Quality Plan

PL-GNR-008

Valdecilla
Instituto de Investigación Sanitaria
IDIVAL

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Company			

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2	Inclusion of the Equality Plan and Transfer Plan. Update on the composition of the Internal Scientific Council. Update of the Quality and R+D+i Policy and Process Map.	08/08/2019

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1. PRESENTATION OF THE VALDECILLA IDIVAL RESEARCH INSTITUTE

Origin:

The Marqués de Valdecilla Research Institute (IDIVAL) was created with the aim of promoting research and innovation in the field of biomedical sciences at the Marqués de Valdecilla University Hospital with the contribution of the University of Cantabria, to place it at a level of national and international excellence.

IDIVAL was born at the end of 2013 by agreement of the Government of Cantabria and the University of Cantabria, as the heir entity of the Marqués de Valdecilla Training and Research Institute. IFIMAV had been established in 2002 as a research management unit within the Marqués de Valdecilla Foundation and grew following the model of health research institutes and in line with the provisions of Royal Decree 339/2004, of 27 February. The constitution of IDIVAL implies, in this way, a decisive support from its founding entities, the University of Cantabria and the Government of Cantabria, to health research in the Valdecilla area.

Purposes:

As stated in Article 1 of its Founding Statutes, IDIVAL is a private organisation belonging to the foundational public sector, non-profit and whose assets have been allocated, in a lasting way, to the achievement of the Institution's own purposes of general interest.

IDIVAL is articulated following the model of Health Research Institutes developed in Royal Decree 279/2016, of 24 June, on the accreditation of these institutes. These aim to develop and harmoniously integrate basic, clinical and public health research, promoting translational research with a better transfer of the scientific advances obtained in the prevention and treatment of the most prevalent health problems in our country. All this is developed through the association of the University of Cantabria, and with the aim of linking up with public research organizations and other public or private research centers.

In line with Article 6 of its Founding Statutes, IDIVAL has the following aims:

a) To bring basic, clinical and health services research closer together.

b) To create a quality healthcare, teaching and research environment to which undergraduate students, training specialists and health professionals are exposed.

c) To constitute the ideal place for attracting talent and the location of large scientific-technological facilities.

2. JUSTIFICATION OF THIS QUALITY PLAN

For the proper development of its core activity, the promotion and development of translational research, IDIVAL requires adequate coordination and alignment of the different elements that compose it, for which it is essential to articulate an adequate Quality Plan.

It should be noted that within the action plans defined in its Strategic Plan 2017-2021, within axis 1 (structure and organization), a specific action plan related to this Quality Plan is included:

ACTION PLAN 1.3: Development of quality policy and maintenance of accreditation as a Health Research Institute

Objectives:

Creation of a working group with representatives of all related areas of activity (groups, management, platforms, etc.) and determine activities to be carried out with their corresponding calendar to implement actions aimed at maintaining accreditation as a Health Research Institute and the development in general of the Institute's quality policy.

Responsible:

Scientific Director, Management Director, Quality Committee / Accreditation Team

The organization's Quality and Continuous Improvement Plan is detailed below: the path to get there; the continuous improvement system implemented; and the processes and documents on which it is based.

3. ORGANIZATION AND RESPONSIBILITIES

As indicated, IDIVAL is an organization with its own legal personality belonging to the foundational public sector.

To facilitate the management of the Institute, and to adapt its characteristics to those necessary for an accredited Health Research Institute, the following organisational structure has been established, with governing bodies, advisory bodies, scientific organisation (research areas and groups) and research support structures:

At the regulatory level, the operation, composition, and functions of the management bodies are set out in IDIVAL's Statutes. Operationally, its operating procedure is developed in the Organisation and Operation Regulations and in the Integration Plan of IDIVAL. Its nominal composition is always updated on the Institute's website.

It is worth mentioning in this Quality Plan the relevance and involvement of these management bodies in the Quality and Continuous Improvement of the organization:

3.1 GOVERNING BODIES

3.1.1 Board

It is the highest governing body of IDIVAL and has the highest level of representation, being chaired by the Minister of Health.

In the responsibilities concerning this Quality Plan, the Board of Trustees is responsible for the approval of the Strategic Plan and the Annual Quality Plans derived from it. In this way, the Board of Trustees prepares and sends to the Protectorate, in the last three months of each year, an Action Plan in which the objectives and activities that are planned to be carried out during the following year are reflected.

Frequency: meets at least biannually.

3.1.2 Executive Committee

The composition of the Delegate Committee is decided by the Board of Trustees. Its President is the Manager of the Marqués de Valdecilla University Hospital.

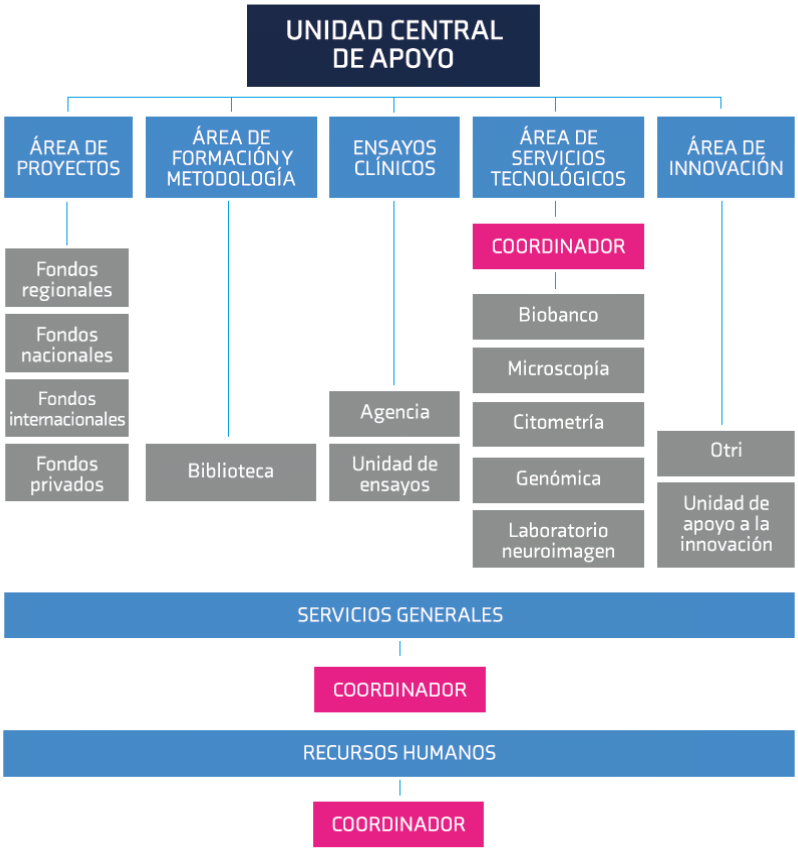
In the responsibilities concerning this Quality Plan, the Executive Committee is responsible for carrying out a periodic monitoring of the management and management tasks of the centre, monitoring the agreements and agreements signed by the Foundation and facilitating the management and management tasks of the Foundation.

Frequency: meets at least biannually.

3.1.3 Managing Director

In the responsibilities concerning this Quality Plan, it is responsible for drawing up and preparing the annual operational programmes, proposing the Action Plan and the Budget of the Foundation and for coordinating the actions aimed at obtaining the necessary resources so that the objectives of the Foundation can be met.

He is in charge of IDIVAL's Central Support Unit, which is organized into seven areas. Both the Technological Services area, the General Services Area and the Human Resources Unit have a Coordinator.



3.1.4 Scientific Director

In the responsibilities concerning this Quality Plan, it is responsible for directing, planning and leading the Foundation's scientific policy, preparing the Scientific Plan and coordinating its development, ensuring the quality of research, coordinating the scientific evaluation of research lines, groups and projects and promoting the evaluation of the scientific activity of the Institute's researchers in terms of excellence and translation.

IDIVAL's Research Areas are the groupings of scientific activity that encompass a series of research groups, which have been recognized based on a strategic analysis. At the head of each Area there is a Coordinator appointed by the IDIVAL Board of Trustees at the proposal of the IDIVAL Scientific Director for a maximum period of four years renewable. Its strategy and organization are defined in the Scientific Plan.

3.2 ADVISORY BODIES

3.2.1 External Scientific Advice

The CCE is a non-hierarchical organic structure for scientific advice that contributes to the achievement of the scientific excellence pursued by IDIVAL.

It is made up of people from the field of health sciences of recognized prestige in the scientific community.

In the responsibilities concerning this Quality Plan, it is a consultative body in charge of advising on the scientific activities of the Foundation and ensuring its scientific quality.

Frequency: meets at least annually.

3.2.2 Internal Scientific Council

The ITC is an advisory body responsible for advising the Directorate in the performance of its functions.

It is chaired by the Scientific Director and is made up of researchers from the Institute, some of them acting as coordinators of each of the research areas.

It should be noted that within its composition are the Quality Coordinator of the HUMV, the Innovation Coordinator of the HUMV and the Training Coordinator of the HUMV.

Thanks to its composition, the CCI acts in all its aspects as IDIVAL's Quality Committee.

In the responsibilities concerning this Quality Plan, and thanks to its composition, it is worth highlighting the advice and support of the IDIVAL Management in the preparation of the Strategic Plan, the annual operational programmes and the annual reports of the Institute's activities. In this regard, the JRC has a particularly relevant role in advising on the preparation, dissemination, monitoring, evaluation and updating of at least the following plans: Scientific Plan, Training Plan, Integration Plan, Communication Plan and Guardianship Plan for Emerging Groups.

Frequency: meets at least 6 times a year.

3.2.3 Other Commissions and Internal Committees

	Composition	Responsibilities concerning this Quality Plan	Minimum frequency
Innovation Commission	Managing Director Research Support Unit Technicians OTRI Director of Innovation at HUMV	Monitoring of objectives and indicators in the field of Innovation.	Weekly
Biobank Quality Committee	Technology Services Coordinator Scientific Director of the Biobank Node Coordinators	Monitoring of Biobank objectives and indicators.	Quarterly
Clinical Trial Quality Committee	Head of the Clinical Trials Unit UEC Staff	Monitoring of UEC objectives and indicators.	Quarterly
HRS4R Committees	Working Group (WG): - HR Coordinator. - Management Coordinator. - SAT Coordinator - European Projects Technician - 2postdoctoral researchers. - R2 Researcher - R1 Researcher Steering Committee (ST): - Managing Director - Scientific Director	- Working Group (WG): Responsible for the development and progress of the approved Action Plan (three-year schedule). - Steering Committee (ST): Responsible for supervising and providing the necessary resources for its proper progress.	WG: Quarterly ST: as needed
Equality Commission	Managing Director HR Coordinator SAT Coordinator Technical staff from the areas of Innovation, Clinical Trials and Administration	Ensure compliance with the positive actions and objectives approved in the Equality Plan	Biannual
Works Council	Elected workers' representatives	Ensure compliance with the workers' well-being at work.	Every two months
Health and Safety Committee	Three prevention delegates Three company representatives	Ensure compliance with Good Practices and the Health of workers.	Biannual

3.2.4 Órganos consultivos Externos

	Composition	Responsibilities concerning this Quality Plan	Minimum frequency
Cantabria Clinical Research Ethics Committee (CEIC-C)	According to RD1090/2015	To ensure the protection of the rights, safety and well-being of the subjects who participate in clinical trials and in general of studies that affect patients. To this end, it evaluates the methodological, ethical and legal aspects of clinical research projects.	Monthly
Bioethics Committee of the University of Cantabria	According to the Internal Regulations in force.	Assess activities that involve animal experimentation or the use of biological agents or genetically modified organisms, ensuring that the use of the latter does not pose a risk to the personnel involved or to the environment.	Quarterly

4. QUALITY POLICY, STRATEGY AND OBJECTIVES

Strategic Plan 2017-2021

In December 2016, the 2017-2021 Strategic Plan was finalized, which, in compliance with Royal Decree 279/2016, includes the following elements:

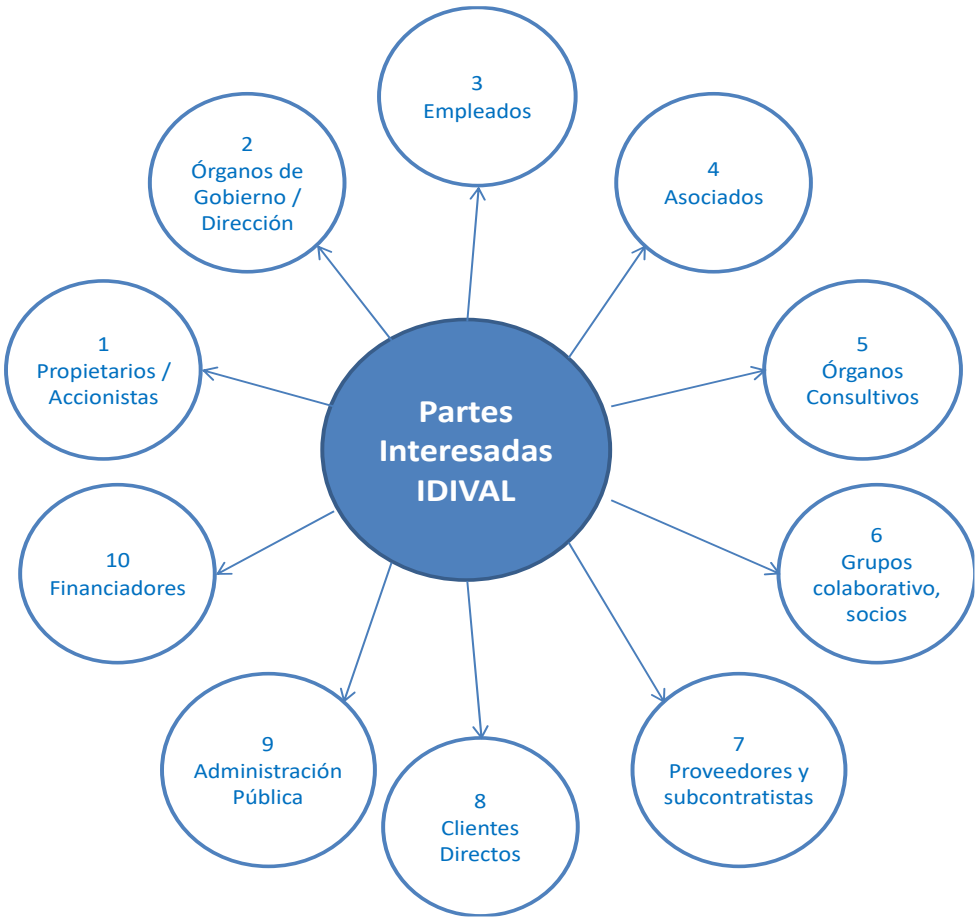
a. Analysis of the internal and external environment.
b. Prioritization of strategic lines of research.
c. Five-year cooperative scientific project, specifying the common areas, objectives and scientific lines, as well as the different actions and actions necessary to achieve the proposed objectives.
d. Evaluation system with indicators and monitoring schedule.
e. Description of the material and human resources of the different centres and research groups dedicated to the project, including a description of the areas of specialisation of biomedical knowledge of the associated centres, the composition and interdisciplinarity of their research groups and their level of competitiveness.
f. Description of the interrelationship between the structure and organisation of research with the training and clinical practice activities of the integrated health centre(s).
g. Research training plan, aimed at the staff of the centres that make up the institute, undergraduate or postgraduate training or other external collaborations.
h. Tutelage actions in emerging research centres and groups that are part of the institute or its environment.
i. Links with other like-minded groups in the same environment to work in stable networks, as well as in international networks.
j. Integration plan for the research groups of the associated hospitals and R+D+i centres, following the areas and/or lines of research of the institute.

The steps followed to achieve it are summarized below, from its conceptualization to the action plans that will allow the expected goals to be achieved:

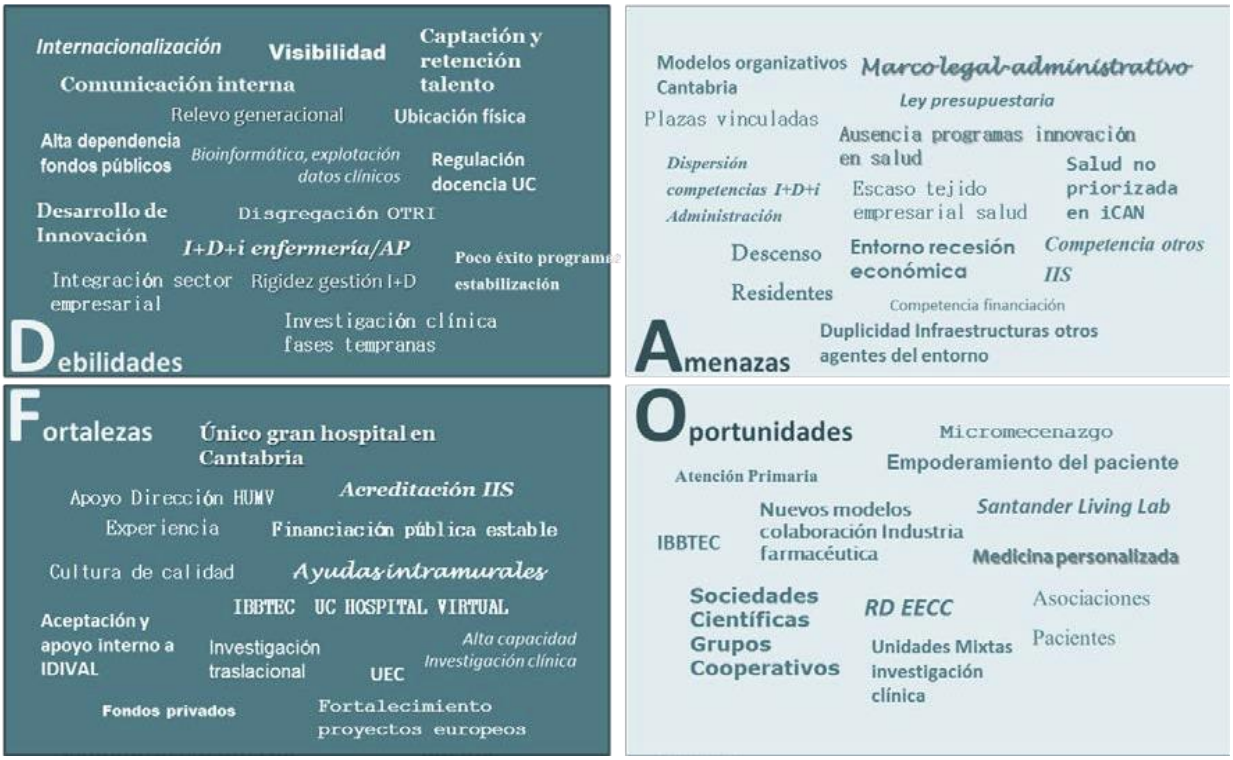
4.1 Context Analysis:

The strategic reflection carried out has as its starting point the analysis of the context:

- An analysis of IDIVAL's environment, including a review of policies and strategies, trends and main characteristics of R+D+i in health at international, state and regional level, with special attention to initiatives within the framework of health innovation.
- An internal analysis that has taken into consideration the elements of the R+D+i value chain, including available resources, an analysis of the processes developed and the results obtained. Likewise, the state of execution and results of the 2011-2016 strategic planning and the requirements for application to the Health Research Institutes established in the current regulations have been taken into consideration, together with the opinion of special interest groups, collected through personal interviews.
- An analysis of the stakeholders and stakeholders with whom we interact and the responsiveness that IDIVAL has to their stated needs and expectations.



The results of these analyses have served as the basis for the elaboration of a SWOT analysis synthesized in the following image:



4.2 Mission, Vision, Values

In cascade, the process of generating the new Strategic Plan has led to the revision of IDIVAL's Mission, Vision and Values

Mission

Thanks to the impetus of its founding institutions, the Ministry of Health of the Government of Cantabria and the University of Cantabria, IDIVAL promotes and develops research and innovation in the biomedical environment of Cantabria, which has as its epicenter the Marqués de Valdecilla University Hospital, with the aim of seeking solutions to health problems and contributing to scientific development. educational, social and economic.

Vision

We want IDIVAL - with the help of the professionals who make it up - to become an international reference centre aimed at patient service through the development of high-quality research, innovative and teaching activity based on excellence.

Values

- Scientific excellence.
- Alignment with the needs of the environment.
- Willingness to compete internationally.
- Vocation to belong to the institution.
- Orientation to attract talent.
- Transparency and equity in the hiring of personnel.
- Focus on innovation and social return.
- Independent external evaluation.
- Sustainability.

4.3 Quality and R+D+i Policy

IDIVAL's quality policy is born from IDIVAL's strategy and is based on the mission, vision and objectives and strategic lines. It was reformulated in 2016 and revalidated after its revision during the preparation and rethinking of the Strategic Plan 2017-2021:

The IDIVAL Management is committed to guaranteeing the research professionals it supports and the bodies that finance it:

- The quality of the services provided,
- Process efficiency,
- The search for continuous improvement,
- The best use of resources.

To achieve this, the Management establishes the following guidelines and commitments:

- Innovation and quality research with good professional practices that meet the needs for the generation of knowledge and solutions for health problems and their potential transfer to clinical practice, as well as compliance with current obligations in terms of ethics, confidentiality and R+D+i management;
- Anticipate and assess the societal implications and impact of research and innovation on society;
- Always keep in mind IDIVAL's MVV, as bases that should guide actions and purposes;
- Quality Management System implemented in accordance with the requirements of the Accreditation Guide for Health Research Institutes of the Carlos III Health Institute and UNE EN ISO 9001 and UNE 166.002 standards in force;
- Transparency, accessibility and equality in the recruitment and promotion of talent, which allow for international projection;
- Improvement of the qualification of researchers and workers of the institute, promoting their education and training;
- Dissemination throughout the organization of the need and advantages of Management Systems, promoting the implementation of policies and procedures in their activities and research projects;
- Establishment and fulfilment of the annual objectives set out in the Institute's Action Plan in order to verify the effectiveness of the Management System;
- Establishment and fulfilment of the annual objectives set out in the Institute's five-year Scientific-Cooperative programme, so that progress is made in the development of the prioritised lines of research;
- Participation of the Organization in the Continuous Improvement process.
- Dissemination of knowledge generated with open science criteria to the whole of society.

El Director de Gestión del IDIVAL

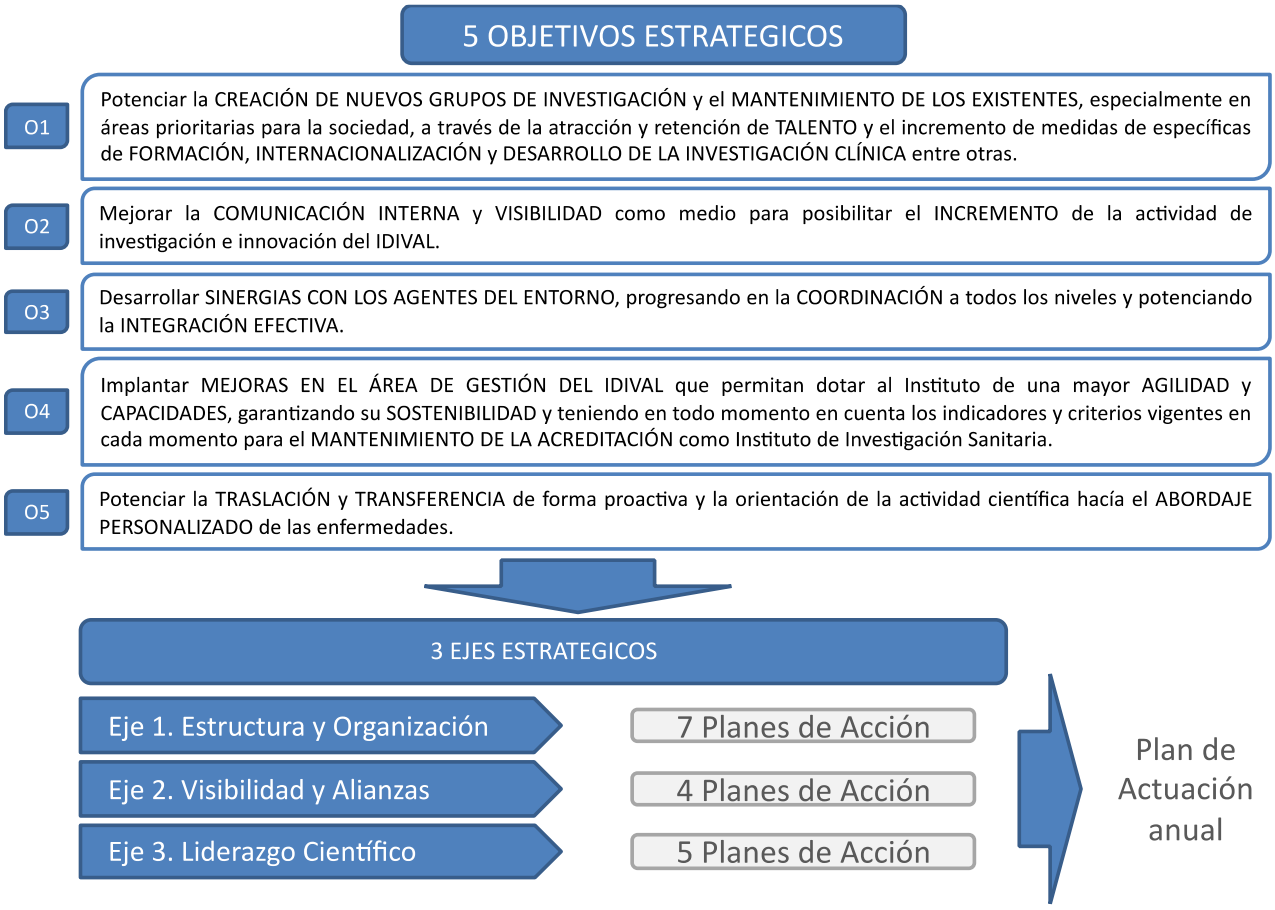
Fdo.: D. Galo Peralta Fernández

A 8 de agosto de 2019

4.4 Objectives and Strategic Axes

Taking into account the proposal to reformulate IDIVAL's Mission, Vision and Values, 5 Strategic Objectives are defined for the coming years.

To achieve them, the following 3 Strategic Axes and the corresponding action plans that develop them are materialized:



The details of the Action Plans are as follows:

4.5 Indicators and monitoring

Each Action Plan identifies those responsible, the planned schedule and the monitoring indicators.

The annual Action Plan, consistent with the Strategic Plan, is approved by the Board of Trustees. The Board of Trustees also participates in the definition of the annual investment plan and development of aid.

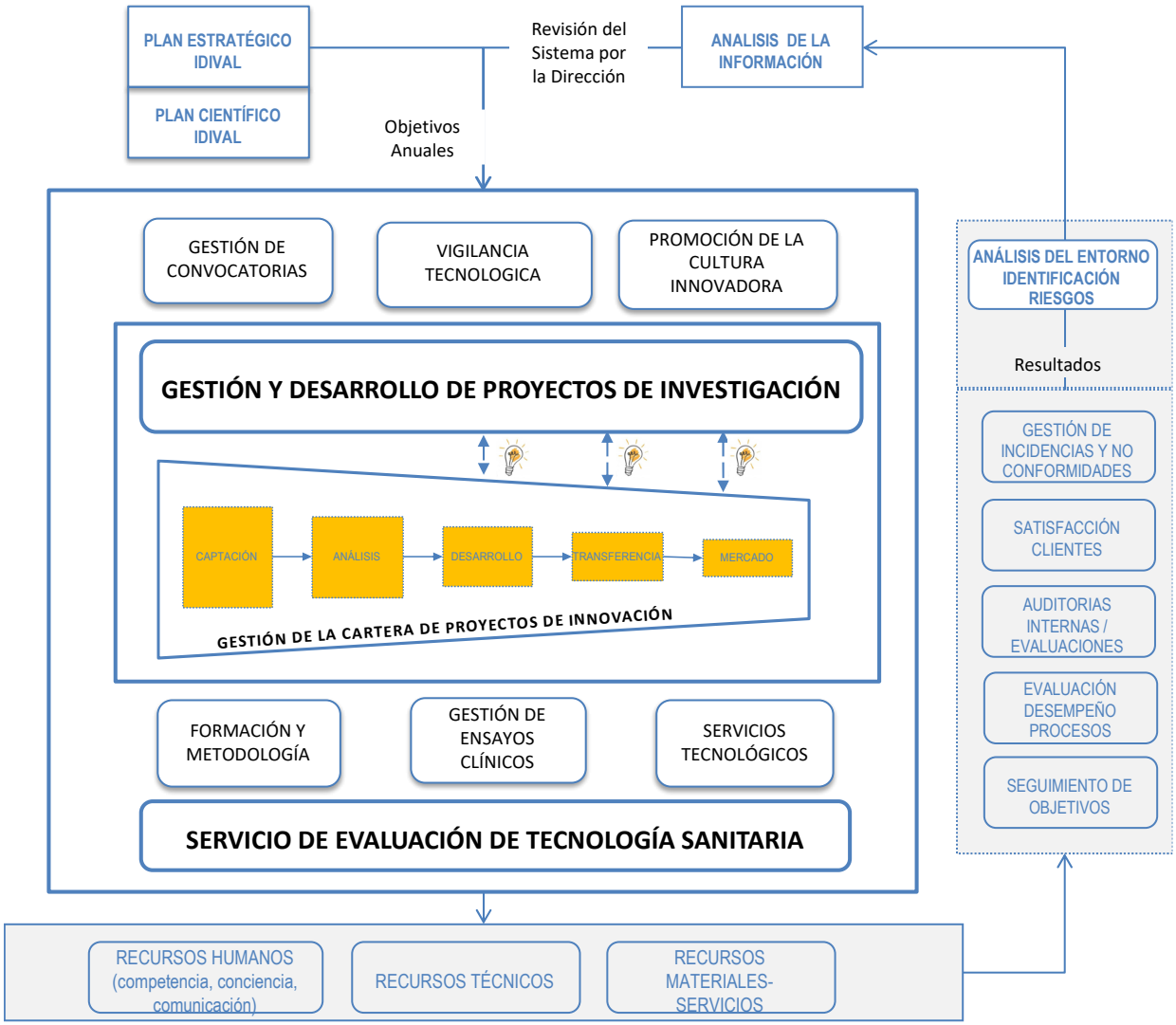
It is the Internal Scientific Council that continuously monitors the progress of the Strategic Plan, with the information provided by the Directorate of Management and Scientific Direction.

IDIVAL's current Strategic Plan, with its action plans, timeline and monitoring indicators, is published on the IDIVAL website for all interested parties.

5. MANAGEMENT SYSTEM

5.1 Process Map

IDIVAL's processes are detailed in the following Process Map and in the development of each of them, which includes those responsible for them and the indicators that will serve as a basis for their review and continuous improvement of the entity.



5.2 Scopes, certificates and accreditations:

As detailed below in the corresponding areas, as of the date of this Quality Plan, IDIVAL is certified based on the UNE 166.002:2014 and UNE EN ISO 9001:2015 standards with the following scope:

Scope of the management system implemented based on the UNE 166.002:2014 standard:

- *Promotion and management of research and innovation in the field of health in the biosanitary environment of Cantabria.*

Scope of the management system implemented based on the UNE EN ISO 9001:2015 standard:

- *BIOBANK: The management (collection, processing, storage and transfer) of quality human biological samples and their associated clinical data, with the purpose of facilitating and promoting biomedical research. Methodological, ethical-legal advice to research groups, and scientific-technical support related to the processing and management of human biological samples.*
- INNOVATION AREA: Dissemination and promotion of innovative culture. Support for the detection, planning, development and valorisation of innovation projects and protection of their results. Health Technology Assessment.
- *CLINICAL TRIALS UNIT.*

Likewise, IDIVAL has received in October 2018 the seal of excellence in Human Resources, known as HRS4R. The European Strategy for Human Resources in Research is a tool adopted by the European Commission through the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers (Charter & Code), which aim to contribute to the development of an interesting European labour market for researchers, promoting their equal rights and obligations throughout the European area. HRS4R seeks to promote the adoption of the 40 principles defined in the Charter & Code that delimit the rights and responsibilities of researchers and employers.

Achieving this certification involves a long-term commitment over many years, including joint efforts and coordination with various internal and external stakeholders. However, it is a process that ensures the institution's transition from progress to quality, in terms of the implementation of the principles of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers promoted by the European Commission. These two references aimed at researchers, employers and funders of research in the public and private sectors are key elements in EU policy to boost researchers' careers.

5.3 Management System:

The document structure developed so that the processes support and the professionals are adequately focused on achieving the objectives set by the IDIVAL Strategy is summarized below.

For better visualization, they have been distributed in 4 large blocks:

- Strategy
- Organization and Regulations
- Operating
- Evaluation and Continuous Improvement

5.3.1 Strategy:

Below is a brief summary of the Plans generated to develop the strategy, and you can find details of the scope, actions, timetable, objectives and specific indicators in each of them. They are always updated and available to interested parties who require them through the IDIVAL website:

5.3.1 STRATEGY					
		Resp.	**Frequency of re-edition of the Plan**	**Follow-up frequency**	**Objectives/Indicators**
1	**Strategic Plan** PL-GNR-001	Internal Scientific Committee Managing Director Scientific Director	Maximum every 5 years	Annual minimum.	Annual monitoring of compliance with the different action plans, deadlines and indicators, within the Quality Committee.
2	**Scientific Plan** PL-GNR-002	Scientific Director	Maximum every 5 years	Annual minimum.	Annual monitoring of compliance with the specific actions to be carried out in each Research Area by the Area Coordinator and the Scientific Directorate.
3	**Integration Plan** PL-GNR-003	Managing Director	Maximum every 5 years	Annual minimum.	Annual monitoring of compliance with the criteria for the incorporation and dismissal of researchers and research groups to the foundation.
				Minimum every 5 years.	Monitoring and evaluation of Research Groups.
				Three years from the date of the initial contract.	Monitoring and evaluation of the scientific performance of staff researchers.
				Annual minimum.	Maintenance of post-MIR researcher integration strategies
				Annual, according to budget	Maintenance of production aid for research groups according to objective criteria.
4	**Guardianship Plan for Emerging Groups** PL-GNR-004	Scientific Director	Maximum every 5 years	Annual, according to budget	Maintenance of aid (Wenceslao López-Albo, Production aid, Inn-Val, Ment-Val, Next-Val,...)
				Annual, according to budget	Maintenance of training with the scope and frequency described in the plan (sessions, general, weekly research seminars, research methodology, ...)
				Continuous	Maintenance of support for research through the UCA.
				Every 3 years	Evaluation of emerging groups according to established international parameters.
				Variable	Evaluation of new researchers according to the established parameters (review of reports, evaluation of contracts, etc.)
				Annual	Annual measurement of the indicators established in the Plan (paragraph 8) and satisfaction surveys.

5.3.1 STRATEGY					
		Resp.	Frequency of re-edition of the Plan	Follow-up frequency	Objectives/Indicators
5	**Training Plan** PL-GNR-005	Managing Director Scientific Director	Annual	Annual, according to budget	Detection and analysis of training needs on an annual basis according to the defined system. Maintenance of training following the lines and frequency described in the plan (IDIVAL Sessions, Translational Research Seminars, Dissemination of Innovation, Research Methodology, Postgraduate and Undergraduate Training,...)
				Annual	Annual measurement of the indicators established in the Plan (assistants, thesis, mentions, capacity to attract funding...), and carrying out satisfaction surveys and assessing the effectiveness of the training.
6	**Communication Plan** PL-GNR-006	Managing Director	Maximum every 5 years	Annual	Compliance with internal communication actions with the scope and frequency described in the plan: weekly newsletter, monthly general sessions, monthly Santander Biomedical Lectures, quarterly UCA dissemination, weekly progress report, ...
				Annual	Compliance with external communication actions with the scope and frequency described in the plan: annual updating of web structural content, daily updating of dynamic content, visits to Institutes, annual participation in the researchers' night, ...
7	**Quality Plan** PL-GNR-008	Managing Director	Maximum every 3 years	Annual	Compliance with the requirements derived from the Plans and processes, especially those related to Continuous Improvement processes (establishment of objectives, audits, monitoring of incidents, evaluation of satisfaction, Review of the System by Management, etc.)
8	**Estrategia RRI**	Managing Director Scientific Director	Maximum every 3 years	Annual	IDIVAL has developed various actions for the adoption of RRI as a framework for research and innovation within each of the 6 aspects of RRI: - Ethics (Equality Plan, HRS4R, Code of Good Practice in Research, ...) - Gender equality (Equality Plan, HRS4R, specific training, ...) - Governance (Participatory Governance, Ethics Committees) - Open access (UCREA adhesion, ORCID code, open publishing...) - Citizen participation (fusion programme, collaboration campaign, Tichron project, ...) - Science education (outreach activities, scientific workshops, guided tours, researchers' night, ...)
9	**HRS4R Strategy**	Managing Director Scientific Director	Maximum every 3 years	Annual	Compliance with the Action Plan approved by the European Institution, following the committed schedule. Annual measurement of the indicators and objectives established in the Plan.

5.3.1 STRATEGY					
		Resp.	**Frequency of re-edition of the Plan**	**Follow-up frequency**	**Objectives/Indicators**
10	**Equality Plan** PL-GNR-007	Equality Commission HR Coordinator Managing Director	Annual	Annual	Compliance with the objectives in terms of equality, following the committed schedule. Annual measurement of the indicators and objectives established in the Plan: - Selection and hiring - Classification of personnel - Career advancement - Working conditions - Rights - Female representation - Fees - Bullying prevention - Communication and image
11	**Translation Plan** PL-GNR-009	OTRI Managing Director	Annual	Annual	Annual monitoring of the objectives and indicators of Translation and impact on Society within the objectives of the Innovation area. Among others: - Clinical Practice Guidelines and Institutional Documents - Patents, SW licenses, intellectual property, utility models, ... - Transfer training activities. - Outreach activities to the public.

5.3.2 Organization and Regulations:

Below is a brief summary of the Regulations, Manuals, Procedures and instructions of a transversal nature that govern the actions of all the professionals of the organization.

5.3.2 ORGANIZATION AND REGULATIONS			
		Objective/Scope	**Principal Responsible**
1	**IDIVAL Statutes**	Public information on the first registration in the Register of Foundations of the Autonomous Community of Cantabria of the Marqués de Valdecilla Research Institute Foundation.	Board
2	**Regulations of Organization and Operation** RE-GNR-01	It includes the purposes and principles of action, the regulatory framework regarding its activity, the structure of its organisation and the operational guidelines in strict compliance with the legal provisions applicable to it and its Statutes.	Managing Director
3	**Regulations for the Use of Facilities** RE-GNR-02	The purpose of this regulation is to establish a regulatory framework that allows an optimal, responsible, efficient, lasting and safe use of the areas intended for the IDIVAL building and in an environment of adequate coexistence of the IDIVAL groups that they occupy.	SAT Coordinator
4	**Guide to Good Practices in Research** MA-GNR-02	Establish an ethical code of conduct for IDIVAL staff, both its own and related staff, which sets the guidelines to avoid conflicts, in order not to engage in unfair practices or falsify the results and that guarantees respect for the authorship of the publications and the ownership of the discoveries. IDIVAL assumes the current CBPI as an adaptation of the Code of Good Scientific Practices and Research Integrity Committee developed by the Carlos III Health Institute.	Managing Director Scientific Director
5	**Laboratory Biosafety Manual** MA-GNR-03	The procedures that are developed in laboratories that work with animal and human material for research entail specific risks, both for workers and for the environment. Minimizing these risks is not only a requirement of legislation, but a necessity that arises from common sense itself. That is why every laboratory must have a Safety Program to prevent or minimize damage, both for the biological material it houses and for the personnel employed. To this end, the Marqués de Valdecilla Research Institute (IDIVAL) has prepared this Biosafety Manual.	SAT Coordinator
6	**Intra-centre Waste Management Manual** MA-GNR-04	This document sets out the necessary rules and indications for the internal management of the waste produced by IDIVAL, in accordance with current regulations, from the collection, selection, packaging, transfer and internal storage of the waste, to the transfer under the agreed conditions, to the final managers.	SAT Coordinator
7	**Security Document Information Security Management System** MA-GNR-05	This Security Document has been prepared to comply with the General Data Protection Regulation. The security standards it develops are applicable to the following IDIVAL resources: • Corporate network. • Central and local servers and the operating system and communications environment in which the files with personal data are located.	Security Manager Managing Director

5.3.2 ORGANIZATION AND REGULATIONS			
		Objective/Scope	**Principal Responsible**
		• The computer systems or applications established to access personal data. • Workplaces, whether local or remote, from which files with personal data can be accessed. • Other computer elements involved in the processing of personal data. • Treatment centres and premises where the files are located or the media containing them are stored. • Non-automated file storage devices.	
8	**IDIVAL Corporate Identity Manual** MA-GNR-06	This manual brings together the basic tools for the correct use and graphic application of the IDIVAL brand. It has been designed thinking about the needs of all those people responsible for applying the brand in its different areas.	Managing Director
9	**Emergency Action Protocol** PR-GNR-02	Organise the action of the centre's staff in an emergency situation to minimise the risks and their consequences.	SAT Coordinator
10	**Management of System documentation and records** PR-GNR-05	Establish the guidelines for the correct structuring, identification, approval, review, dissemination, use and archiving of the documented information of the Management System implemented by IDIVAL. It is also applicable to documentation that may affect or is related to the Quality System, such as internal and external standards, customer documentation, etc.	Managing Director
11	**IDIVAL Security Procedures** PR-GNR-06	The purpose of this procedure is to describe how the identification and authorisation of user access to IDIVAL's information systems is carried out.	Security Manager Managing Director
12	**Procedure for registration, entry and exit of documentation** PR-GNR-13	This procedure establishes the guidelines for the correct processing of the entry and exit registration, a fundamental corporate process at IDIVAL. This procedure is applicable to all relevant documentation, information and applications received in person, by post or electronically at IDIVAL. In addition to the documents delivered or sent to different Bodies or entities that, due to their characteristics, are susceptible to greater monitoring, control and management by making an exit record.	Managing Director

5.3.2 ORGANIZATION AND REGULATIONS			
		Objective/Scope	**Principal Responsible**
13	**Procedures for organising group visits** PR-GNR-17	Define the method used for the organisation of activities that involve the visit of groups of people to participate in training or dissemination activities, establishing rules that ensure, as far as possible, that these activities are carried out in an organised manner and in a safe environment for their visitors and without altering the activity of IDIVAL staff. This document applies to all visitors from educational centres (schools, secondary schools, vocational training students) or from other institutions or the general public who come to IDIVAL to participate in a training or informative activity.	Health and Safety Committee
14	**Protocol for Prevention and Action against Harassment** PR-GNR-18	Recognise, prevent and, where appropriate, eradicate all those behaviours and organisational factors that reveal violent behaviour in the workplace and promote a healthy work environment, both physical and psychological.	Health and Safety Committee

5.3.3 Specific Operations:

5.3.3 OPERATIVA ESPECÍFICA			
1. GESTIÓN Y DESARROLLO DE PROYECTOS DE INVESTIGACIÓN			
	Relevant documentation that supports your operation	**Objective/Scope**	**Resp.**
1	**Research Project Management Instructions** IN-GNR-02	It applies to research projects that are managed by IDIVAL. They include projects financed with funds of public origin (including funds awarded by IDIVAL) or private, competitive or not.	Managing Director Scientific Director
2	**Instructions for Signing Scientific Publications** IN-GNR-03	To promote the standardization of the signature of IDIVAL researchers in their scientific publications, both in terms of personal and institutional name	Managing Director Scientific Director
3	**Group Onboarding and Tracking Manual** MA-GNR-08	The objective is to facilitate the incorporation of research groups, providing the necessary information about the institute and its organizational structure, the current research areas and groups, the requirements to be met by the staff of the IDIVAL groups, the procedures to acquire the status of IDIVAL group, rights and duties, and the monitoring system of the groups (report, periodic evaluation)	Managing Director Scientific Director
	Areas	**Scope**	
1	**National R+D+I Plan**	This Support Unit of the R+D+I Management Area of IDIVAL, manages the funds from the General State Administration. The Programme available to the Ministry of Science and Innovation (with the central competences in terms of research and technological development) is the National R+D+i Plan. This plan is articulated on the basis of Instrumental Lines of Action. The Strategic Action in Health (AES) is also articulated and is managed by the Carlos III Health Institute (hereinafter ISCIII).	
2	**European projects**	This Support Unit of the R+D+I Management Area of IDIVAL provides support to the Institute's research staff in the preparation of research project proposals in international programmes. Its activity is mainly focused on the management of European projects, and specifically on the Horizon 2020 programme.	
3	**Equity**	IDIVAL promotes research in its environment through grants aimed at researchers in its environment, and especially grants aimed at researchers in training, innovation and their research groups.	
4	**Private Funds**	Through this Unit, IDIVAL supports the management of donations, agreements and contracts for research services both in their preparation and monitoring, provided by third parties to the Institute's research groups and to the entire Cantabrian Health Service.	

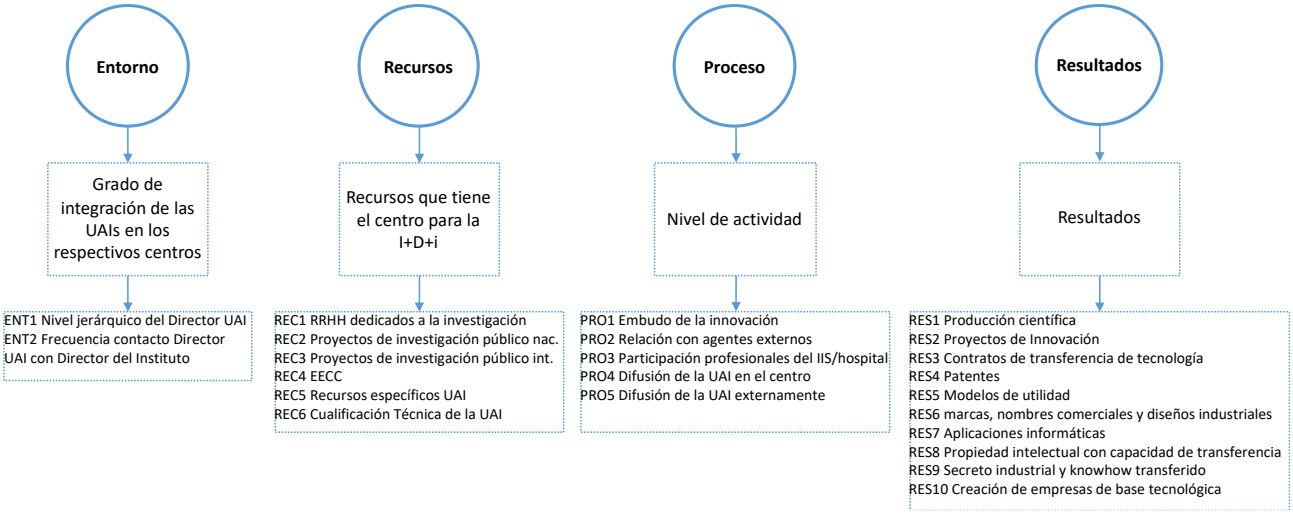
5.3.3 SPECIFIC OPERATIONS			
2. INNOVATION MANAGEMENT			
	Relevant documentation that supports your operation	**Objective/Scope**	**Resp.**
1	**Promotion of innovative culture in the Valdecilla area.** PR-INN-01	This procedure details the way to carry out the planning and management of innovation promotion and training days in the IDIVAL Innovation Area with the aim of promoting an innovative culture in the biohealth environment. The activities include dissemination days in this field (patents, companies) and creativity workshops that try to promote the culture of innovation. Likewise, presentations are made in different courses at the request of interested institutions. Basic Tools: - Annual planning of actions. - Recording and evaluation of actions carried out.	Innovation Area Technicians
2	**Technology Watch** PR-INN-02	Este procedimiento detalla la manera de llevar a cabo el proceso de vigilancia tecnológica por parte del Instituto de Investigación Marqués de Valdecilla (IDIVAL). De esta manera, quedará estructurado dentro de la institución el proceso de escucha y observación del entorno para apoyar la toma de decisiones. Herramientas: - Fuentes de Información. - Boletines.	Técnicos del Área de Innovación
3	**Innovation Project Portfolio Management** PR-INN-03	The key to the development of innovation is its systematization and organization; the Institute's innovative capacity will depend on how it organizes and manages the process of systematizing innovation, since most innovations are the result of systematic work to search for ideas and opportunities and transform them into realities. The objective of this written procedure is to describe the activities to channel innovative ideas or proposals, from the moment the idea arises, to its possible protection, valorization and commercial exploitation. Tools: - Patent Valuation BPMs - FUNDANET INNOVA	Innovation Area Technicians OTRI Manager
4	**Health Technology Assessment** PR-INN-04	eValTec® uses Human Factor Engineering to understand and improve the relationship of professionals with healthcare technology, care processes and the work environment, making them more efficient and safer for patients and professionals. The objective of this procedure is to define the different services and areas of action in human factor. It evaluates health technology both for the Cantabrian Health Service as support for acquisition decision-making and support in its implementation as well as for other Health systems and companies.	eValTec Technicians

5.3.3 SPECIFIC OPERATIONS			
2. INNOVATION MANAGEMENT			
	Relevant documentation that supports your operation	**Objective/Scope**	**Resp.**
		Evaluate and redesign care processes. It evaluates health technology in the design phase before it is put on the market by manufacturers, with a view to its improvement. Evaluates existing technology for optimal use within healthcare processes	
5	**Support in the consolidation of innovation in the national health environment** PR-INN-05	One of the objectives of the IDIVAL Innovation Area is to carry out a proactive activity of training, dissemination and promotion of the innovative culture, both inside and outside the institution (Hospital, University, Company, Society), thus trying to facilitate public-private collaboration and transfer. This procedure defines the system of participation in working groups, networks and associations by the Innovation Area, with the aim of facilitating the systematic management and communication of actions within the Area.	Innovation Area Technicians

Since its inception in 2010, IDIVAL has been part of the Platform for Innovation in Health Technologies (ITEMAS), a national reference network in healthcare innovation promoted by the Carlos III Health Institute.

IDIVAL currently coordinates this platform at the national level.

The indicators of the ITEMAS Platform give us an excellent basis for assessing our performance, as well as allowing a certain comparison with other research institutes on the platform. They are summarized in the following figure. The set of indicators constitutes an extensive and detailed map that reflects the different aspects related to innovation in the healthcare environment:


Entorno
Grado de integración de las UAIs en los respectivos centros
ENT1 Nivel jerárquico del Director UAI
ENT2 Frecuencia contacto Director UAI con Director del Instituto
Recursos
Recursos que tiene el centro para la I+D+i
REC1 RRHH dedicados a la investigación
REC2 Proyectos de investigación público nac.
REC3 Proyectos de investigación público int.
REC4 EECC
REC5 Recursos específicos UAI
REC6 Cualificación Técnica de la UAI
Proceso
Nivel de actividad
PRO1 Embudo de la innovación
PRO2 Relación con agentes externos
PRO3 Participación profesionales del IIS/hospital
PRO4 Difusión de la UAI en el centro
PRO5 Difusión de la UAI externamente
Resultados
Resultados
RES1 Producción científica
RES2 Proyectos de Innovación
RES3 Contratos de transferencia de tecnología
RES4 Patentes
RES5 Modelos de utilidad
RES6 marcas, nombres comerciales y diseños industriales
RES7 Aplicaciones informáticas
RES8 Propiedad intelectual con capacidad de transferencia
RES9 Secreto industrial y knowhow transferido
RES10 Creación de empresas de base tecnológica

5.3.3 SPECIFIC OPERATIONS			
3. CLINICAL TRIALS			
	Relevant documentation that supports your operation	**Objective/Scope**	**Resp.**
1	**Provision of Services in the Valdecilla Clinical Trials Unit.** PG 05	It develops the necessary requirements for the adequate provision of services in the Clinical Trials Unit throughout the process: - Request for Services and preparation of budget. - Assessment of the application and planning of the activity. - Preparation and Execution of the Clinical Trial. - Periodic Implementation Evaluations. - Completion of work and delivery of results. Customer compliance and billing. Specific SOPs are developed for critical activities, highlighting among them: -PNT002 Provision of first aid in the most likely emergency situations, such as cardiac arrest, anaphylactic shock and hypotension. -SOP 004 Requirements for the compulsory permanence of personnel in the Unit during the Test. Medical coverage. -PNT 006 Communication with the Physician in Charge of the Trial. -PNT 008 Communication of adverse reactions and adverse events to the sponsor, the Clinical Research Ethics Committee and the Health Administration. -PNT 010 Medication Management in Clinical Research. -PNT 016 Sample management.	Head of the Clinical Trials Unit

IDIVAL is part of the SCReN (Spanish Clinical Research Network) Clinical Research Support Platform of the Carlos III Health Institute through this area.

The most relevant indicators handled by the Clinical Trials Unit are summarised below:

- Specialties contacted, new services incorporated.
- Major deviations from the Protocol detected by follow-up letters from monitoring visits.
- Minor deviations from the Protocol detected by follow-up letters from monitoring visits.
- Average number of visits/month
- Number of patients treated in the year
- Patient training in the use of electronic devices
- Hours of training of staff in the field of clinical research
- Hours of retraining/retraining

5.3.3 SPECIFIC OPERATIONS			
TECHNOLOGICAL SERVICES:		**VALDECILLA BIOBANK FLOW CYTOMETRY AND CELL SEPARATION UNIT LASER AND ELECTRON MICROSCOPY UNIT NEUROIMAGING UNIT**	
	Relevant documentation that supports your operation	**Objective/Scope**	**Resp.**
1	**Manual for the Organization and Use of Technological Services** MA-SAT-01	This manual has a double objective: 1. Describe the structure and organization of the Technological Support Services, of the Units that make them up, and establish the functions and obligations of the personnel of each of them, as well as the duties and rights of the users. 2. Describe the procedures for requesting the services provided by the different SATs Units in order to make optimal, organized, responsible and efficient use of them, and the general conditions of use of the SATs and particular ones established by each of the Units.	SAT Coordinator
2	**Procedure for the provision of Technological Services** PR-SAT-01	The purpose of this procedure is to systematize the activities to be carried out by each of the Units that make up IDIVAL's Technological Services to ensure traceability and control of the management of the provision of services to researchers (IDIVAL or another research institution), from the request for the same to the issuance of the corresponding invoice. The Technological Services qualified to sell their services, both to internal and external customers in IDIVAL are: 1. Biobanco; 2. Flow Cytometry and Cell Separation Unit; 3. Laser and Electron Microscopy Unit 4. Neuroimaging Unit	SAT Coordinator
3	**Internal Operating Regulations of the Valdecilla Biobank** RE-SAT-01	The purpose of these regulations is to establish a regulatory framework for the objectives, structure, organization and operation of the Valdecilla Biobank in accordance with current legislation and the provisions of the Manual for the Organization and Use of IDIVAL's Technological Services (MA-SAT-01).	Biobank Coordinators Biobank Scientific Director

The Valdecilla Biobank is part of the National Network of Biobanks and the Biobank Platform, promoted and financed by the Carlos III Health Institute.

5.3.3 SPECIFIC OPERATIONS			
4. HUMAN RESOURCES			
	Relevant documentation that supports your operation	**Objective/Scope**	**Resp.**

5.3.3 SPECIFIC OPERATIONS			
1	**Labor Hiring Procedure for IDIVAL Personnel** PR- GNR-16	This procedure establishes the itinerary to be followed to carry out the employment of temporary staff by IDIVAL. This procedure is applicable to temporary staff hired by IDIVAL: • Hired for research project • Contracted as a result of a competitive call (for a research project, contract for access to the science and technology system and predoctoral contract) • Interim Replacement Contract This procedure does not apply to permanent contracts, since the current framework does not allow this modality in the foundational public sector.	HR Coordinator Managing Director
2	**IDIVAL Welcome Manual** MA-GNR-07	The objective of this manual is to facilitate the incorporation of personnel by providing the necessary information about the institute, the incorporation process, access to resources and incident management. It provides information on IDIVAL's operating regulations and their accessibility.	HR Coordinator Managing Director
3	**Training Plan** PL-GNR-005	The main objective of IDIVAL's Training Plan is to promote and enhance the capacity of its professionals in the field of biomedical research, through the recruitment and training of new researchers, and the development of the skills of all professionals to achieve excellence in their environment. It describes the system for identifying the training needs of the different stakeholders and how to plan, execute and evaluate their effectiveness.	HR Coordinator Managing Director Scientific Director

HR EXCELLENCE IN RESEARCH

As mentioned above, IDIVAL has been awarded the HRS4R seal of excellence in Human Resources since October 2018.

5.3.3 SPECIFIC OPERATIONS			
5. MAINTENANCE OF EQUIPMENT AND FACILITIES			
	Relevant documentation that supports your operation	**Objective/Scope**	**Resp.**
1	**Procedure for the Use and Maintenance of Scientific/Technological Facilities and Equipment** PR-GNR-10	The objective is to establish the guidelines that regulate the proper use and maintenance management of the laboratory facilities, as well as that of IDIVAL's scientific/technological equipment. It will apply to the laboratory facilities located in the IDIVAL building, directly controlled by the Institute's staff, as well as to the scientific-technical equipment for biomedical research acquired and/or transferred for use at IDIVAL.	SAT Coordinator Managing Director
2	**Procedure for Assigning Spaces** PR-GNR-03	To establish the mechanisms, bases and conditions through which IDIVAL research groups interested in settling in the IDIVAL building can request spaces to carry out their research activity and access them.	SAT Coordinator Managing Director

5.3.3 SPECIFIC OPERATIONS			
6. ECONOMIC AND FINANCIAL MANAGEMENT			
	Relevant documentation that supports your operation	**Objective/Scope**	**Resp.**
1	**Purchasing and Inventory Procedure** PR-GNR-01	The purpose of this procedure is to define the system for managing the purchase of IDIVAL material, equipment or services, as well as the subsequent processing of orders, with the final result being the entry of products/services that meet all the requirements of the organization. The guidelines to be followed for the selection and evaluation of suppliers of products and services with an impact on the Quality Management System will also be established.	Management Coordinator Managing Director
2	**Internal Services Purchasing Procedure** PR-GNR-04	The purpose of this procedure is the systematization of the activities to be carried out in the R+D+i Management Area to ensure the traceability and budgetary control of the expenditure involved in the research groups, responsible for the budget of projects financed through subsidies collected by the Marqués de Valdecilla Foundation. the purchase of technological and support services provided in units included within the Institute itself (self-invoicing)	Management Coordinator Managing Director
3	**Asset Inventory Management Procedure** PR-GNR-12	This procedure aims to establish the main guidelines for the management of IDIVAL's fixed assets inventory movements. It defines the main tasks for the identification and subsequent management of fixed assets until they are deregistered. The areas of action that will be dealt with in this document are: • Identification of frozen assets • Register of fixed assets • Internal and external movements of fixed assets - Transfers • Disposals of fixed assets	SAT Coordinator Managing Director
4	**Third-party file management procedure** PR-GNR-14	Guidelines are established for the correct identification, use and archiving of third-party files received, by all natural or legal persons who have any type of relationship with IDIVAL.	Management Coordinator Managing Director

5.3.4. Evaluación y Mejora Continua:

5.3.4 EVALUATION AND CONTINUOUS IMPROVEMENT				
	Relevant documentation that supports your operation	**Objective/Scope**	**Frequency**	**Resp. Realization/ Resp. Analysis**
1	**Processing of Non-conformities and customer complaints** PR-GNR-07	It describes the system established in IDIVAL to identify, document, analyze and report Non-Conforming products and services with respect to the specified requirements, in order to implement the necessary actions to prevent the use or delivery of the product/service. Try to make sure that all professionals learn from the incidents.	Continuous. Annual Analysis in System Review by Management	Area Managers. Internal Scientific Council.
2	**Customer satisfaction**	There is no specific procedure/instruction that describes it. In each area, it is a matter of compiling the perception that the selected stakeholders have of our work. To this end, online tools are used to facilitate their realization and analysis.	Annual. Annual Analysis in System Review by Management	Area Managers. Internal Scientific Council.
3	**Internal System Audits** PR-GNR-09	Establish the system to verify, through annual Internal Audits: - compliance with the requirements of the reference standards in which the organization is certified. - compliance with the requirements of IDIVAL's Quality Management System and applicable regulations. - the degree of compliance and effectiveness of the Quality System implemented. Minimum annual frequency, carried out by qualified auditors.	Annual. Annual Analysis in System Review by Management	Managing Director Internal Scientific Council.
4	**Process Performance Evaluation**	There is no specific procedure/instruction that describes it. It is a matter of compiling, for each person in charge assigned to the different operational and management processes, the results of the indicators and objectives of these processes and carrying out an analysis of them that serves to determine if the desired level of quality is being met.	Continuous. Annual Analysis in System Review by Management	Area Managers. Internal Scientific Council.
5	**Goal tracking**	There is no specific procedure/instruction that describes it. It is a matter of compiling, for each person in charge assigned to the different Areas, the results of their objectives and carrying out an analysis of them that serves to determine if the desired level of quality is being met. Objectives are available in the certified scopes, the objectives of the Strategic Plan and the management objectives.	Continuous. Annual Analysis in System Review by Management	Area Managers. Internal Scientific Council.
6	**Environmental analysis and risk identification**	A reproducible system is available, mainly implemented in certified systems, which allows risks and opportunities to be identified and actions to be established to address them.	Annual. Annual Analysis in System Review by Management	Area Managers. Internal Scientific Council.
7	**Management Review**	IDIVAL's management reviews the Quality Management System at least annually, in order to ensure its suitability, adequacy, efficiency and continuous alignment with the company's strategic direction.	Annual. Management System Review Report	Internal Scientific Council.

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