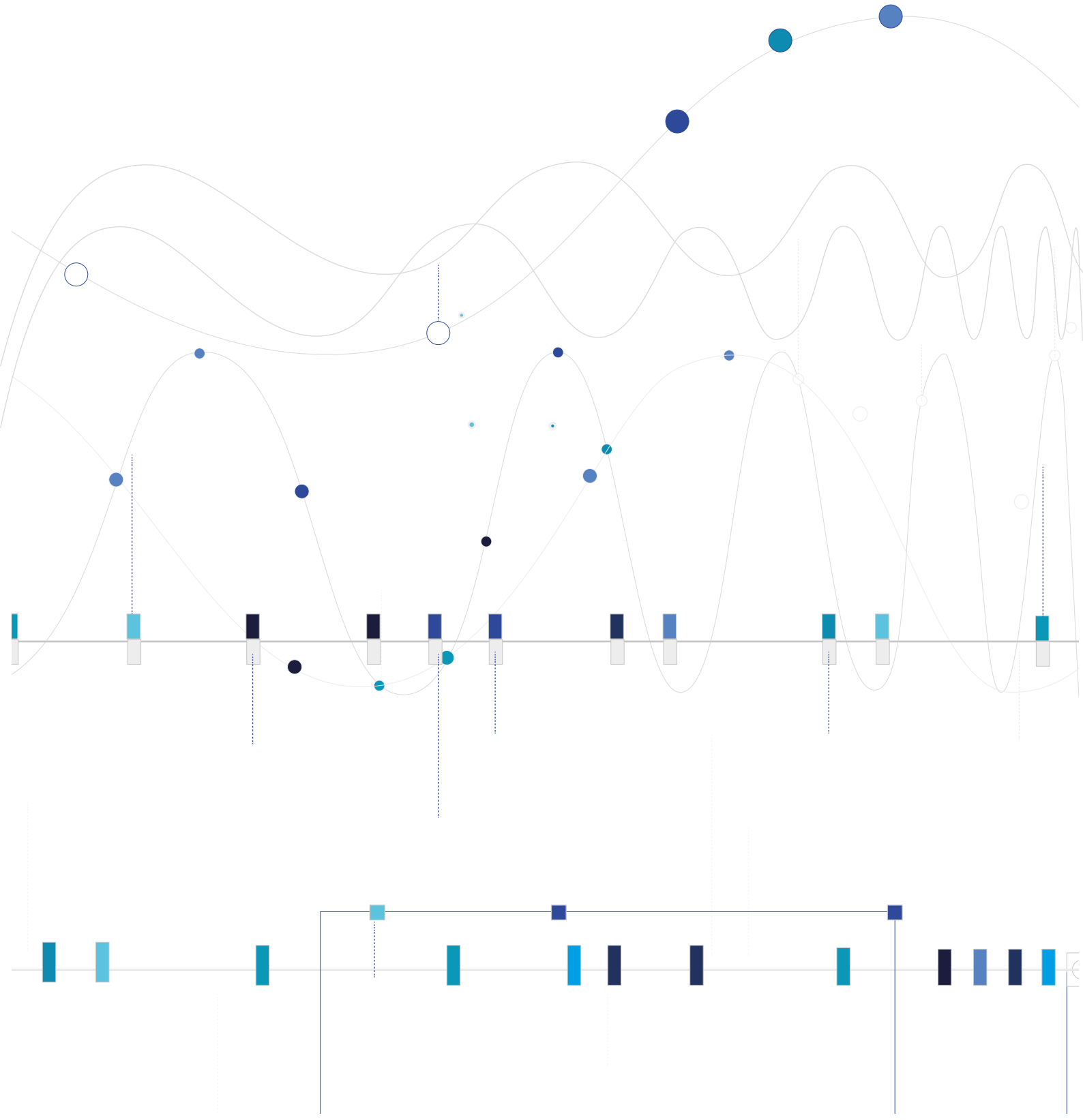
Precision oncology strategy of Galicia

Executive summary



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DE GALICIA

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Diseño, maquetación_
KRISSOLA DESEÑO, S.L.U.

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SUMMARY

Personalised, precision or stratified medicine are common terms whenever trends in innovative medicine are discussed. Beyond the subtle conceptual differences in terminology, at the core of all these terms lies the understanding of medicine as an integrative approach that considers individual biological, lifestyle and environmental factors for appropriate disease risk estimation and targeted prevention. This approach also aims to precisely define the pathological process to facilitate early diagnosis, prognosis, and optimal treatment selection and monitoring.

Indeed, the potential of personalised medicine to improve and optimise health promotion, and disease prevention and management is already being realised. The great challenge in this field now is to translate the vast amount of research results into clinical practice, facilitating their adoption by healthcare systems, and developing management and evaluation models that ensure the sustainability of the system. For this translation to be possible, it is necessary to ensure that the population-based analysis of available patient care data feeds back into the development of new technologies and therapies, closing the loop to improve the health of future patients.

Globally, there have been several initiatives to accelerate the deployment of knowledge in personalised and precision medicine and to accelerate their availability in healthcare. The focus of all these approaches is on rare diseases and cancer. The applicability of precision medicine in rare diseases - between 5,000 and 7,000 afflictions affecting approximately 7% of the world's population - is more than evident.

The application of precision medicine in cancer, with rising incidence rates, has progressively become standard practice, accounting for almost 90% of the targeted therapies introduced on the market. Targeted therapies have been developed to treat different types of tumours, now approached as diverse entities at the molecular level, with their characteristics determining

disease management and therapeutic strategies. The correct implementation of a personalised medicine strategy in cancer is a challenge due to its complexity and the need for coordination of resources, as well as the evaluation of results, which is essential to guarantee the sustainability of health systems. This document presents the response of the Galician Health Care Service to this challenge.

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METODOLOGY

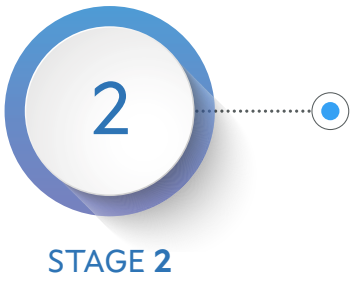
We have developed the current Strategy for Precision Oncology in Galicia following a consulting process, where professionals raised their concerns and gave their opinions, complemented with the conclusions drawn from the study of the main international and national trends (external context) and the state of affairs in the Galician Health Care Service (internal context).

After analysing these sources of information, we have identified the unmet needs - due either to weaknesses in the system or to external risk - that the current strategy will target, and the opportunities and levers for change to achieve each objective, through a route marked by specifically designed action plans.

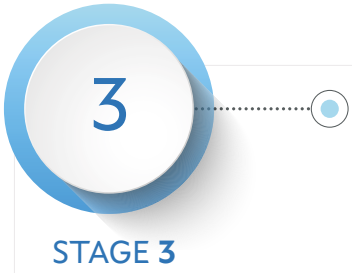
We followed six stages for building the Strategy:

STAGE **1**

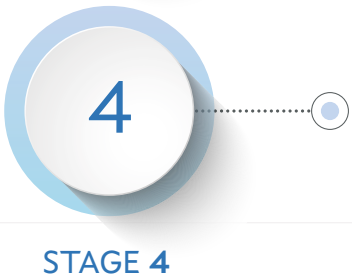
Scope definition. We studied relevant documents such as scientific publications, national and international strategies, policy documents of governmental organizations, scientific societies, etc. We established the most common set of central problems and challenges for the implementation of precision oncology. Carrying out an analysis of the internal context, we established the starting point for the development of strategic lines and action plans.



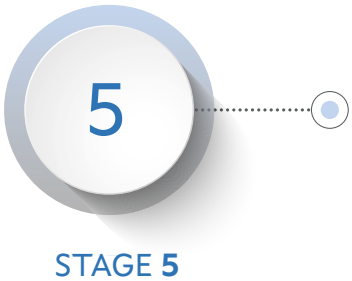
Definition of needs and levers for change. At this stage, we held personal or group meetings with the heads of medical oncology, anatomic pathology and haematology services, as well as with the FIRES working group (oncology pharmacy), the head of FPGMX (Fundación Pública Medicina Xenómica) and different managers of the Galician Health Service and the Regional Ministry of Health. In these meetings, we analysed the opinions on the scope and the needs and challenges for the incorporation of precision medicine in the next five years.



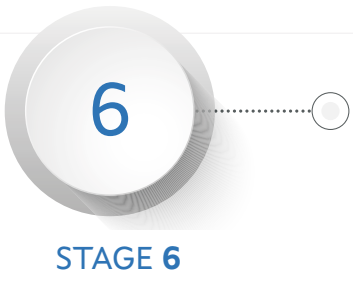
Construction of the tree of unmet needs and consensus analysis through surveys. We established the degree of agreement of the professionals with the general structure of the strategy prior to the development of the action plans.



Preparation of action plans. We developed the plans based on opportunities and levers for change identified to respond to the unmet needs.



Presentation and readjustment of the proposal. At this stage, we submitted the document for discussion and approval by the steering committee of the Regional Ministry of Health. Subsequently, it was presented to and discussed with professionals participating in the initial stages, and we made the pertinent corrections to reach a consensus. Here, we incorporated the final contributions of the scientific societies, patient associations and other stakeholders.



Prioritisation of actions. We established an initial roadmap that allowed the strategy to be finalised, with a defined start-up timetable for the design and implementation of the action plans.

KEY GOALS

The present strategy aims to develop an action plan to manage existing resources and, if necessary, to generate new resources and organisational mechanisms that will ensure the implementation of precision oncology in the Galician Health Care Service within the next five years. It should ensure access to all patients requiring the application of this type of diagnostic and therapeutic methods.

The Strategy also contemplates all the opportunities and synergies that may arise from its application, not only benefiting current patient care but also allowing for the development of research that may benefit future patients. Advancement of knowledge in personalised medicine hinges critically on processing of real-life data, and hence an approach based on intergenerational responsibility is of utmost importance.

The following Key Goals will therefore guide the deployment and implementation of this plan:

Secondary to these main healthcare objectives, this strategy will help placing Galicia in a prominent position in the development of research and innovation in precision oncology. In addition, it will contribute to the development of a new economic sector based on scientific knowledge.

ACTION LINES

Most of the strategic plans and guidelines for introduction of personalised medicine – and precision oncology in particular – in healthcare systems consider collaborative work as a keystone to ensure the efficiency needed to provide an appropriate service. The need of agile collaboration is due to the high degree of specialisation and the fast speed at which new knowledge is generated.

The European Union defined as a major initiative within its Europe's beating cancer plan the establishment of a European Network of National Comprehensive Cancer Centres located in each member state, with a reference population of around 5 million people. This network ensures that all patients have access to quality-assured diagnosis and treatment.

The Galician Health Care Service is divided into seven health areas, with specialised care centres - of varying degrees of complexity - distributed in 14 health districts and an extensive and dispersed primary care network, consistent with the structure of the region's population centres. This care dispersion is also consistent with the structure of its population pyramid, one of the most aged in Europe, and with the need to provide services to elderly citizens with little or no means of traveling to health facilities.

As a result, when designing the delivery of public services, and especially in healthcare services, proximity to the patient's home is one of the critical factors to be considered.

Hence, the implementation of personalised medicine in the Galician Health Care Service has to combine international recommendations with the regional characteristics and its pre-existing healthcare network.

There is therefore a need to develop a collaborative and coordinated network structure of precision oncology, with nodes in health areas. This network structure will integrate and distribute:

- The knowledge of its professionals: clinical committees and expert groups.
- The available services: networked molecular analysis platform with a common catalogue of basic tests, reference nodes for specialised techniques, and a quality assurance programme coordinated throughout the network.
- Information, taking into account the potential of the Galician Health Care Service for the management and analysis of aggregated information: digital biobank, clinical trial network and clinical audit system.

Thus, the implementation of all the actions will follow the principles of a Comprehensive Cancer Care Network in personalised medicine, adapted to the singularity of the Galician Health Care Service:

Care nodes

acting in a coordinated manner through a molecular tumour committee and with common governance, in order to achieve their objectives more effectively and efficiently through collective synergies. Operating in nodes will ensure that patient diagnosis and treatment is carried out from the closest possible location to the patient's home and keeping their reference professionals as a contact throughout the patient's care. The nodes will also make it easier for professionals at all hospitals to have access to technology and maintain their training and networking.

Clinical standards, protocols and quality assurance programmes

to ensure both the quality of care and patient experience.

Transversal management of corporative information

will enable aggregated data analysis, ensuring equity and improved health outcomes, while allowing secondary use of data for translational research through data lakes.

Care practice integrated with translational research

to enable patient access to the most innovative treatments through clinical trials.

Following the diagnosis of the situation and the work sessions held with groups of professionals involved in the organisation we detected areas in where it is necessary to develop reinforcement measures or radical transformations. These actions are critical to ensure the implementation of personalised and precision oncology in the short term and its sustainability in the medium and long term.

Each of the following action lines emerges from the combination of the needs identified with the existing levers and opportunities for change, which allow us to set the objectives for the implementation of each of the defined actions.

The action lines also include those needed for the sustainability and financing framework, which, together with implementation indicators, will make it possible to transform this strategy into a Precision Oncology Plan fully deployed and operational in the Galician Health Care Hospitals by 2025.

Action lines

01	Constitution of **the molecular oncology committee of the multicentre precision oncology network**
02	Development of a **catalogue of molecular biomarkers for oncology and onco-haematology**
03	Development of an update mechanism for **the biomarker catalogue**
04	Creation of **the genetic-molecular analysis network of galicia**
05	Development and implementation of a **quality assurance programme for the genetic-molecular analysis network of galicia**
06	Development of an **informed consent form for genetic analysis**
07	Definition of a **protocol for the implementation of precision oncology linked to the catalogue of authorised techniques and biomarkers.**
08	Programme for **access to advanced therapies in oncology**
09	Constitution of the **onco-haematology network unit of galicia and central clinical pathology committee**
10	Creation of **the decentralised clinical trials network unit forpersonalised medicine in galicia: labsaude oncotrials**
11	Strengthening of **the network of biobanks in galicia**
12	Creation of a **training program in precision oncology.**
13	Incorporation of **new profiles for the creation of multidisciplinary teams.**
14	Adaptation of **technologies and data management policies for precision oncology. Creation of the molecular clinical history.**
15	**Document support and management of healthcare activity for the effective incorporation of precision oncology into corporative applications.**
16	Development of **a clinical audit system based on real-life data.**
17	Creation of **the galician precision oncology data lake: digital biobank precision oncology digital**

CONSTITUTION OF **THE MOLECULAR ONCOLOGY COMMITTEE OF THE MULTICENTRE PRECISION ONCOLOGY NETWORK**

01

OBJECTIVE_ *To establish a multicentre network for precision oncology in Galicia. It will consist of a molecular oncology committee as the central node and seven nodes, one per health area. The central committee will have a dual function: consulting and assistance in complex cases, and coordinating and advising for the implementation of the precision oncology strategy. The committee will be connected with other national and European committees for collaboration and exchange of knowledge and experiences.*

ACTION PLAN

SELECT a working group that will form the initial core of the central committee.

CONDUCT a lessons-learned analysis of molecular oncology committees with an established track record in other Spanish and/or European institutions, in order to extract good practices to be incorporated.

DEFINE the structure and governance of this multidisciplinary committee: its final composition, internal operating rules and protocols for the presentation of clinical cases to ensure comparable functioning throughout the network of molecular committees. Examples of the protocols for presentation of clinical cases include the case filtering mechanism, minimum reports/data prior to study, minimum contents of the registration documents, mechanisms for knowledge management and distribution, etc.

IDENTIFY the organisational needs derived from the implementation of the committee. E.g. protected time for preparation and holding of meetings, access to all professionals involved regardless of their institution of origin.

CONSTITUTE the regional molecular oncology committee, in accordance with the established governance model and start of initial operations in a centralised way.

IDENTIFY oncology committees or networks outside Galicia and establish collaborations for regular and stable knowledge exchange.

01

Sustainability and financing

→ Protection of time for preparation of committees, assess possible impact on Chapter 1 (human resources).

Indicators for monitoring of the implementation

Number of cases analysed in the committee, report delivery time, decision report time, clinical decision clinical decision time, clinical outcomes.

→ Number of reviews of new markers /number of new marker recommendations /review-establishment of quality criteria.

→ Number of new protocols/ number of workshops.

DEVELOPMENT OF **A CATALOGUE OF MOLECULAR BIOMARKERS FOR ONCOLOGY AND ONCO-HAEMATOLOGY**

02

OBJECTIVE_ *To establish an authorised catalogue of precision oncology biomarkers in the Galician Health Care Service, including conventional and advanced techniques of molecular genetic analysis and phenotypic characterisation.*

ACTION PLAN

TO DELEGATE on the Central Molecular Oncology Committee and the Central Clinical Pathology Committee the role of planning and management committee for molecular studies, as set out in the Galician Cancer Plan, for the development of the catalogue of precision oncology biomarkers. This committee will act as an expert advisor in the field of the precision oncology biomarker catalogue, at the request of the advisory committee for the incorporation of new techniques, technologies or procedures in Galician Health Care Service.

TO ESTABLISH which biomarkers are included in routine clinical practice in each of the seven health areas, the annual demand and the place of use.

TO DEFINE AND ESTABLISH a minimum catalogue of conventional biomarkers – such as analysis of point mutations or individual genes by Sanger, RT-PCR, analysis of structural alterations of the genome using arrays or FISH, basic cytometry... – which should be available in the seven health areas. Establish also which biomarkers should be centralised in centres of reference due to low demand or technical specialisation, and their turnaround time.

TO DEFINE AND ESTABLISH the minimum catalogue of biomarkers derived from next generation sequencing and other advanced techniques, which should be immediately accessible in specialised centres in Galicia, guaranteeing equivalent response times for all requesting centres.

TO PUBLISH the catalogue of biomarkers as defined in the previous actions and their update mechanism as defined in the following line of action.

02

Sustainability and financing

→ Conduct an analysis of the demand for biomarkers of new implementation and estimate their overall cost to manage resources ensuring the viability and sustainability of the proposal.

Implementation monitoring indicators

→ Turnaround times for conventional biomarkers (aggregated, recorded at individual marker level for detailed management, deviation analysis and continuous improvement).

→ Turnaround times for next generation sequencing (aggregated, recorded by area and the level of panel/wes/wgs for detailed management, deviation analysis and continuous improvement).

DEVELOPMENT OF AN UPDATE MECHANISM FOR **THE BIOMARKER CATALOGUE**

03

OBJECTIVE_ *To develop a mechanism for the periodic review of the biomarker catalogue, so that new products or technologies for the determination of biomarkers may be included. The process will consist of three levels:*

- *Assessment and authorisation when there is regulatory authorisation and evidence endorsed by scientific societies or other national/international bodies.*
- *Inclusion as "early adopters" in the case of new markers where there is initial evidence but their clinical usefulness – or social, ethical, or organisational and/or economic implications – are not yet fully established. In this case, the adoption will be conditional to the establishment of a plan for evidence collection.*
- *Pilot projects for the gene ration of clinical evidence on products or markers for which there is no evidence of clinical utility yet, or it is at a very early stage.*

ACTION PLAN

ESTABLISH the minimum criteria for assessment of each new proposal (regulatory, evidence of clinical usefulness, cost-effectiveness, etc.) and define a standard application form for provision of evidence related to these criteria.
ESTABLISH the thresholds for the selected criteria to create three levels of biomarkers:
Biomarkers to be included in the catalogue, because their clinical usefulness has been demonstrated.
Biomarkers subject to annual re-evaluation with a high level of evidence but not fully demonstrated clinical usefulness.
Biomarkers in pilot studies, in the evidence generation phase and which may be used in authorised studies by the Galician Ethics Committee. These biomarkers would only be used in the context of the pilot study.

ESTABLISH criteria to prioritise applications for pilot studies and biomarkers in follow-up. Prioritisation is necessary to keep the number of evaluations at a level that guarantees the correct dedication of resources for assessment and follow-up. The criteria will take into account various aspects for the decision (previous level of evidence/degree of uncertainty, impact on unmet needs, incidence of the pathology, ease of introduction ...)

Sustainability and funding

→ Budgetary aspects should be taken into account in the evaluations.

Monitoring indicators implementation

→ % biomarkers under evaluation that are formally included in the catalogue.

CREATION OF **THE GENETIC-MOLECULAR ANALYSIS NETWORK OF GALICIA**

04

OBJECTIVE_ *To establish a network of genetic-molecular analysis laboratories in Galicia, which ensures access to the necessary resources for the performance of standard techniques in all health areas and to new generation technologies. Access includes not only performance of the test itself, but also the necessary training and exchange of skills and knowledge.*

ACTION PLAN

ASSESS the need for equipment and reagents arising from the approved portfolio of conventional biomarkers in centres where they are not yet available. Procurement of resources as needed.

DETERMINE the demand for sequencing, as well as the availability or need of infrastructure according to the processing capacity of the equipment and the availability of trained professionals to take on the needs and/or possible extensions of equipment. Evaluate the workload.

REORGANISE the existing resources, ensuring the immediate establishment of a "core facility" to provide technological response to the needs of new generation sequencing of solid tumours in Galicia.

ASSESS the existing capacity at the FPGMX for analysis of haematological tumours biomarkers and genetic variants, and to carry out the necessary scaling up to guarantee the current turnaround times, making the scaling up flexible in case of growing demand.

DEFINE a network of people responsible for analysis, interpretation and reporting of results. Develop a model for the verification of competence through an in-house training programme and/or participation in benchmarking exercises. The professionals of this network may not necessarily be at the technological infrastructures location. Membership to this network will be determined by the accredited competence of the professionals, and by the need for trained resources to guarantee the established response times.

04

CONSTITUTE a networked platform with different "core facilities". The platform will be a cooperative unit for resource management, technology updates and optimisation of facility use. The platform will manage the facilities resources, so each node process an adequate number of samples to ensure efficiency and sustainability. For example, specific sequencing panels may be assigned to a node. When demand analysis highlights the need for an increase in capacity, there will be a planned and managed scale up of the necessary resources (e.g. equipment procurement, training, process validation).

ESTABLISH a group of experts within the platform who will provide support or advice to the rest of the professionals and will be responsible for peer-to-peer training and implementation or transfer of new methods amongst others.

PUBLISH a new instruction for the management of genetic tests including the newly defined structure.

Sustainability and financing

→ Estimate the cost of new equipment (acquisition and/or maintenance, licences, etc.) for the constitution of the network of core facilities.

Indicators for monitoring the implementation

→ Turnaround times for conventional biomarkers (aggregated, recorded at individual marker level for detailed management, deviation analysis and continuous improvement).

→ Turnaround times for next generation sequencing (aggregated, recorded by area and the level of panel/wes/wgs for detailed management, deviation analysis and continuous improvement).

DEVELOPMENT AND IMPLEMENTATION OF A **QUALITY ASSURANCE PROGRAMME FOR THE GENETIC-MOLECULAR ANALYSIS NETWORK OF GALICIA**

05

OBJECTIVE_ *To establish a regional Quality Assurance Programme (QAP) ISO 15189 accredited, to ensure the use of common criteria for the analytical process of the genetic-molecular analysis network platform. Accredited activities would include the ability to interpret the data taking into account the information provided by the reference physician.*

ACTION PLAN

TO FORM a coordination team for the implementation of the QAP, including professionals from all network nodes (FPGMX, pathological anatomy laboratories and others), as well as from the quality area of the centres with previous experience in the ISO 15189 accreditation scheme.

TO PERFORM a baseline audit of all the nodes by an external company qualified to audit according to the ISO 15189 standard in the area of genomic medicine / pathological anatomy.

TO IDENTIFY the initial scope of accreditation, at a minimum for NGS. If the accreditation is not global, we will define a roadmap for successive incorporation of relevant techniques/biomarkers to the scope or establish flexible scopes. We will define which protocols may be centre specific and which ones must be unified at regional level. We will develop an implementation plan by health areas.

TO NOMINATE a person who will be responsible for implementation in each centre and assign responsibilities and tasks derived from the implementation plan amongst the members of the unit.

05

TO GENERATE the necessary documentation to support the QAP. The documentation will include common network protocols for detection of somatic mutation in cancer as well as in oncological haematology and familial cancer. We will coordinate the documents with the FPGMX protocols, and will take into account any relevant criteria derived from the IMPACT initiative. The documentation should ensure at least:

- The application of identical pre-analytical techniques, with consensus criteria for acceptance and rejection of samples (minimum acceptance values of integrity, purity and quantity of DNA/RNA, amongst others).
- The development of standardised reports. As a guideline, the reports would include testing technique, capture kit, nature and version of any analysis algorithms, sequencing coverage and average depth, general findings and specific results, consequence analysis of the results and classification of variants according to their degree of pathogenicity.

TO IMPLEMENT the plan for each of the nodes to be accredited, taking into account the necessary improvements detected in the initial audit. After the implementation time, we will perform an internal audit.

TO PERFORM an external audit under the ISO 15189 standard in all nodes and obtain accreditation.

Sustainability and financing

→ Cost analysis related to the development and implementation of the PGC (consultancy support, working hours of personnel, need for calibration programmes and other methodological improvements, accreditation and reaccreditation).

Implementation monitoring indicators

→ % accredited nodes

→ % activity of each node carried out within the scope of accreditation

→ % concordance in inter-laboratory tests.

DEVELOPMENT OF **A COMMON INFORMED CONSENT FORM FOR GENETIC ANALYSIS**

06

OBJECTIVE_ *To develop a model and protocol for informed consent for genetic analyses using next generation sequencing techniques. The consent process will include ethical issues such as the possibility of incidental finding of susceptibility to pathologies that were not the initial object of the test, and the possibility of authorisation for re-purposing of data.*

ACTION PLAN

TO ESTABLISH contact with the IMPaCT working team to explore the possibility of reusing (within the timeframe of the strategy implementation plan) of the materials and models generated in the project for use in our hospitals.

TO ANALYSE all the cases in which a genetic analysis may be requested and assess whether they are all included in the IMPaCT models. In the event that these are not applicable, to generate specific models that contemplate all the legal precepts.

TO DEVELOP appropriate information sheets as part of the consent document, and design a protocol for information and consent management setting out the responsibilities for both the act of information and subsequent actions.

TO EVALUATE different avenues for obtaining authorisation for secondary uses of clinical health care data, remaining samples and/or additional samples, and include them in the protocol according to their regulatory status.

TO EDIT AND DISTRIBUTE the consent documents amongst the health areas and institutions of Galician Health Care System.

Sustainability and financing

→ No special implications foreseen.

Implementation monitoring indicators

→ % samples with correct informed consent in audit of accredited laboratories.

DEFINITION OF **A PROTOCOL FOR THE IMPLEMENTATION OF PRECISION ONCOLOGY LINKED TO THE CATALOGUE OF AUTHORISED TECHNIQUES AND BIOMARKERS**

07

OBJECTIVE_ *To define and document specific clinical protocols and guidelines reflecting the new organisational structure after implementation of the personalised medicine strategy in oncology. It will include the molecular oncology committee, catalogue of biomarkers, network platform for genetic-molecular analysis, criteria, access routes, turnaround times, etc.*

ACTION PLAN

TO PRODUCE a standard flowchart for access to technology platforms. We will analyse the applicability to all centres in the network and refine the flowchart accordingly, identifying and establishing the required support mechanisms to ensure application of the protocols in all sites (e.g. procedure for transporting samples with compliance QAP parameters). We will define performance metrics and timelines.

TO REVIEW the current oncology flowcharts and if necessary update or generate new documents, reflecting any modifications as needed.

Sustainability and financing

→ If the procedures result in an unexpected cost, we will produce an annual forecast for assessment, authorisation and updating by the Galician Health Care Service.

Monitoring indicators for implementation

→ Ratio of samples processed by the network/ reference population of each area.

→ Average turnaround times for each area.

PROGRAMME FOR **ACCESS TO ADVANCED THERAPIES IN ONCOLOGY**

08

OBJECTIVE_ *To develop an organisational and support model for research and clinical care that facilitates the implementation of a programme for access of patients in the Galician Healthcare system to advanced therapies in onco-haematology and oncology.*

ACTION PLAN

TO CONSTITUTE the Coordination Unit for Advanced Therapy Medicines (COMETA) to manage access to advanced therapy medicinal products (ATMPS), both industrial and in research. The Subdirección Xeral de Farmacia, supported by the relevant clinical committees (Central Clinical Pathology Committee, or Molecular Oncology Committee), will lead COMETA. It will be the Galician route to the procedure established by the Spanish CAR-T Plan of the National Health Care System.

TO DEVELOP specific procedures, circuits and a management system for COMETA, establishing both the internal operations in Galicia as well as coordination with the national strategy.

TO ESTABLISH mechanisms for the Public Procurement of Innovation or Pre-Commercial Procurement of newly authorised ATMPS for cases out of the national programme scope.

TO ESTABLISH collaboration agreements for the manufacture and use of academic CAR-T therapies in early development or already developed by other centres in Spain. To obtain the corresponding manufacturing authorisation according to the type of drug in the Centre for Production of Advanced Therapies in Galicia.

TO PROMOTE the development of a cooperative research unit in advanced therapies, for development of clinical and preclinical clinical research projects on advanced cell therapies in Galicia.

08

Sustainability and financing

→ Budget allocation for new ATMPS according to each drug's pricing and procurement mechanisms.

→ REACT-EU funds already marked and current expenditure already considered in the start-up of the centre. Fabrication costs will be considered for each new drug.

→ Competitive calls and possibility of investing internal funds for research projects with new drugs.

Monitoring indicators implementation

→ % of patients meeting requirements who are treated with an industrial CAR-T.

→ % of patients meeting requirements who are treated with an academic CAR-T.

CONSTITUTION OF **THE ONCO-HAEMATOLOGY NETWORK UNIT OF GALICIA AND CENTRAL CLINICAL PATHOLOGY COMMITTEE**

09

OBJECTIVE_ *Creation of the Onco-haematology Unit of Galicia (UROHG), which will consolidate knowledge and experience to improve care in the complex field of onco-haematology.*

ACTION PLAN

TO CONSTITUTE a network of seven clinical-pathological committees (one per health area) coordinated by a central committee. The central committee will provide advice in complex cases and will coordinate and advise on the implementation of the strategy on personalised oncology.

TO DEFINE the functional plan of the UROHG as a supra-hospital unit bringing together capacities, resources, and experience. The functional plan should include a care plan, portfolio of services, organisational model and care and teaching plan.

TO DEFINE and implement protocols for action, including care and patient referral circuits.

TO PRODUCE and implement joint clinical protocols for areas such as CAR-T therapies, where the concentration of expertise is necessary due to their complexity and paucity of long-term experience.

Sustainability and financing

→ Protection of time for preparation of committees, assessing possible impact on chapter 1.

Indicators for monitoring implementation

→ Number of cases analysed in each of the committees, report turnaround time, time to care decision, clinical outcomes.

→ Number of reviews of new marker/number of new marker recommendations/review-establishment of quality criteria.

→ Number of new protocols/workshops.

CREATION OF **THE DECENTRALISED CLINICAL TRIALS NETWORK UNIT FOR PERSONALISED MEDICINE IN GALICIA: LABSAUDE ONCOTRIALS**

10

OBJECTIVE_ *To create LABSAUDE – OncoTRIALS, a networked unit for clinical trials in precision oncology with a protected population of 2.7 million inhabitants. This unit will facilitate the inclusion of patients in clinical trials and manage healthcare resources from the entire network. The unit will also coordinate decentralised clinical trials with the aim of increasing the availability of early-stage targeted therapies for patients within Galicia.*

ACTION PLANS

TO ESTABLISH a working group for the design of the network's operating model, involving clinicians with experience in clinical trials, regulatory experts, and managers.
TO ORGANISE co-creation workshops with stakeholders who can contribute to the model (pharmaceutic industry, patient associations, and regulatory agencies).
TO ASSESS the possibility of using Innovatrial (a clinical trial tool) to provide access to information on all active clinical trials for any healthcare professional of the Galician Health Service and to include patients in the trials carried out in the LABSAUDE-OncoTRIALS unit.
TO ANALYSE the applicable existing regulations and, if necessary, update the regional legislation to provide a regulatory framework for LABSAUDE-OncoTRIALS.
TO ADJUST the existing corporative information systems so that the decentralised clinical trials unit can be managed as any other centre in the Galician Healthcare Service.
TO ANALYSE AND DEVELOP the appropriate regulatory framework ensuring that the development of clinical trials in precision oncology can and must be run through LABSAUDE-OncoTRIALS, to guarantee equal access to all patients in Galicia and the correct monitoring and analysis of results.

10

Sustainability and financing

→ Develop a model for reinvestment of revenues from industry-sponsored clinical trials for sustainment and growth of the unit.

Monitoring indicators after implementation

→ Number of clinical trials conducted/year.
→ Number of patients recruited/year.
→ Number of professionals involved/year.

STRENGTHENING OF **THE NETWORK OF BIOBANKS IN GALICIA**

11

OBJECTIVE_ *To strengthen the Galician Biobank network model, establishing coordination procedures for single management of transversal projects and ensuring the harmonisation of protocols, and technical and sample banking criteria.*

ACTION PLANS

TO ANALYSE the current technical and administrative management of the Galician Health Care Service biobanks and private collections.

TO ESTABLISH, at a regulatory level, the possibility of banking remnants of healthcare samples and of generating specific additional samples for personalised medicine and precision oncology studies.

TO ESTABLISH and implement a single model for the management and organisation of biobanks that allows them to act in a coordinated way, with a single point of contact for corporative projects.

TO DEVELOP a model of sample governance with clear protocols for samples collected outside biobanks, and which establishes responsibilities related to their treatment, conservation, cessions and other procedures that may be required.

Sustainability and financing

→ Potential costs arising from technical assistance in the analysis phase.

Implementation monitoring indicators

→ % of sample requests managed.

→ % of private collections under the management of the biobank.

CREATION OF A **PROGRAM FOR TRAINING PROGRAM IN PRECISION ONCOLOGY**

12

OBJECTIVE_ *To prepare a training programme in precision oncology aimed at health professionals and the citizens. The professional program aims to facilitate continuing education and to accredit the competencies acquired where there is an internal training programme. The citizen side of the program will provide access to information needed for being active participants in their own medical processes, improve their quality of life, and raise awareness of their potential contribution to development of new knowledge and new therapies.*

ACTION PLAN

TO ESTABLISH skill matrices for each professional profile and area of specialisation as a basis for the design of the training programme.
TO INVESTIGATE The training needs based on the competency profile. We will design a program addressing the needs detected for each profile and level of training.
TO INCORPORATE specific training routes into the program (e.g. molecular laboratory technicians, experts in analysis of advanced molecular studies).
TO ANALYSE existing resources, both internal and external that could be incorporated into our training programmes and our e-learning platforms. For any external resources of interest, we will establish collaborations and agreements for use.
TO DEVELOP new content for needs not covered by existing training content, guaranteeing regular updates with new knowledge in the field.
TO INCORPORATE the program into the yearly training plans, and establish training objectives (ADX) in specific target groups.
TO DEVELOP a program of validated contents for patients, through collaboration between health professionals and patient associations. To develop general contents for open dissemination at the Citizens' School. To carry out specific training actions for media professionals.

12

Sustainability and financing

→ Quantify the cost of developing new training content and the cost to access to existing content.

→ Explore possible collaboration agreements to exchange training content with other entities.

Indicators for monitoring implementation

→ Indicators for training programs already in use.

INCORPORATION OF **NEW PROFILES FOR THE CREATION OF MULTIDISCIPLINARY TEAMS**

13

OBJECTIVE_ *To ensure that the Galician Health Care Service has the professionals to guarantee a multidisciplinary approach to precision oncology. To promote the development of clinical immunology in Galicia and to ensure the recruitment of non-clinical profiles such as molecular biologists and bioinformaticians.*

ACTION PLAN

- **TO CONSOLIDATE** Immunology departments as specific independent units. We will develop a working plan for each unit, defining the current responsibilities and a roadmap for expanding them to include the development of multidisciplinary onco-haematology care teams.
- **TO DEFINE** the qualifications needed for professionals who will work in multifunctional precision oncology teams, as well as their tasks, responsibilities and different levels of specialisation.
- **TO ESTABLISH** the appropriate professional categories according to the situation in other regions, and their legal framework according to current applicable regulations and/or regional competences.
- **TO INVESTIGATE** whether the professional categories of current workers who may be integrated into the precision oncology teams can be switched to newly defined categories.
- **TO DEFINE** the immediate and medium-term needs, so that we can adapt the relevant staffing and recruitment processes.

Sustainability and financing

→ Calculation of budget increase in chapter I.

Indicators for monitoring implementation

→ % Health areas with immunology units created and with functional plan implemented.

→ % of new profiles identified, and with new category created.

→ % of new professionals integrated.

ADAPTATION OF **DATA INFRASTRUCTURE AND DATA MANAGEMENT POLICIES FOR PRECISION ONCOLOGY. CREATION OF THE MOLECULAR CLINICAL HISTORY**

14

OBJECTIVE_ *To create a corporative project for data management in precision oncology and the provision of the associated infrastructures. To facilitate the incorporation of data derived from omics technologies and the treatment process into the patient's clinical records, creating an interoperable data space for primary and secondary use.*

ACTION PLAN

- **TO BUILD** a project team for deployment of IT infrastructure in precision oncology.
- **TO ANALYSE** the physical infrastructure requirements for storage of information derived from advanced genomic analysis associated with the precision oncology strategy implementation. To design the data architecture to support storage with views to data interconnection for secondary use.
- **TO DEFINE** a corporative economic data management policy with specific standardised protocols for the management of molecular data that define the format and storage system, the quality of metadata and guarantee security in storage and access.
- **TO ESTABLISH** the requirements for the integration of genomic analysis equipment with corporative infrastructure, as well as specific policies for the use of advanced processing tools and their integration.
- **TO INCORPORATE** advanced bioinformatics analysis tools for -omics data and for appropriate processing of NGS data.
- **TO PILOT AND IMPLEMENT** the plan.

Sustainability and financing

→ The economic needs arising from this line should be budgeted during the development phase so that they are included in funds from the Precision Medicine Program of the Ministry of Health, SEDIA or/ and of the Ministry of Economic Affairs and Digital Transformation.

Implementation monitoring indicators

→ Standard indicators for IT project management.

INCORPORATION OF **DOCUMENT SUPPORT AND MANAGEMENT OF HEALTHCARE ACTIVITY** FOR INCLUSION OF PRECISION ONCOLOGY INTO CORPORATIVE APPLICATIONS

15

OBJECTIVE_ *To adapt the different corporative applications and information management systems to the needs detected for the implementation of precision oncology strategy.*

ACTION PLAN

TO DETERMINE which lifestyle and environmental factors to record in the corporative electronic medical health record application (IANUS).
TO INCLUDE the new informed consent form in IANUS. We will implement a system that allows the registration and automatic filtering of patients consenting to the secondary use of excess data/samples.
TO INCLUDE in the procurement applications the references to the catalogue of approved biomarker determinations.
TO DEVELOP OR INCORPORATE support, management and analysis applications for the development of tumour molecular committees.
TO DEVELOP a new generation sequencing report template in line with the standardised content in the QAP and containing the necessary standardisation parameters. This will allow not only the correct storage in IANUS but also the ability to exploit data for aggregate analysis of results. It will include a separate section in IANUS for the genetic data.

TO INTEGRATE the Onco-haematology pharmacological management systems of the different hospitals with electronic medical health records and other necessary corporative applications. We will standardise the information and functionalities of these systems to ensure maximum quality and safety in the entire treatment roadmap for these patients. The integrated systems will allow management of drug reception, dispensing, and home or hospital pharmacy delivery, hence supporting the activity of the Galician decentralised clinical trials network unit.

15

Sustainability and financing

→ The economic needs arising from this line should be budgeted during the development phase so that funds are included in projects from the Precision Medicine Program of the Ministry of Health, SEDIA or/ and of the Ministry of Economic Affairs and Digital Transformation

Implementation monitoring indicators

→ Standard indicators for IT project management

DEVELOPMENT OF **A CLINICAL AUDIT SYSTEM BASED ON REAL-LIFE DATA**

16

OBJECTIVE_ *To design and develop a clinical audit system based on real-life data to evaluate the implementation of precision oncology protocols to patient subsets, using aggregated patient data.*

ACTION PLAN

TO DEFINE the expected system use cases, treatments to monitor, type of information to analyse (structured/unstructured), and data sets needed.
TO DEFINE The technological needs for the required functionalities. To assess the availability of resources within the available information system infrastructure or, if need be, identify market technologies that can respond to these needs.
TO CALCULATE the human and economic resource requirements of the project.
TO DEVELOP and pilot the prototype. To implement it throughout the organisation.

Sustainability and financing

→ The economic needs arising from this line should be budgeted during the development phase so that funds are included in projects from the Precision Medicine Program of the Ministry of Health, SEDIA or/ and of the Ministry of Economic Affairs and Digital Transformation

Implementation monitoring indicators

→ Standard indicators for IT project management

CREATION OF **THE GALICIAN PRECISION ONCOLOGY DATA-LAKE: DIGITAL PRECISION ONCOLOGY BIOBANK**

17

OBJECTIVE_ *To incorporate sequencing data into the Galician Health Care Service data-lake in accordance with relevant regulations, and combine the data with other clinical information to form a precision oncology digital biobank.*

ACTION PLAN

TO ANALYSE AND DEVELOP a model for an –omics data repository in the Galician Health Care Service data-lake, and integrate it within existing data management policies.

TO STUDY the technical and legal requirements for storage and incorporation of the FPGMX genomic data into the Galician Health Care Service data-lake.

TO DEVELOP accountability measures, such as issuing regular reports about data use.

Sustainability and financing

→ The economic needs arising from this line should be budgeted during the development phase so that funds are included in projects from the Precision Medicine Program of the Ministry of Health, SEDIA or/ and of the Ministry of Economic Affairs and Digital Transformation

Indicators for monitoring implementation

→ Increase of accessible data/year.

→ Number of research projects using the data/year.

MANAGEMENT

To guarantee the correct implementation of this strategy we have designed a management structure with representation of all the necessary levels of intervention:

Steering Committee for the Precision Oncology Strategy

The Steering Committee for the Precision Oncology Strategy will sit at the highest hierarchical level to ensure institutional support and power to solve administrative bottlenecks during implementation of the Strategy.

The General Manager of Dirección Xeral Asistencia Sanitaria will direct the committee, which will additionally have the following members:

- One member from each unit with responsibilities related to the deployment of action plans,
- A representative of each Health Area,
- The presidents of the Molecular Oncology Committee and the Central Clinical Pathological Committee,
- A representative of the Galician Ethics Committee
- The person responsible for the Oncology Precision Strategy.

Technical-assistance committees

For management of the Strategy, the Molecular Oncology Committee and the Central Clinical Pathology Committee will advise the steering committee and coordinate the development teams. They will communicate and synchronise efforts of the implementation teams and the steering committee.

During the implementation phase and in routine operation, the Committees will evaluate results and quality indicators, monitoring and communicating the implementation progress and suggesting improvements.

Development teams

The development teams shall be responsible for defining and fulfilling the technical description of the action plans, transforming them into projects that the organisation can implement and deploy. They will be coordinated by the technical-assistance committees and the Office for Precision Oncology Strategy. The IT central unit (Subdirección Xeral de Tecnologías de la Información) will coordinate the development teams in charge of IT action plans.

Office for Precision Oncology Strategy

The Office will support the steering committee and will be responsible for receiving progress reports from the development teams, monitoring that the established planning is followed, locating possible bottlenecks, and reporting to the steering committee to identify corrective measures. It shall be responsible for modifying lines of the plan should scientific developments or newly available evidence make it advisable to do so.

Expert groups

The Steering Committee, either on its own initiative or on the recommendation of the other members of the management structure, may request that expert groups convene. They may be multidisciplinary or focused, and shall cover different areas of expertise that may be required at the advisory or evaluation level of the measures. As a guideline, the following may form part of the groups: clinicians or scientists with a recognised expertise in the field of study, scientific societies, patient associations, biotech and pharma societies...

IMPLEMENTATION PLAN

START-UP PHASE
_ June 2023-September 2023

After a phase for presentation of allegations, the strategy will be presented and the working groups will be set up in the following order:

Steering Committee and Office for the Precision Oncology Strategy.

Technical-assistance committees.

Development Teams.

Developments teams may be gradually set up for action plans that do not fall within the first stage. Experts Groups will be set up on demand throughout the implementation of the strategy.

We have identified the following priorities for the start of the development phase, as they form the basis for building the Precision Oncology model or are required for development of further areas:

- Constitution of the molecular oncology committee for the precision oncology network
- Development of a molecular biomarker catalogue for oncology and onco-haematology
- Development of an update mechanism for biomarker catalogue
- Creation of the genetic-molecular analysis network of Galicia
- Development and implementation of a quality assurance programme for the genetic-molecular analysis network of Galicia
- Programme for access to advanced therapies in oncology
- Constitution of the onco-haematology network unit of Galicia and the central clinical pathology committee
- Creation of a training program in precision oncology.
- Adaptation of technologies and data management policies for precision oncology. Creation of the molecular clinical history.

The Steering Committee, on advice from the scientific and technical committees, will decide when to address the remaining action plans.

DEVELOPMENT PHASE
_ October 2023-October 2026

Each development team shall draw up a work plan to ensure that implementation is timely. The work plans will include milestones for each action in the corresponding plan, and it will form the basis for the Office to report on monthly progress.

The development teams will elaborate their proposals according to the established schedule. The proposals will be presented to and discussed with the technical-assistance committees, who will subsequently defend these proposals before the steering committee in order to be approved and to progress to the next phase.

The strategy lines are organisational transformation projects with a broad scope, and require significant time for their design and subsequent implementation in the healthcare centres. In some cases, it may be necessary to adapt their timetable to that of other projects to align with higher order policies (e.g. interoperability and implementation of the national and European data space in the case of IT solutions).

It is therefore advisable to accompany their design and implementation by development of specific projects in some areas (e.g pilot projects for the introduction of a new biomarker), which can be easily set up and that at the same time, it could serve as a training ground for the development of new technologies in the future.

These pilot projects should be oriented towards improved health results in three key areas of impact:

- **Prevention and early detection**
- **Early diagnosis and monitoring**
- **Improved treatment response**

IMPLEMENTATION PHASE

_ January 2024-June 2028

After the development of all the contents included in the strategy lines, they will be implemented and incorporated in the different health areas and/or organisations that form the Galician Health Care Service.

Each clinical manager and specialist teams in each clinical service will be responsible for the implementation of any measures within their area of responsibility. However, they will abide by orders of the network to ensure coordination.

The implementation phase will start as soon as one of the lines can be implemented, which may be during the development phase. The implementation phase will run until the end of the action period of this strategy.

Throughout the implementation phase, technical-assistance committees shall be responsible for the evaluation of results and quality of the measures implemented, issuing periodic reports on the implementation indicators and recommendations for improvement. The plan may be modified during its yearly evaluation and monitoring if necessary due to new knowledge or evidence becoming available. In the event that changes in the context make it advisable to modify the plan before the yearly evaluation, specific recommendations may be issued and presented to the steering committee.

MONITORING

As described in the previous sections, there will be different systems for monitoring the development and implementation of the strategy.

Firstly, we have identified indicators to monitor progress of the action plans and the result of their implementation in the organisation.

Secondly, the plan will be monitored by the committees and offices defined in the management structure.