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INTRODUCTION

The Alliance of Health Research Institutes ([Alliance of IISs - ISCIII Web Portal](#)) establishes a stable space for collaboration and joint work between the Carlos III Health Institute (hereinafter ISCIII) and accredited Health Research Institutes (hereinafter IIS). Established by ISCIII in November 2019, after this five-year period it has consolidated its position as a hub for reflection, shared learning, and cooperative innovation in biomedical R&D&I, with a special focus on the National Health System, and as such forms part of the Spanish Science, Technology, and Innovation System (SECTI).

Its main objectives are as follows:

- Address the needs of the IIS in the dynamic R&D&I environment.
- Guide the scientific policies of IISs, aligning them with the strategic lines of the European regulatory framework.
- Promote cooperation among IISs, creating synergies that increase their competitiveness.
- Strengthen the participation of IISs in defining the ISCIII's lines of action.

One of the main spaces for developing these objectives are the working groups (hereinafter WGs) of the Alliance of IISs. These groups analyze the situation, development, and limitations of those aspects of particular interest for the strategic planning and scientific development of IISs.

This results in the creation of reflection documents, available on the ISCIII website in the [Reports from the Alliance of IISs](#) series.

Continuing the work carried out in previous years, in March 2024, WGs were set up to address five priority topics within the Alliance. The composition of each group was based on the priorities of interest communicated by the 35 IISs, respecting the order expressed as far as possible.

Each WG is made up of 9 to 12 IISs, two of which are responsible for coordination to facilitate the progress of the work. Participation in each IIS in each WG is established at the level of Scientific Management.

The documents prepared by each WG are submitted to all IISs, which provide their considerations, contributions, and suggestions after reviewing them. Once this process is complete, the final document is approved in a plenary session of the Alliance of IISs, at which point it becomes a definitive report.

This third issue of the Reports from the Alliance of IISs series compiles the documents drafted and approved in 2025.

WORKING GROUPS OF THE ALLIANCE OF IISs. 2025 Reports

- WG1. Incorporating citizen engagement into IISs.

Coordinated by the IISs IRYCIS and ibs.GRANADA management teams

- WG2. New Professional Profiles at IISs

Coordinated by the IISs IDIPAZ and ISPA management teams

- WG3. Impact measurement.

Coordinated by the IISs IDIBELL and BIOGIPUZKOA management teams

- WG4. Capabilities map of IISs

Coordinated by the IISs IDIS and IDISNA management teams

- WG5. Artificial Intelligence

Coordinated by the IISs Ir-HUVH, IBSAL, and IdISSC management teams.

INCORPORATING CITIZEN ENGAGEMENT INTO HEALTH RESEARCH INSTITUTES (IIS).

WG1. Alliance of Institutes. 2025.

Coordination: IRYCIS and ibs.GRANADA

Responsible parties: Dr. LAURA GARCÍA BERMEJO and Dr. MARÍA JOSÉ SÁNCHEZ PÉREZ

1. OBJECTIVE

Establish a common operational framework that facilitates the structured and effective incorporation of citizens into Health Research Institutes (IISs), promoting their active engagement at every stage of the research process: from the identification of priorities to the design, development, implementation, dissemination, and evaluation of research activities.

This common framework will be flexible and adaptable to the specific characteristics of each IIS, and can also be tailored to the stage of each project.

The purpose of this procedure is to ensure that research is more inclusive, representative, and responsive to the real-world needs of society, while strengthening the open science approach, institutional social responsibility, and the principle of patient-driven and patient-centered research.

It also contributes to meeting the criteria established by the Carlos III Health Institute (ISCIII) regarding governance, participation, and social responsibility, within the framework of the accreditation, monitoring, and evaluation processes for health research institutes.

Finally, this procedure aims to establish standardized indicators that will enable the ISCIII to monitor and compare the implementation of citizen engagement across the various IISs, thereby promoting the harmonization of standards, continuous improvement, and the consolidation of a participatory culture in biomedical and social-health research.

2. SCOPE

Incorporating citizens has the potential to profoundly transform the research process, leading to more inclusive and socially relevant results. In the health sector, numerous studies have shown that the active participation of patients, caregivers, and other affected individuals—through mechanisms designed to actively include vulnerable groups, minorities, and people with low scientific literacy—contributes to better alignment of scientific priorities, as well as greater effectiveness in the implementation of treatments, interventions, and health policies, as they are more closely aligned with the needs, expectations, and values of those who use health services.

This procedure applies to all initiatives—including research projects, structures, and bodies—carried out within IISs that involve or facilitate citizen engagement in the field of biomedical and social-health research. Its purpose is to ensure the consistency, quality, and standardization of such participation throughout the Institute and among the various IISs, improving the harmonization of standards among IISs with different structures and resources (common tools, methodological guidelines, or support networks) and, therefore, promoting a more open, inclusive, and socially responsible research model. The implementation of the procedure could include pilot or launch phases to allow for a progressive implementation tailored to the specific characteristics of each IIS.

Incorporating citizens in the research process is recognized as an indicator of best practices and responsible research and innovation (RRI), and has been incorporated as a cross-cutting theme in the European Framework Program for Research and Innovation, Horizon 2020, and further reinforced in the Pact for Research and Innovation in Europe, adopted by the Council of the European Union in 2021.

This shift has marked a turning point for many funding agencies and research organizations, which have begun to systematically incorporate the perspectives of patients, family members, and citizens into their strategies and calls for proposals across the board.

Along the same lines, European Commission Recommendation (EU) 2024/736, published on March 1, 2024, establishes a *Code of Good Practice on Citizen Engagement for Knowledge Valorisation*, and underscores the importance of such engagement as a key element in aligning research with societal needs and strengthening public trust in science. Furthermore, various patient and citizen organizations have produced documents and materials on engagement in the area of healthcare (https://plataformadepacientes.org/wp-content/uploads/2024/03/documento_consenso_participacion_hospitalaria_vf.pdf) (<https://forodepacientes.org/categorias-biblioteca/documentacion-formacion-fep/>).

Furthermore, for citizen engagement to truly add value to the research process, it is essential to provide citizens with the appropriate tools, as well as to offer training (materials, workshops, etc.), support, and guidance that promote the development of the skills necessary for informed, active, and effective engagement. Similarly, it is essential to ensure that collaboration takes place on an equal footing, by consciously and responsibly managing any power imbalances among the various stakeholders involved and ensuring safe and equitable spaces.

By adopting an inclusive, horizontal, and participatory approach, the co-production of knowledge can significantly improve the relevance, applicability, and transfer of research findings, thereby contributing to the development of more effective solutions to complex health challenges. Only by adhering to these principles is it possible to create an environment that enables citizens to make a meaningful contribution to research and innovation, and ensure sustained engagement with a transformative impact.

3. DEFINITIONS

- **Non-scientific stakeholders:** Individuals who do not take part in research activities or hold management positions in R&D&I, but who can add value to scientific activity by playing an active and prominent role, both in the research process and in the use, impact, or application of its results. This engagement may take place on an individual basis or through an affiliation with organizations such as scientific societies, NGOs, patient associations, and others.
- **Citizens:** The group of individuals who use the healthcare system, including patients, caregivers, patient associations, social organizations, and the general public interested in health research.
- **Open Science:** An approach to the scientific process based on collaborative work, open tools, and the open dissemination of knowledge, which promotes transparency, inclusion, and accessibility at every stage of health research
- **Citizen science:** The voluntary and active participation of non-professionals in the scientific field who contribute to research and innovation at various stages of the process and at different levels, ranging from the definition of scientific priorities and policies to the collection, processing, and analysis of data and the

evaluation of research results. Citizen science promotes research that is more open, inclusive, and aligned with social needs, strengthening the bond between the scientific community and society.

- **Research ethics:** A set of principles and standards that regulate and guide the design, conduct, management, application, and dissemination of research involving living beings, whether human or animal, in order to ensure respect for their dignity, integrity, and rights.
- **Citizen engagement:** A set of mechanisms and actions aimed at incorporating citizens (patients, family members, and society at large) into the various stages of the biomedical research process (participatory decision-making, application, and follow-up processes), from a co-creation approach, in order to improve the quality and transparency of policies, as well as adherence to them, at the local, national, and EU levels. This includes identifying needs, setting priorities, generating ideas, participating in study design, joining research teams, seeking funding, developing and implementing projects, analyzing and disseminating results, as well as applying or translating them into clinical practice.
- **Knowledge Valorization:** the process of creating social and economic value from knowledge by linking different fields and sectors, as well as by transforming data, technical knowledge, and research findings into sustainable, knowledge-based products, services, solutions, and policies that benefit society.

4. GUIDING PRINCIPLES OF THE PROCEDURE

Citizen engagement in IISs will be guided by the following fundamental principles, which ensure their legitimacy, quality, and impact:

- **Transparency:** Ensure clear, open, and accessible communication regarding the objectives, methodologies, roles, limitations, and results of participatory processes, thereby promoting mutual understanding and accountability.
- **Inclusion:** Promote the active engagement of all individuals and groups with an interest in or potentially affected by the research, particularly those who are traditionally underrepresented, thereby ensuring a diversity of perspectives, experiences, and contexts.
- **Scientific integrity:** Ensure that citizen engagement is conducted in accordance with the ethical principles and standards of integrity that govern research, promoting honesty, transparency, reliability, and responsibility at every stage of the scientific process. This principle entails avoiding any form of bias, manipulation, or exploitation of citizens; ensuring the traceability and accuracy of data and results; and fostering a culture of mutual respect, methodological rigor, and accountability. Scientific integrity applies to both researchers and citizen participants, thereby strengthening public trust in science and the social legitimacy of the results obtained.
- **Representativeness:** Ensure that the composition of participating citizen groups reflects, to the extent possible, the diversity of the population targeted by the research, taking into account factors such as age, gender, socioeconomic status, geographic origin, health status, and other relevant determinants.
- **Equity:** Ensure fair, respectful, and dignified treatment for all those involved, by providing accessible conditions for participation that are tailored to different needs, and by recognizing the value of experiential knowledge as a complement to scientific knowledge.
- **Scientific and social added value:** Participation should effectively contribute to improving the quality,

relevance, applicability, and acceptance of research, thereby generating a positive impact in the scientific community as well as on social well-being and decision-making in healthcare.

- **Open Science:** Ensure the promotion of transparency, inclusion, and accessibility at every stage of health research
- **Sustainability:** Ensure that citizen engagement processes are consolidated over time through stable structures, adequate resources, mechanisms for evaluation and continuous improvement, and a sustained institutional commitment that enables their impact to be maintained and increased.
- **Acknowledgments:** Ensure that citizens' contributions are appropriately valued and recognized, acknowledging their experience, time, and commitment, both in scientific practice and in research outputs (authors, acknowledgments, citations, certifications, etc.).

For citizen engagement to be meaningful and sustainable, it is essential that the individuals involved be regarded—and regard themselves—as full members of the research team. This means recognizing their contribution on an equal footing with that of other research staff, based on their level of training, experience, and degree of involvement in each stage of the process. In addition, clear, understandable, and inclusive language should be used throughout the initiative, ensuring that the information is accessible and tailored to the diverse circumstances of the participants. Communication should promote mutual understanding and shared decision-making.

It is equally necessary to establish clear provisions regarding intellectual property and the recognition of authorship, taking into account the role of citizens in the generation of knowledge. This includes their participation in scientific publications, manuscripts, descriptions of results, and other project outputs, while always adhering to ethical principles, data confidentiality, and privacy protection.

In addition, due consideration should be given to the time, knowledge, and effort contributed by participants, which may involve various forms of recognition, depending on the nature of the project and the institutional context.

Finally, it will be essential to establish a monitoring and evaluation system that allows for an assessment of the degree of compliance and the effectiveness of citizen engagement. This system should incorporate both qualitative and quantitative indicators and take into account the participants' experiences, the impact of their contributions on the project's results, and the organizational improvements resulting from the process.

5. PROCEDURE

The following phases are proposed for the implementation of the Procedure:

5.1 ESTABLISHMENT OF AN INSTITUTIONAL FRAMEWORK

To ensure meaningful, systematic, and sustainable citizen engagement in IISs, it is necessary to establish a **robust institutional framework** that brings together the principles, structures, resources, and mechanisms required for its effective implementation. This framework will be based on three key pillars:

Establishment of a Citizen Engagement Working Group (CEWG) at the IIS:

- **Composition:** The CEWG will consist of a multidisciplinary team comprising researchers, healthcare professionals, administrative staff, members of the institute's committees, patient committees,

representatives of patients, family members, and members of civil society associations. Efforts will be made to ensure balanced and diverse representation, taking into account criteria such as gender, age, socioeconomic and professional profiles, as well as the specific scientific and health-related areas of interest of each institute.

– Functions:

- Establish a code of conduct that ensures respect, transparency, equity, and confidentiality in all participation processes. The code of conduct itself will be reviewed on a regular basis, with citizen representatives participating in the review.
- Oversee the implementation of this procedure at the IIS and ensure compliance through periodic evaluations and the preparation of public reports.
- Propose improvements and adjustments to the procedure based on experience gained, evaluations conducted, and identified needs.
- Review, on a regular basis, the process for recruiting and onboarding citizens.
- Serve as a strategic liaison between the IIS and citizens, facilitating smooth and ongoing two-way communication.

- Operation: The roles and responsibilities of each member of the CEWG will be explicitly defined. The CEWG will meet at least once a year, in accordance with each institution's specific procedures, and will make its decisions in a documented, transparent, and consensus-based manner.

• **Development of a Citizen Engagement Policy:**

The IIS must develop and adopt a Citizen Engagement Policy to serve as a reference document and operational guide for all stakeholders. This policy must include:

- Establish guiding principles for citizen engagement at every stage of the research process (identification of priorities, design and planning, development and operations, evaluation, dissemination of results, translation), which will guide engagement, such as transparency, equity, mutual respect, inclusivity, and shared benefits.
- Set clear goals for citizen engagement:
 - Improve the relevance and applicability of research.
 - Promote collaboration, co-creation, and shared leadership/decision-making among patients/family members/citizens and research staff in carrying out research activities.
 - Increase public trust in science.
 - Optimize the design and implementation of studies.
 - Facilitate the effective and accessible dissemination and communication of processes and results.
 - Ensure the active inclusion of patients/family members/citizens in biomedical research and innovation.
- Establish priority areas for engagement: specify the stages or types of research in which citizen engagement will be prioritized, in alignment with each institute's areas of interest. This may include project design, ethical review, reporting of results, or the identification of health needs.

- Ensure alignment with current ethical guidelines and data protection regulations by ensuring that all aspects of citizen engagement strictly comply with current ethical guidelines (research ethics committees) and data protection regulations (such as the GDPR in Europe). This includes the management of informed consent, information privacy, and data confidentiality.
- Implement evaluation mechanisms to measure the effectiveness of current and future citizen engagement initiatives.
- Promote the inclusion of patients and citizens in governance bodies by establishing mechanisms to include them in decision-making and as coordinators.
- Promote training and awareness by implementing educational programs for patients, family members, and citizen organizations, helping them understand the research process, as well as programs that foster a shift in the culture and values of the scientific community, including training for scientific staff.
- Promote the specialization of scientific management staff, patients, and/or their family members in the area of citizen engagement.
- Create spaces for communication where participating citizens can interact with one another, share experiences, resources, and lessons learned, fostering mutual support and community building.

- **Resource Allocation:**

- Allocate funds for training, logistical support (travel, materials, etc.), organizing courses, participating in conferences and meetings, and designing and producing specific materials.
- Appoint staff dedicated to coordinating, managing, and supporting citizen engagement initiatives, ensuring continuous support. This staff will serve as an institutional point of reference aligned with the Citizen Engagement Working Group, if one exists.
- Incorporate the concept of citizen engagement as an eligible expense into the various research funding programs.

5.2. IDENTIFICATION AND RECRUITMENT OF CITIZEN REPRESENTATIVES

- Promote opportunities for participation through multiple channels, including social media, patient associations, health centers, community events, local media, and partnerships with social organizations.
- Ensure the inclusion of different demographic, socioeconomic, and cultural groups, ensuring diversity in terms of gender, age, socioeconomic profile, and pathology.
- Ethics of engagement will be applied, ensuring that citizens are not exploited and that their pace, motivations, and limits are respected.
- Promote the establishment of agreements and/or partnership programs with patient associations and relevant social organizations that act as facilitators and promoters of engagement.
- Conduct interviews or informational meetings to assess commitment, expectations, and motivation, and to determine whether their profile aligns with the specific needs of the initiatives.
- Strengthen ongoing support and facilitate feedback, that is, extend it beyond the initial stage.

5.3. EDUCATION AND TRAINING FOR CITIZENS AND RESEARCH STAFF

- Provide and promote initial training on how health research works, research ethics, basic scientific terminology, and the specific role that citizens will play in each context.
- Provide training to research and healthcare staff on how to involve citizens and patients as active participants in the institute's research.
- Provide different types of materials that are accessible and tailored to different levels of knowledge. It would be desirable for these materials to be part of a potential annual training program that is common to and shared by all IISs.

5.4. ONBOARDING INTO THE IIS GOVERNING BODIES:

- **Onboarding and Engagement Phases: Research Design and Prioritization:**
 - **Design of Recruitment Strategies: Citizen Consultation.** Conduct workshops, focus groups, or surveys to identify health needs and research priorities from the citizen's perspective, as well as the appropriate profiles to be onboarded into each institution, always applying the ethical principles of engagement mentioned above.
 - **Onboarding into the governance structures of the institutes:** Boards of Trustees and Governing Councils, in accordance with the provisions of the founding charters of each institute.
 - **Onboarding at least one representative of patients/family members/citizens into the External Scientific Committee and/or the Internal Scientific Committee,** to directly involve them in matters such as reviewing departmental plans, joint collaborative activities, the evaluation of intramural projects, etc.
- **Execution and Development of Research:**
 - **Members of Ethics Committees:** Onboard citizens into ethics committees, provided that the regulations governing such committees permit it, to ensure that studies are relevant and respectful of their participants, and also to ensure that the committee adheres to an code of ethics for representation.
 - **Scientific or Advisory Committees.** Internal Scientific Committee (ISC) and External Scientific Committee (ESC). Enable participation in the oversight and evaluation of projects, ensuring that they remain focused on patient needs and take a translational approach.
 - **Citizen Engagement Working Group and specific Working Groups:** Involve citizens in the IIS's CEWG and in specific working groups organized by pathologies or lines of research to address specific aspects of project development
 - **Project Co-creation:** Invite citizens to participate in formulating research questions, designing studies, and selecting methodologies.
- **How key non-scientific stakeholders in the system participate** in research, based on their degree of interaction:
 - **REPORTING:** A one-way interaction in which research activity is communicated to the various stakeholders in the system, with balanced and objective information.
 - **CONSULTING:** Research staff gathers perspectives from stakeholders on key aspects of the research

before making decisions.

- **CREATING INVOLVEMENT:** Work is conducted in a two-way (dialogue-based) and direct manner with stakeholders so that their aspirations and concerns are understood and considered jointly before decisions are made. Establish mechanisms for ongoing feedback between research staff and citizens.
- **CO-CREATING:** Work is conducted jointly and in multiple directions by partnering with the various stakeholders in the system in each aspect of the decision. Promote **project co-creation** with citizens starting from the design phase.
- **EVALUATING:** Citizens and patients will participate in evaluating the institute's scientific activities in terms of their impact and will propose contingency measures if necessary.

- **Dissemination of Results and Knowledge Transfer:**

- **Co-authorship in dissemination and innovation outputs:** Recognize the contribution of citizens as co-authors in abstracts, conference and workshop communications, scientific publications, or intellectual property, when their participation warrants such recognition in accordance with international agreements on authorship.
- **Design of Communication Strategies:** Work with citizens to develop accessible and easy-to-understand outreach materials for the general public (infographics, videos, informative summaries, etc.), ensuring that key messages are effectively conveyed.
- **Participation in Outreach Events:** Invite citizens to actively participate in the presentation of results at conferences, seminars, community events, open houses, and through the media, sharing their perspectives and experiences.

- **Evaluation and Monitoring:**

- Conduct **satisfaction surveys** and **focus groups**.
- **Develop specific indicators** to measure the extent and quality of citizen engagement, as well as its impact on the institutes' research.
- Use the results of the evaluation to **identify areas for improvement**, adapt the participation process, and demonstrate the added value of citizen involvement.
- Promote a **culture of continuous improvement** to address the areas for improvement identified in each evaluation.

6. RESOURCES

The effective and sustainable implementation of citizen engagement in Health Research Institutes requires specific resources—including human, material, and technological resources—to support its development.

- **Budget allocation:** Each IIS must establish a specific and adequate budget item that is stable and sustained over time to cover the costs associated with citizen engagement, including training activities, travel, per diem allowance, materials, the organization of meetings, and, where applicable, financial compensation justified in accordance with institutional regulations.
- **Technical support staff:** It will be essential to have specialized technical staff who can serve as facilitators and coordinators of citizen engagement, providing ongoing support to participants, ensuring internal

coordination, monitoring planned actions, and planning initiatives for the ongoing training of these staff members in participatory methodologies.

- **Digital tools and platforms for engagement:** The IIS will have technological tools (a digital platform or other tailored solutions that ensure digital accessibility) to facilitate the efficient management of communication with citizens, the provision of information relevant to their participation, the documentation of processes, the monitoring of indicators, and impact assessment.
- **Resources for institutional recognition:** Establish formal recognition mechanisms for participating citizens (certificates, commendations, participation in events) that acknowledge their contributions.
- **Inter-institutional collaboration network:** Foster alliances with other IISs, universities, associations, and public entities to share resources, experiences, and best practices, facilitating cross-cutting services such as patient repositories developed in collaboration with patient organizations, dissemination tools, the organization of conferences and events, or procedures to ensure the absence of conflicts of interest.

7. CONFIDENTIALITY AND ETHICS

Citizen engagement in research must take place within a framework that fully respects the dignity, fundamental rights, and integrity of all individuals involved, in accordance with bioethical principles and current regulations.

- **Confidentiality Agreements:** All participants must sign confidentiality agreements governing access to, use of, and protection of sensitive or confidential information related to the research projects.
- **Compliance with bioethical principles:** Respect for the fundamental principles of bioethics—autonomy, beneficence, non-maleficence, and justice—as well as the rights of the participants will be ensured at all times. Participation must comply with the recommendations of research ethics committees and with data protection regulations, particularly the General Data Protection Regulation (GDPR) at the European level.
- **Voluntary participation and withdrawal procedures:** Transparent and regulated mechanisms will be established to allow for both the voluntary participation and withdrawal of citizens in a respectful, safe, and documented manner, ensuring the protection of participants and the continuity of the research process.
- **Commitment to not exploit citizens:** Mechanisms will be put in place to ensure equitable, voluntary, and informed collaboration, while respecting each person's autonomy and conditions for participation.
- **Conflict Management and Shared Decision-Making Protocols:** Secure channels will be made available to citizens for expressing disagreements, along with techniques for consensus-based decision-making and mechanisms for structured dialogue, particularly in environments characterized by multiple interests, varying levels of power, and differing perspectives.

8. SCORECARD

The purpose of this scorecard is to facilitate the monitoring and evaluation of the *Procedure for Onboarding Citizens into Health Research Institutes (IISs)*. It compiles the key indicators, actions, and mechanisms associated with the process, enabling an assessment of their level of implementation, consistency, and effectiveness. Its

purpose is to ensure structured, inclusive, and sustainable citizen engagement in biomedical and social-health research, in line with the principles of transparency, equity, and open science.

The indicators included in this scorecard will be reviewed annually by each IIS through its Citizen Engagement Working Group or equivalent structure. The results of this review will be included in the institute’s annual scientific report and will be submitted to the ISCIII as part of the process for monitoring and evaluating citizen engagement in Health Research Institutes.

This scorecard therefore serves as a support tool both for the internal management of each IIS and for the harmonization and comparative evaluation led by the ISCIII, ensuring consistency among the institutes and evidence-based collective learning. The following proposed scorecard is intended to be operational, manageable, and, in principle, low in complexity and administrative burden.

SEE ANNEX IV. ADDITIONAL DOCUMENTATION: SCORECARD

NEW PROFESSIONAL ROLES IN ACCREDITED HEALTH RESEARCH INSTITUTES (IISS)

WG2. Alliance of Institutes. 2025.

Coordination: ISPA and IDIPAZ

Responsible parties: Dr. GUILLERMO MUÑIZ ALBAICETA and Dr. JAVIER DE CASTRO CARPEÑO.

1. EXECUTIVE SUMMARY

This report proposes an operational catalog of new professional profiles that should be onboarded— in a consistent and coordinated manner—into Health Research Institutes (IISs) accredited by the Carlos III Health Institute (ISCIII). The proposal addresses four areas of change: (i) personalized medicine and omic technologies; (ii) the secure use of clinical data with artificial intelligence (AI); (iii) the growing regulatory complexity surrounding clinical trials, advanced therapies, and devices; and (iv) the need to transfer knowledge to the production sector in a manner that ensures sustainability and social participation. Clinical-research, technical-scientific, R&D&I management, clinical trials and regulatory affairs, responsible innovation, training and career development, AI and ethics, and technological transformation and infrastructure profiles are considered. It is accompanied by an implementation plan that includes metrics and recommendations for staffing policies for the National Health System (SNS). These profiles should be adapted to the realities of the autonomous communities within a common framework for cooperation aimed at developing the various research career profiles in the SNS.

Expected results from deploying these profiles:

Higher quality and faster translational research; improved regulatory compliance; increased competitive funding; accelerated technology transfer and innovation; reduced ethical and legal risks; and measurable improvements in health outcomes and in the experience of patients and healthcare professionals.

2. CONTEXT AND OBJECTIVES

Spain has a well-established network of IISs accredited by the ISCIII that are integrated with hospitals, universities, and public research organizations. In recent years, there has been a growing demand for interdisciplinary professionals capable of working in complex clinical settings, managing large volumes of data, complying with stringent regulatory frameworks (GDPR/LOPDGDD (Organic Law on the Protection of Personal Data and the Guarantee of Digital Rights), MDR/IVDR, ICH-GCP, RD 1090/2015), and translating knowledge into health and economic impact. The purpose of this report is: (1) to identify priority profiles; (2) to describe skills, functions, and organizational placement; (3) to propose hiring and funding mechanisms; and (4) to establish performance and sustainability metrics.

The profiles described in this document are not intended to be an exhaustive or rigid guide for the framework to be developed; rather, Health Services and partner Institutes should be able to adapt these profiles by prioritizing the actual and strategic needs of each institution, ensuring that available resources are directed toward the profiles that provide the greatest added value based on the activities and size of each IIS.

European biomedical research networks have profiles similar to those described in this document; therefore, developing such networks could facilitate convergence with these structures. For example:

- Within the ECRIN-ERIC networks and their national nodes, these roles are filled by clinical project managers, trial coordinators, data managers, and monitors, who are skilled in trial design, monitoring, GCP-compliant data management, and multinational coordination.
- BBMRI-ERIC has developed biobank coordinator/manager and quality manager models supported by quality system working groups, audit programs, and quality labeling schemes, which require expertise in ISO 20387, ISO 9001, and ethical and legal regulations governing human samples.
- ELIXIR and its nodes have explicitly identified the profiles of data steward and bioinformatician/data steward, with responsibilities in research data management, the design of data plans, the implementation of FAIR principles, and methodological support for scientific groups.
- EATRIS, ECRIN, and BBMRI have developed professional structures for scientific project managers, who are responsible for consortium coordination, financial reporting, and intercultural management in large-scale projects under Horizon Europe and other European funding calls.

Onboarding individuals with the profiles described above can help address the SNS's challenges related to digitalization and sustainability, as well as public employment policies in science, by attracting highly competitive talent to the SNS.

3 CLINICAL-RESEARCHER PROFILES IN HEALTHCARE

3.1 CLINICAL RESEARCHER IN HEALTHCARE

Healthcare professionals (specialists in medicine, pharmacy, psychology, biomedicine, and physics; graduates in nursing, physical therapy, etc.) with dedicated time for research, maintaining healthcare activity. These profiles follow the model of the current “Juan Rodés” contracts, but they should be incorporated into the staffing of the various healthcare facilities. Functions: Designing and developing studies, recruiting and monitoring cohorts, assisting with sample collection, coordinating with biobanks, overseeing informed consent, and leading lines of research.

Two methods for stable onboarding are suggested:

- Specific professional category for research staff (Art. 85.1 of Law 14/2011 on Biomedical Research): for researchers with a proven track record (such as Juan Rodés, Miguel Servet, or similar profiles with equivalent careers), who devote between 50% and 100% of their workday to research. A single category for basic-translational and clinical researcher in healthcare profiles; in the case of clinical researchers in healthcare, this is combined with clinical duties accounting for up to 50% of the workday (in addition to the possibility of continuing care), depending on the specialty or specific qualifications required for the position. This profile should be developed within the framework of the various Health Departments, after which specific calls for proposals will be issued. In order to determine the appropriate size of this team, it would be advisable to compile a list of healthcare staff who meet this profile (such as the Juan Rodés researcher registry or the like).
- Stabilization of positions in healthcare professional categories, in positions where a portion of the workday is consistently set aside (e.g., for six-year periods subject to evaluation) to be dedicated to research.

Areas of expertise: Clinical methodology, research ethics, applied statistics, patient communication, clinical data management, and proficiency in GCP.

Placement: Clinical research units integrated into healthcare services, primary care, and other healthcare facilities. Indicators: recruitment, data quality, clinical publications, and health outcomes.

4. SPECIALIZED TECHNICAL AND SCIENTIFIC PROFILES

4.1 POSTDOCTORAL RESEARCHER

Functions: Conducting research as part of a group, under the supervision of a principal investigator, but without assuming the principal investigator's specific functions. Collaboration on project development, teaching, the preparation of research findings, etc.

Areas of expertise: Technical skills, supervision of trainees, skills in scientific output.

4.2 DATA MANAGER

Functions: Design and development of case report forms (CRFs), collaboration on study design, database management, implementation of data collection systems, and preparation of reports on the execution of clinical trials.

Areas of expertise: Design and execution of clinical trials, technical skills in data collection and analysis, and software for CRFs.

4.3 BIOINFORMATICIAN / BIOSTATISTICIAN / DATA SCIENTIST IN HEALTHCARE

Functions: Genomics/transcriptomics/proteomics/metabolomics analysis; clinical data analysis, complex survival analysis, trajectory modeling, multi-omic integration with electronic medical records; development of reproducible pipelines; statistical modeling and machine learning; and support for data committees.

Areas of expertise: Programming, HPC, basic MLOps, FAIR data and data protection, knowledge of national interoperability and governance strategies (Spanish Digital Health Network, SNS Data Science Plan).

Placement: Statistical and/or methodological support units, the IIS cross-functional data unit, and integration into specific groups.

4.4 BIOMEDICAL / ICT ENGINEER IN HEALTHCARE

Functions: Integration of medical devices, laboratory equipment, and monitoring systems; interoperability with HL7-FHIR/DICOM standards; support for advanced medical imaging; image segmentation (CT/MRI); CAD design and manufacture of biomodels for surgical planning and teaching; support for biomanufacturing; technical validation of prototypes; and applied cybersecurity.

Areas of expertise: Embedded systems, hospital networks, validation/verification, and lifecycle management; software for segmentation, materials, precision validation, and integration with surgical committees.

Placement: IIS innovation units, IIS engineering research groups, etc.

4.5 SPECIALIST IN BIOBANKS AND SAMPLE MANAGEMENT

Functions: Sample processing, control over human samples, traceability, clinical data management and custody, equipment management, cold chain, sample and domestic and international shipment management, SOPs, and compliance with ethical and legal frameworks.

Areas of expertise: ISO 20387, ISO 9001, LIMS, broad consent, and risk management.

Placement: IIS biobank.

4.6 OMICS PLATFORM AND CORE FACILITIES TECHNICIAN

Functions: Development and oversight of laboratory techniques, maintenance, operation of sequencers, flow cytometry, mass spectrometry, advanced imaging; microscopy; anatomical pathology; maintenance and QA/QC; support for experimental design and service budgeting.

Areas of expertise: GLP, method validation, and technical documentation.

5 SPECIFIC R&D&I MANAGEMENT

5.1 NATIONAL PROJECT MANAGER

Functions: Gathering information on calls for proposals (AES and equivalents, regional calls, or calls from foundations, etc.), preparing proposals, budgeting, forming consortia, preparing technical and financial reports, and conducting audits.

Areas of expertise: Proficiency in ISO 56001:2024, PMO, project accounting, technical English, and the use of specific project management tools (e.g., GANTT chart software, timelines, task tracking, automated reports, etc.).

5.2 INTERNATIONAL PROJECT MANAGER

Functions: Gathering information on calls for proposals, negotiation of consortium agreements (CA) and grant agreements (GA), supervision of deliverables and KPIs, and liaising with funding agencies (NIH, European Commission, HaDEA, HERA, etc.).

Areas of expertise: Proficiency in ISO 56001:2024, PMO, project accounting, scientific English, and the use of specific project management tools (e.g., GANTT chart software, timelines, task tracking, automated reports, etc.), knowledge of the Indicative Audit Program (specific financial reporting regulations), intercultural management, effective communication in multicenter settings, and management of large consortia.

5.3 TECHNOLOGY TRANSFER (TTO)

Functions: Opportunity and market assessment, state-of-the-art studies, preparation of specific calls for innovation proposals, patentability and freedom-to-operate assessments, intellectual property protection, agreements (NDAs, MTAs), licensing, spin-offs, public procurement of innovation, and industry relations.

Areas of expertise: Intellectual property, technology valuation, negotiation, and regulation of devices/therapies.

5.4 CLINICAL-BUSINESS COLLABORATION MANAGER

Functions: Designing co-developed projects, partnership programs, and trials with sponsors; tracking milestones; and impact KPIs.

Areas of expertise: Public procurement and public-private cooperation, compliance and risk management.

5.5 SCIENTIFIC PRODUCTION AND OPEN SCIENCE MANAGER.

Functions: Bibliometric analysis, strategic leadership in open science.

Areas of expertise: Knowledge of bibliometrics, records management, publication strategies, access standards and publication licenses, and repository management.

5.6 RESEARCH DATA STEWARD / DATA MANAGER.

Functions: Providing advice on data management/open science policies, designing, managing, and maintaining databases, including ICT functions

Areas of expertise: Data management, handling, and storage technologies, data security, data quality, knowledge of relevant laws and institutional policies.

6. CLINICAL TRIALS AND REGULATION

6.1 CLINICAL TRIAL MANAGER (CTM)

Functions: Trial planning and execution, coordination with research ethics committees (CEIm)/Spanish Agency of Medicines and Medical Devices (AEMPS), site supervision, monitoring and management of deviations, training in ICH-GCP E6(R2). Indicators: Time to first patient, recruitment, queries per case, and compliance.

6.2 QUALITY AND REGULATORY AFFAIRS MANAGER (QA/RA)

Functions: design and implementation of the quality system (ISO 9001, 15189, 17025, and 20387), internal/external audits, CAPA management, document control, and compliance with MDR 2017/745 and IVDR 2017/746 for medical devices and in vitro diagnostic devices.

6.3 DATA ENTRY

Functions: Completing case report forms (CRFs), data validations and dictionaries, managing queries, reconciling safety data, and submitting data for statistical analysis. Areas of expertise: EDC, CDISC, SDTM.

7 RESPONSIBLE INNOVATION AND INVOLVEMENT

7.1 MANAGER OF RESPONSIBLE RESEARCH AND INNOVATION (RRI) AND CITIZEN/ PATIENT ENGAGEMENT

Functions: Integrating ethics, equality, and open science; plans for patient and citizen involvement; and social impact assessment, project co-design, focus groups, comprehensible materials, and patient experience evaluation.

Areas of expertise: RRI, scientific communication, impact metrics and governance, facilitation, health literacy, qualitative evaluation.

7.2 INSTITUTIONAL SCIENTIFIC COMMUNICATION

Functions: Outreach, media relations, social media, open science and repositories; support for open data plans.

Areas of expertise: Copywriting, multichannel, alternative metrics.

8 TRAINING AND PROFESSIONAL DEVELOPMENT

8.1 DOCTORAL AND POSTDOCTORAL COORDINATION AND MENTORING

Functions: Cross-disciplinary training programs, supervision of thesis/postdocs, joint supervision of clinical and research careers, guidance on funding, leadership, publication strategy, mobility, and work-life balance.

Areas of expertise: Doctoral regulations, mentoring, internationalization, advising researchers, understanding the research career path, legal framework, training, interaction with other stakeholders (universities, other research centers).

8.2 DIVERSITY, EQUITY, AND INCLUSION (DEI) SPECIALIST

Functions: Equity plans, gap analysis, work-life balance measures, and bias prevention.

Areas of expertise: Legal framework, DEI indicators, training.

9. ARTIFICIAL INTELLIGENCE, DATA, AND ETHICS

9.1 SPECIALIST IN AI APPLIED TO HEALTHCARE

Functions: Development and validation of predictive and clinical decision-support models; performance evaluation; translation into clinical practice; and ethical aspects of AI.

Areas of expertise: ML/DL, clinical validation, impact assessment and management of the change, knowledge of national interoperability and governance strategies (Spanish Digital Health Network, SNS Data Science Plan).

9.2 BIOETHICS AND DATA PROTECTION (RESEARCH DPO)

Functions: Consulting on consent, impact assessments (DPIA), data governance, and international data transfers; support for ethics committees.

Areas of expertise: GDPR, LOPDGDD, biomedical ethics, and information security; knowledge of national interoperability and governance strategies (Spanish Digital Health Network, SNS Data Science Plan).

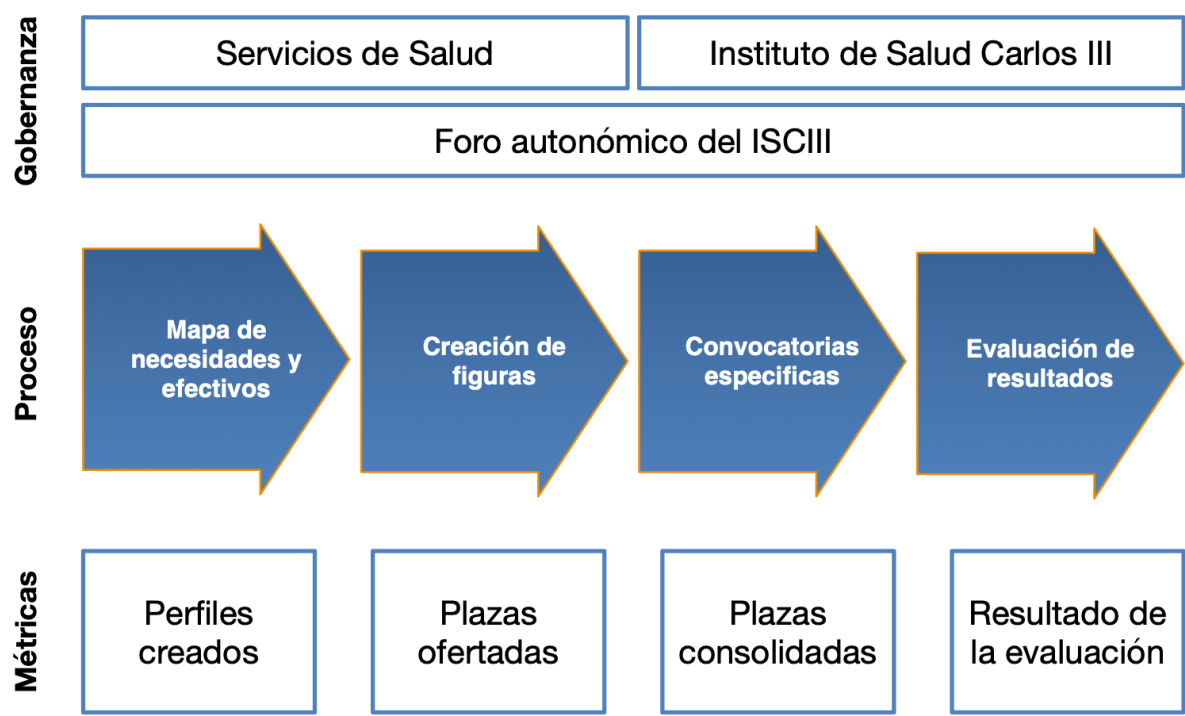
9.3 RELIABLE DATA SCIENCE

Functions: Model deployment, monitoring, and auditing; traceability, data versioning, and reproducibility; and bias assessment.

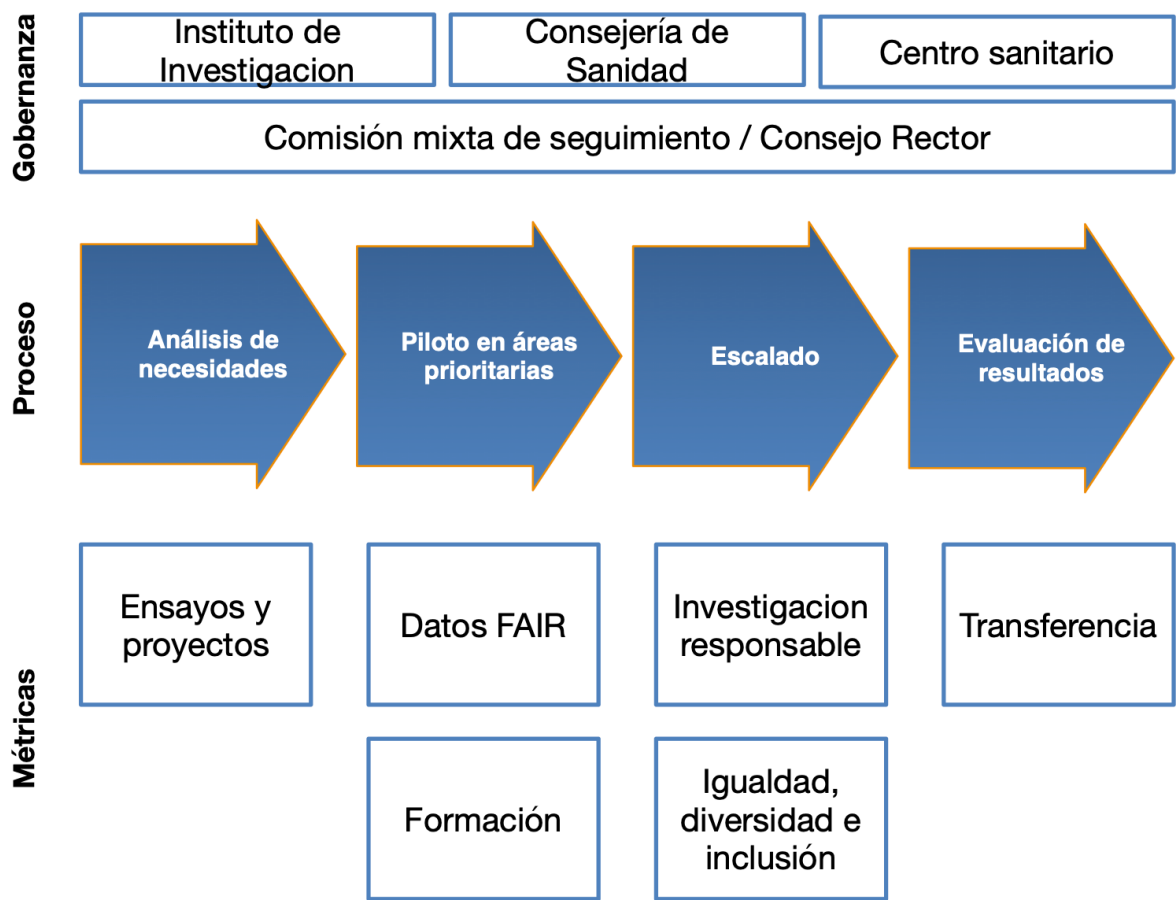
Areas of expertise: Data pipelines, containers, validation, and quality.

10 IMPLEMENTATION: ONBOARDING PLAN AND METRICS

The implementation of the proposed initiatives requires action at both the institutional and local levels. With regard to the first level, it is necessary to assess the situation at the national level in order to identify the resources needed to implement these initiatives. Then, the necessary figures must be created in order to develop the program later. The Health Ministries of the various autonomous communities must collaborate with the Carlos III Health Institute on this institutional development.



At the local level, a parallel framework is proposed for needs analysis, the launch of pilot tests, the scaling up of solutions, and the evaluation of results.



11. SYNERGIES BETWEEN PROFILES

The various profiles proposed for the IISs generate synergies that strengthen the entire biomedical research cycle. Collaboration among clinicians, trial managers, data stewards, and bioinformaticians enables the integration of high-quality data from the study design through to advanced analysis. In turn, biobanks and technology platforms provide standardized resources that enhance reproducibility and translation. Project management, quality, transfer, and innovation profiles ensure coordination, regulatory compliance, and the valorization of results. Finally, communication, RRI, and DEI facilitate interaction with patients, citizens, and strategic partners, creating a more efficient and impact-driven ecosystem.

Simplifying and combining profiles can result in more agile and efficient structures, especially in IISs with limited resources. Integrating related functions—for example, combining project management with regulatory support, or combining bioinformatics with data stewardship—allows for the optimization of capabilities without compromising quality. Similarly, cross-functional roles such as communications, RRI, and DEI can be grouped into institutional impact units, or ELSI specialist profiles can be created that encompass Ethics, Legal (DPO), and Social Issues (DEI). These mergers facilitate coordination, reduce duplication, and ensure operational continuity, provided that core responsibilities are clearly defined and adequate training is ensured. The result is a more flexible and sustainable organization that is able to adapt to the changing needs of research.

12. STRATEGIC RECOMMENDATIONS FOR HR IN THE SNS

Recognition of research as an integral part of the SNS. Health Departments must recognize that scientific output, knowledge generation, innovation, and the translation of these results into practical applications for society are an essential part of their mission. In addition to purely healthcare-related outcomes, research activity is another “output” of Health Departments. Given this, it is clear that there is a need for professional profiles that contribute to this aspect of the healthcare system, which requires specific funding and resources—both human and material. Therefore, in addition to potential calls for proposals led by the IISs or other organizations, the onboarding of these professionals must be supported by a specific budget allocation from the health system.

Official recognition of emerging profiles in (SNS) catalogs and collective bargaining agreements. The appropriate positions must be created, both for researchers involved in healthcare activity and for researchers with a more basic profile who are part of the Health Service. Profiles related to the management of research and innovation activities should also be recognized. These positions must maintain competitive hiring conditions and provide for a balance between healthcare activity and research work, protecting the time dedicated to each one. The creation of these positions should be accompanied by a system for accessing such positions that places significant weight on research track records and positions within the research career path in the SNS.

- Stable, mixed healthcare-research staff; avoid exclusive dependence on projects or funding from research groups. The creation of these positions—for both researchers and managers—should not come at the expense of staff dedicated exclusively to healthcare; rather, the recruitment of these profiles should serve as an incentive for the receiving Department, rather than a drain on resources. This approach also prevents excessive dependence on research foundations and the payroll burden that these positions may represent for them.

- Targeted funding for technical, data, QA/RA, translation, and RRI profiles.
- Cross-functional units shared across IISs-hospitals (data, quality, clinical trials, transfer).
- Training and recruitment/retention programs with clear career paths for non-RP profiles.
- University-business alliances and participation in European programs.
- Impact assessment using common indicators and an annual public review.

13. CONCLUSIONS

The systematic integration of these profiles will enable IISs to accelerate translation, comply with regulatory frameworks, optimize data management, and strengthen transfer and sustainability. The key lies in formally recognizing them, providing them with stable funding, and organizing them as cross-functional units integrated with clinical services. The proposed metrics should guide continuous improvement and accountability.

ANNEXES

ANNEX A. MATRIX OF PROFILES AND KEY FUNCTIONS

Block	Profile	Key functions	Indicators
Clinical-researcher	Clinical researcher in healthcare	Study design; recruitment; coordination with biobanks; GCP	Recruited patients; data quality
Clinical-researcher	Research nursing	PROs; health education; adherence; patient safety	Improvements in health outcomes
Technical-scientific	Bioinformatician/ Data Scientist	Pipelines; data integration; ML; FAIR	Analysis time; reproducibility
Technical-scientific	Biomedical/ICT Engineer	Interoperability; devices; imaging; segmentation; biomodels; validation; cybersecurity	Availability; incidents; models delivered; precision
Testing/Regulation	CTM/CRA	Planning; monitoring; GCP	Time to activation; queries
Testing/Regulation	QA/RA	Quality system; audits; MDR/ IVDR	Non-conformities; CAPA
Data/ethics	Research DPO	DPIA; governance; security	Incidents; assessment time
Management	Management	Support for research and innovation activities, project management, and contracts.	Projects, supporting documentation

IMPACT MEASUREMENT: HEALTH RESEARCH INSTITUTES (IIS)

WG3. Alliance of Institutes. 2025.

Coordination: BIOGIPUZKUA and IDIBELL

Responsible parties: Dr. ITZIAR VERGARA Mitxabila and Dr. GABRIEL CAPELLÁ MUNAR

Technical coordination:

Bellvitge Biomedical Research Institute - IDIBELL (Gabriel Capellá, Beatriz Pinilla)

Biogipuzkoa Institute for Health Research (Olatz Arrizabalaga, Maider San Torcuato)

1. INTRODUCTION

Following the activities and results compiled in [Report 1](#) (2024), Working Group (WG) 3 of the Alliance of Health Research Institutes (IISs) on **Impact Metrics** resumed its activities in 2025 with the aim of advancing the **definition of an operational and training framework** for measuring the impact of biomedical and health research.

This year's work has focused on two key recommendations directed at both the IISs and the Carlos III Health Institute (ISCIII):

- Define a **set of impact metrics and indicators** to be piloted in the ISCIII's evaluation tools.
- Explore **tools for teaching, training, and highlighting the value of impact measurement**.

Throughout 2025, the group has implemented a roadmap consisting of three complementary phases:

- a. An **initial survey** conducted among group members to evaluate the suitability of the indicators included in the GTE.
- b. A **second survey** conducted among all IISs within the Alliance, expanding the analysis to include the areas of co-creation, translation, governance, and information systems.
- c. A **cross-checking and discussion phase**, held as part of the *UNED and ISCIII Summer Course* in Ávila, and an interactive Mentimeter activity with 46 participants.

A training session led by CREAM was also included to determine whether it could be offered to the other IISs.

This report presents the results of these three phases, the conclusions, and a **proposal for indicators** to guide the group's next steps.

2. METHODOLOGY

The project was structured in three successive phases:

Phase I – Evaluation of GTE Indicators

First survey (April–May 2025) sent to the ten IISs that make up the working group, with seven complete responses. It focused on sections 2 (“Strategy, capabilities, and scientific performance”) and 3 (“Impact on society”) of the GTE, with the aim of assessing the suitability of the existing indicators and their utility in reflecting the impact on health.

Phase II – Survey of the Alliance's IISs

Second survey (August–September 2025), sent to the 35 accredited IISs, with 24 responses.

The goal was to expand the sample and analyze specific aspects of impact measurement in greater depth:

- The utility and limitations of bibliometric indicators.
- Participation in Clinical Practice Guidelines (CPGs).
- Translating results to clinical practice.
- Citizen engagement and co-creation.
- Communication and institutionalization of the impact.
- Inclusion of non-scientific stakeholders and institutional capabilities.

Phase III – Cross-checking and validation in Ávila

During the *Summer Course “Advancing Knowledge for a Healthier Society: The Impact of Health Research”*, the group shared the results of both surveys with the IIS community.

The session included:

1. **Open discussion** on new dimensions of impact.
2. **An interactive survey on *Mentimeter***, which gathered feedback from 46 participants on the relevance and feasibility of new indicators.

In addition, and separately, a specific training session on impact narratives was organized by CREAM (Center for Ecological Research and Forestry Applications, Bellaterra, Barcelona) and offered to the members of the Working Group (Annex 1) as a prerequisite for developing any training proposals.

3. TRAINING IN IMPACT NARRATIVES – CREAM SESSION

In line with the goal of strengthening institutional capabilities for impact measurement, Working Group 3 organized a **specialized training session** entitled *“Impact Narratives: How to Communicate the Influence of Research Beyond Scientific Results”*, led by **Anabel Sánchez**, *Impact Officer* at **CREAM (Center for Ecological Research and Forestry Applications)**, a center distinguished with *Severo Ochoa* accreditation and with established experience in developing comprehensive impact frameworks.

The training session, held on **July 14, 2025**, was part of the group’s commitment to the principle of **responsible research assessment**, and sought to transfer to IISs practical methodologies for **identifying, documenting, and communicating qualitative impacts**.

The content was structured around four main blocks (presentation available in *Annex 1*):

1. From measuring results to narrating change

The speaker presented the international approach that proposes **assessing impact as a process of change**, not merely as a set of measurable outcomes. She provided a theoretical overview of the different levels of impact—potential, intermediate, and final—and discussed how each of these can be integrated in the planning and monitoring of research activities. She emphasized that narratives make it possible to **explain how research contributes to change**, by contextualizing the results within complex systems of healthcare, innovation, or public policy.

2. Elements of a strong narrative

She listed the components that an effective impact narrative should include:

- **Context and identification of the problem** addressed by the research.
- **Intervention or contribution** by the institute and its researchers.
- **Evidence of the change** brought about (in knowledge, clinical practices in the case of IISs, policies, training, or scientific culture).
- **Stakeholders involved** and **geographical or social scope** of the impact.
- **Lessons learned** and future outlook.

The speaker emphasized the importance of basing every claim on **verifiable evidence**, supported by quantitative indicators, case studies, testimonials, media reports, or adopted policies.

3. Practical application and institutional experiences

The session included real-world examples of impact studies conducted at CREAF, demonstrating how these are integrated into its **strategic plan, evaluation processes, and public communication**. Best practices for institutionalizing impact measurement were presented, such as:

- Incorporate the narrative into annual reports and project progress reports.
- Form multidisciplinary teams that combine **scientific communication, transfer, and data management**.
- Create internal repositories of impact cases and evidence.

4. Transferability to the healthcare sector

The subsequent discussion examined the specific characteristics of the biomedical and clinical settings, identifying parallels between ecological research models and health research. The participants highlighted the importance of narratives for:

- Communicating the added value of research to patients, managers, and decision-makers.
- Facilitating the **qualitative evaluation in accreditation processes and competitive calls for proposals**.
- Fostering an organizational culture focused on impact and not just on scientific output.

The session concluded with the speaker's presentation of a proposed narrative framework tailored to Health Research Institutes (IISs), in which impact is structured around six interconnected dimensions:

- Scientific: relating to advances in knowledge, methodologies, and technologies resulting from research.
- Clinical: focused on improving clinical practice, health outcomes, and the quality of care.
- Social: related to the well-being of citizens, equity, and interaction with patients and communities.
- Economic: related to value creation, employment, competitiveness, and impact on the production system.
- Training: encompassing the training, recruitment, and development of research and clinical staff.
- Governance: focused on institutional strengthening, sustainability, transparency, and alignment with public health R&D&I policies.

This workshop marked a turning point in the group's work, providing participants with **language, tools, and practical examples**, which were later used as a reference in the discussion and the *Mentimeter* session at the Ávila meeting. The benefits of offering this training to the other IISs were also highlighted.

4. RESULTS

FIRST SURVEY

The first survey, targeting members of Working Group 3, assessed the **suitability of the impact indicators included in the GTE** (see survey in *Annex 2* and results in *Annex 3*).

Seven IISs participated, with an 80% consensus on the overall utility of the indicators, particularly those related to scientific communication and engagement (section 3.2).

Main findings

- Bibliometric indicators **do not fully reflect the impact on health**. The following is proposed:
 - Review them in accordance with COARA guidelines: reduce the number of impact-based indicators for journals or associated categories.
 - Penalize publications with restricted access.
 - The possibility of incorporating indicators on publications involving **patient and citizen engagement** is being considered, although the difficulty of implementing this is acknowledged.
- **Clinical Practice Guidelines** identify monitoring difficulties, although they are considered high-value indicators.
- **Co-creation** is considered a key component of impact, and the proposal is to measure the number of projects integrating patients and citizens. In this case, unlike with publications, measurement seems more feasible.
- It is considered important to include **non-scientific stakeholders** in strategic plans and governing bodies, provided they have received prior training and clear protocols are in place.

SECOND SURVEY

The second survey expanded participation to 24 IISs and allowed a more in-depth look at actual impact measurement practices (see the survey in *Annex 4* and the results in *Annex 5*).

The results show a **general consensus on the importance of measuring impact**, although **feasibility is perceived as moderate or low** in many areas.

Bibliometric indicators

- Only 46% of participating IISs believe that they adequately reflect the impact.
- Twenty of the 24 ISCIII institutions consider it important or very important to align with CoARA and to incorporate indicators that capture and highlight the diversity of scientific contributions, while also making responsible use of traditional indicators.
- In most cases, the difficulty of adapting is perceived as “relative” or “significant.”
- There is widespread opposition to excluding publications with restricted access.
- Other notable points include the costs of Open Access, the lack of common guidelines, and the recognition of biases focused on productivity and citations.

Clinical Practice Guidelines (CPGs)

- 96% support including participation in CPGs as an impact indicator.
- 88% defend establishing clear criteria for authorship of these works so that they can be considered.
- There is a significant contradiction: 75% of respondents consider it very important to measure their implementation, but the majority (88%) do not see a feasible way to do so.
- Key challenges include a lack of clinical data, the absence of protocols, and reliance on healthcare decisions.

Translating results to clinical practice

- 96% consider it a very important area.
- 88% believe that IISs should collect this information, although 50% believe that an external entity should do so as well.
- Only 2 IISs have their own registration mechanisms; 71% do so partially.
- Coordination between hospitals and institutes is recommended, along with the potential role of an independent body.

Co-creation

- 62% consider co-creation to be a relevant or very relevant indicator.
- 21 of the 24 IISs that responded identified it as an impact indicator.
- 71% believe it is appropriate to include it in the definition of strategic lines, although they have practical concerns.
- Comments: need for training, critical mass, and distinct engagement mechanisms for associations and citizens in general.

Communication and institutionalization of the impact

- 10 IISs believe they have impact strategies in development.
- 4 already have an impact plan, and 92% consider it essential to have one.
- The lack of an institutional culture and the need to incorporate impact into communication plans is highlighted.

Participation of non-scientific stakeholders

- 20 out of 24 recognize its importance; 15 consider its inclusion in governing bodies to be a key indicator.
- Comments: The participation of non-scientific stakeholders should be considered a best practice, but its impact must be measured in terms of results; there is a lack of training and available profiles.

Information systems

- 20 out of 24 consider that current systems are not suited to these needs.
- The main barriers identified are non-interoperable systems, a lack of human resources, and insufficient training.
- High or very high priority for impact measurement (100%), but low economic feasibility.

In general, it can be said that the IISs that participated share a mature and realistic perspective: they agree that measuring impact is a priority, but that it requires **resources, systems, and institutional leadership**.

MENTIMETER – IIS ALLIANCE MEETING (ÁVILA)

During the *UNED–ISCIII Summer Course*, WG3 presented the progress made in 2025 and the results of both surveys.

Following that, a **discussion was held with all attendees**, and a **participatory Mentimeter poll (46 responses)** was launched to gather insights and proposals regarding new dimensions of impact.

Discussed dimensions

The working group had decided to identify three emerging dimensions on which to base the delamination of new indicators:

- a) **The IIS's capability to generate employment.**
- b) **Science education and the promotion of STEM careers.**
- c) **Digital impact and dissemination through media and social media.**

The discussion revealed **a clear dichotomy** among the IISs regarding the ability of these dimensions to reflect a real impact. There were also many questions about the definition of these metrics, as well as the tools available for measuring them.

Additional proposals that emerged from the discussion

- Incorporate **internationalization** as a cross-cutting dimension of impact.
- Consider the **number of patients recruited or who have benefited from** the centers' research as a direct indicator of clinical impact.
- Strengthen the measurement of the economic impact and employment derived from research activity.

The exchange of ideas made it possible to identify areas of consensus and methodological uncertainty that will guide the group's next steps:

- There is a consensus on the importance of measuring impact beyond the published science.
- The need to define clear, measurable, and sustainable indicators.
- The importance of pilot testing new metrics before incorporating them into the GTE.

PROPOSAL FOR INDICATORS AND NEW AREAS

With regard to traditional measures of impact, and having recognized the objective difficulty of reliably measuring the scope of impact, we offer two proposals:

- Consider the number of patients recruited or who have benefited from research at the centers (including both clinical trials and other types of research projects) as a direct indicator of clinical impact.
- Take into account the authorship of the center's researchers in the CPG indicator. Two options could be considered: using the current indicator supplemented by the guidelines with the participation of IIS professionals, or considering solely guidelines with the participation of IIS professionals. Given the difficulty detected in measuring this indicator, pilot testing potentially more significant measures (the implementation or adaptation of CPGs in the clinical setting) in a small number of centers will be considered.

In addition to the traditional areas of impact (scientific, clinical, social, and economic), we propose considering the inclusion of three new areas: job creation as an indicator of economic impact, science education, and digital impact. It is recognized that reaching a consensus on measuring impact through job creation is difficult due to the need to distinguish between different types of contracts (permanent, temporary, project-based) and the difficulty in establishing uniform criteria. It is also recognized that measuring the impact on science education is difficult, whereas measuring digital impact and dissemination may be simpler.

This working group proposes to continue working on defining feasible indicators that have sufficient consensus in these three new areas for pilot testing. Examples of best practices will be sought from the various IISs to explore the possibility of implementing them more widely. It will also work on the role that governance should play in addressing the identified feasibility and resource barriers.

CONCLUSIONS

The second report from WG3 builds on a collaborative working process that has enabled progress on three fronts:

- **Institutional diagnosis:** This has led to a more precise understanding of the situation of IISs in terms of impact metrics.
- **Capability strengthening:** There is a clear need for specific training in impact narratives, and training that could be offered to all IISs has been identified.
- **Proposal for new indicators:** The perspective to include socioeconomic and educational dimensions is expanded.

The group reaffirms its commitment to ISCIII to continue developing a common framework for measuring impact that is aligned with CoARA, evidence-based, and adaptable to the realities of the IISs.

The group also proposes refining some of the indicators currently updated in more established areas: the number of citizens included in/benefiting from studies, or those related to CPGs.

The need to proceed with caution when incorporating new areas for impact measurement (socioeconomic, science education) where there is not yet a consensus on the potential indicators, which require a common framework of reference prior to their formal adoption, is emphasized.

There is an established need for training in impact, particularly in impact narratives. The WG will evaluate existing training proposals in order to make recommendations to the IISs.

Finally, and after having identified significant feasibility barriers in impact measurement, the WG will focus on the Governance and Infrastructure dimension to address the identified feasibility and resource barriers. It is also proposed to develop recommendations for the development of the Strategy and Impact Plan at the IISs.

ACKNOWLEDGMENTS

WG3 would like to thank the Carlos III Health Institute, the Alliance's member IISs, the 8 participating institutes, the 24 institutes that responded to the second survey, and the 46 participants at the Ávila meeting for their collaboration. Their participation has been essential in taking a step toward strengthening the culture of impact within the health research system and moving toward a more open, accountable, and transformative evaluation.

CAPABILITIES MAP OF ACCREDITED HEALTH RESEARCH INSTITUTES

WG4. Alliance of Institutes. 2024.

Coordination: IDIS AND IdISNA

Responsible parties: Dr. MARÍA LUZ COUCE AND Dr. NICOLÁS MARTÍNEZ VELILLA

1. EXECUTIVE SUMMARY

The Carlos III Health Institute (ISCIII) has created a working group to propose the structure of an information system that will enable the identification of the R&D&I capabilities of the Health Research Institutes (IISs), infrastructure, human capital, areas of leadership, know-how, existing collaborations, etc. The distribution of this information allows for the creation of a database that represents a Capabilities Map of IISs in Spain, with the aim of promoting synergies between the Institutes, optimizing resources, and paving the way for collaboration, in accordance with the strengths of each research center.

To this end, the task force held meetings to define the structure of a questionnaire, establishing core areas of capabilities, as well as the relevant strategic lines and sub-lines in each of these core areas, with the aim of obtaining information that is as concise, organized, and complete as possible. The content of the questionnaire is based on the Spanish Strategy for Science, Technology, and Innovation (2021–2027), the State Plan for Scientific, Technical, and Innovation Research (2024–2027), and the ISCIII's technical guide for the evaluation of the accreditation of its IISs. After receiving responses from the 35 accredited IISs, the results were analyzed and the strengths of the Spanish R&D&I system in the defined cores were identified, as well as areas requiring greater attention or improvement.

The data obtained was used to develop an interactive, open-source web application that shows an interactive map showing the scientific and technical capabilities of the IISs accredited by the ISCIII. The tool will enable information to be explored dynamically using advanced filters across scientific, technological, translational, and collaborative areas. In addition, it will incorporate an AI-based virtual assistant that will answer questions in natural language and generate customized reports, making it easier to identify potential strategic partners and promoting visibility, transparency, and cooperation among the IISs.

2. INTRODUCTION

The goal is to create a Capabilities Map to foster synergies among Spanish Health Research Institutes (IISs) and pave the way for collaboration by identifying and displaying the strengths of each research center and their existing potential.

This map will make it possible to identify both the established capabilities and the R&D&I potential of research groups and research support platforms. To this end, detailed information on the areas of expertise, resources, and activities of each Institute must be collected and then presented in a clear and visually appealing manner. This tool is intended to be useful for establishing an information system that allows for the identification of the research capabilities of the IISs, infrastructures, human capital, areas of leadership, know-how, existing collaborations, among others. Its objective is to enhance synergies between IISs, promote cooperation, and facilitate complementary actions that strengthen areas of strength and opportunities for growth, as well as to communicate the experience and resources available to potential partners, funders, the scientific community, and society in general.

The purpose is to establish a proposed database structure that provides more detailed and in-depth information on the capabilities of research groups and more effectively promotes the participation of the entire health ecosystem in R&D&I programs, optimizing the use of available resources in accordance with the strengths and interests of health research institutes.

Updates should be made on a regular basis, or at least following the resolutions of new calls for proposals to fund major equipment or infrastructures.

3. THEORETICAL FRAMEWORK

A literature review on the subject has been conducted to develop a strategy and prepare a questionnaire that will provide the information needed to prepare the report. Thus, the Spanish Strategy for Science, Technology, and Innovation (2021-27); the State Plan for Scientific, Technical, and Innovation Research (2024-27); and the criteria of the technical guide for the evaluation of the accreditation of IISs have been taken into account. Some definitions included in the Ministry of Science and Innovation's Map of Unique Scientific and Technical Infrastructures (ICTS) 2021-2024 have been discussed and agreed upon with the task force.

4. METHODOLOGY

In order to draw up this report, the following was taken into consideration:

4.1. PATHWAY TO FOLLOW WITH THE FOLLOWING STEPS:

- Firstly, a series of meetings were held between the coordinating centers in order to structure the work to be carried out.
- Subsequently, a draft questionnaire was jointly drawn up in order to obtain information from each of the Health Research Institutes involved in this project.
- Meetings were held with the centers participating in the working group in order to assess and work on the aspects included in the draft survey, producing a final document.
- The Carlos III Health Institute distributed the questionnaire to all accredited Health Research Institutes.
- Completed questionnaires have been received from all accredited IISs. The information was compiled and the results of the survey were analyzed in order to prepare this report.
- Meetings were held between the coordinating centers to jointly assess the results obtained and draw conclusions.
- A first draft has been sent to ISCIII and the centers participating in the surveys.
- Once that report was approved, a technical memorandum was prepared for the development of an interactive tool to be implemented on the ISCIII website.

4.2. CHARACTERISTICS OF THE QUESTIONNAIRE

The aim is to identify and present the different areas of knowledge, available resources and technologies, the capability to transfer results, and the ability to collaborate with other centers, whether national, international, and/or companies, in each institute. A questionnaire has been developed for accredited IISs to complete, focusing on four main types of capabilities:

- Scientific capabilities: representation of the subject areas in which the institutes specialize.
- Equipment and technology: indication of the equipment, unique platforms, and technologies available at the institutes.
- Capabilities for transferring research results to society.
- Collaborations within Health Research Institutes.

The questionnaire is structured around four main core areas:

CORE AREA 1. Scientific capabilities. Human capital and areas of leadership. In the following section, each center must show its potential and main areas of leadership within the strategic lines of research described in the 2021-2027 State Plan for Science, Technology, and Innovation, so that a map can be drawn up showing the main strengths of each center.

This core area establishes four strategic lines subdivided into several topics as multiple-choice questions:

Strategic line 1. Precision medicine

1. Personalized medicine, beyond omic techniques;
2. Integration of genomics, proteomics, epigenomics, metabolomics, and other technologies;
3. Sociological, psychological, economic, and ethical aspects, artificial intelligence, and digital health in personalized medicine;
4. Personalized nutrition and diet;
5. Personalized medicine in cancer, rare diseases, mental health, and other pathologies.
6. Other

Strategic line 2. Infectious Diseases

1. Immune response
2. Emerging and re-emerging diseases caused by fungi, bacteria, and viruses
3. Zoonoses
4. Vaccines
5. Antibiotic resistance, diseases caused by multidrug-resistant bacteria
6. Environmental effects (climate change, migration, globalization) on the emergence and spread of infectious diseases
7. New methods of prophylaxis, detection, and treatment
8. Health surveillance and epidemiology
9. Other

Strategic line 3. New diagnostic and therapeutic techniques

1. Biomedical engineering
2. New imaging-based diagnostic techniques
3. Pharmacology, pharmacogenomics, new drugs, and therapies
4. Gene therapy
5. Regenerative medicine
6. New biomedical materials
7. Artificial Intelligence
8. Nanotechnology applied to biomedicine
9. Implants and artificial organs
10. New surgical techniques
11. Digital health
12. Car-T
13. Other

Strategic line 4. Cancer and geroscience: aging and degenerative diseases

1. Molecular profiles of healthy aging
2. Impact of aging on disease (neurodegenerative, cardiovascular, metabolic, cancer)
3. Interaction of environment, nutrition, and psycho-sociological factors in healthy aging
4. Integrated development of multidisciplinary programs from cellular and molecular biology of aging to systems biology and medicine
5. Frailty and disability prevention
6. Other

CORE AREA 2. Technological capabilities/services. The objective is to show the infrastructure, equipment, platforms, or general services of each IIS and identify unique infrastructure, equipment, or services. The group uses the Ministry of Science and Innovation's Map of Unique Scientific and Technical Infrastructures (ICTS) 2021–2024 to define “unique infrastructure,” extrapolating this definition to equipment.

Unique infrastructures are defined as those that are one of a kind, which may be:

-Large equipment that allows for the observation, analysis, and interpretation of phenomena of interest.

-Complex experimental infrastructures designed to create, reproduce, and study physical, chemical, or biological phenomena of interest.

-Large experimental infrastructures for engineering and for the development of new technologies for application in various fields.

-Infrastructures necessary to facilitate scientists' access to natural environments that offer and present unique characteristics for research.

Infrastructures that have been funded through specific calls for proposals, such as the ISCIII's State Infrastructure Subprogram for Strategic Health Action, are also considered **particularly unique**. On the other hand, it has been agreed to define general equipment as useful equipment that is available for sharing with other centers.

Technological capabilities and services are divided into several areas of technology that are relevant to health research:

- Omic technologies
- Imaging technologies
- Animal experimentation units
- Cell Biology Units
- Services and infrastructures of interest in clinical research
- Unique services or equipment for methodological support, bioinformatics, statistics, or AI
- Other equipment, units, or infrastructures
- Accredited infrastructures, units, or platforms

The unique scientific infrastructures funded by the AES infrastructure subprogram fall within two of the indicated technology areas, namely:

Omic technologies:

-Biomedical Proteomics Unit for Research in Single-Cell Precision Medicine - Health Research Institute of the Principality of Asturias (ISPA)

-Multi-omic analysis platform for molecular imaging based on ultra-high-resolution mass spectrometry - Balearic Islands Health Research Institute (IdISBa)

Imaging technologies:

-Multiphoton microscope – Santiago de Compostela Institute for Health Research (IDIS)

-Spatial and Temporal Super-Resolution Imaging Platform (ISRET): STED and multiphoton technology combined with advanced confocal fluorescence microscopy - Institute of Biomedical Research, Hospital Universitario de la Princesa

CORE AREA 3. Capabilities for transfer to society/patients. The following section seeks to identify the units existing in each center for the management of transfer and innovation, the management of clinical trials, channels of communication with patient associations, data management, etc.

Questions are asked in relation to the following institutional units and services:

- Transfer and innovation units
- Clinical studies units
- Channels of participation
- Data management
- Open document repository

With regard to know-how and intellectual property, a multiple-choice question is established according to types and areas of knowledge in which the IIS has generated intellectual property.

- Diagnostic techniques
- Therapy
- Devices
- Prevention
- Cardiovascular
- Oncology
- Rheumatology
- Nutrition or metabolism
- Genetics
- Infectious diseases
- Surgery
- Epidemiology
- Other

CORE AREA 4. Collaboration capabilities. The objective is to identify the main existing collaboration networks.

1. Thematic collaborations. Participation in CIBER consortia
2. Thematic collaborations. Participation in RICORS
3. Participation in ISCIII platforms: Itemas, Biobanks and Biomodels, and Sren
4. Participation in clusters
5. Health cluster
6. Technology cluster
7. Other
8. International collaborations. European project partnerships.
9. International collaborations. International networks.
10. Collaboration with technology-based companies

Since the information is collected through individual questionnaires, the results may be subject to self-reporting biases. The responses reflect the perceptions of each participant or group of participants in the survey regarding their institute's technical and technological capabilities; therefore, there may be differences between what was reported and the actual situation. Consequently, some aspects of the technical and technological capabilities may have been overestimated or underestimated, particularly with regard to the interpretation of unique infrastructure. The results should be interpreted with this potential source of bias in mind.

5. RESULTS

A total of 35 responses to the questionnaire were ultimately received. In alphabetical order of Autonomous Community: IBIMA Platform BIONAND, IBiS, ibs.GRANADA, IMIBIC (Andalusia), IIS Aragon (Aragon), ISPA (Asturias), IDISBa (Balearic Islands), IDIVAL (Cantabria), IBSAL (Castile and León), I3PT, IDIBELL, IGTP, IMIM, IR Sant Pau, IRB Lleida, FRCB-IDIBAPS, VHIR (Catalonia), IIS La Fe, INCLIVA, ISABIAL, (Valencian Community), IDIS, IIS GALICIA SUR, INIBIC (Galicia), i+12, IDIPAZ, IDIPHISA, IdISSC, IIS FJD, IiSGM, IIS Princesa, IRYCIS (Madrid), IMIB (Murcia), IdiSNA (Navarre), IIS Biobizkaia, IIS Biogipuzkoa (Basque Country).

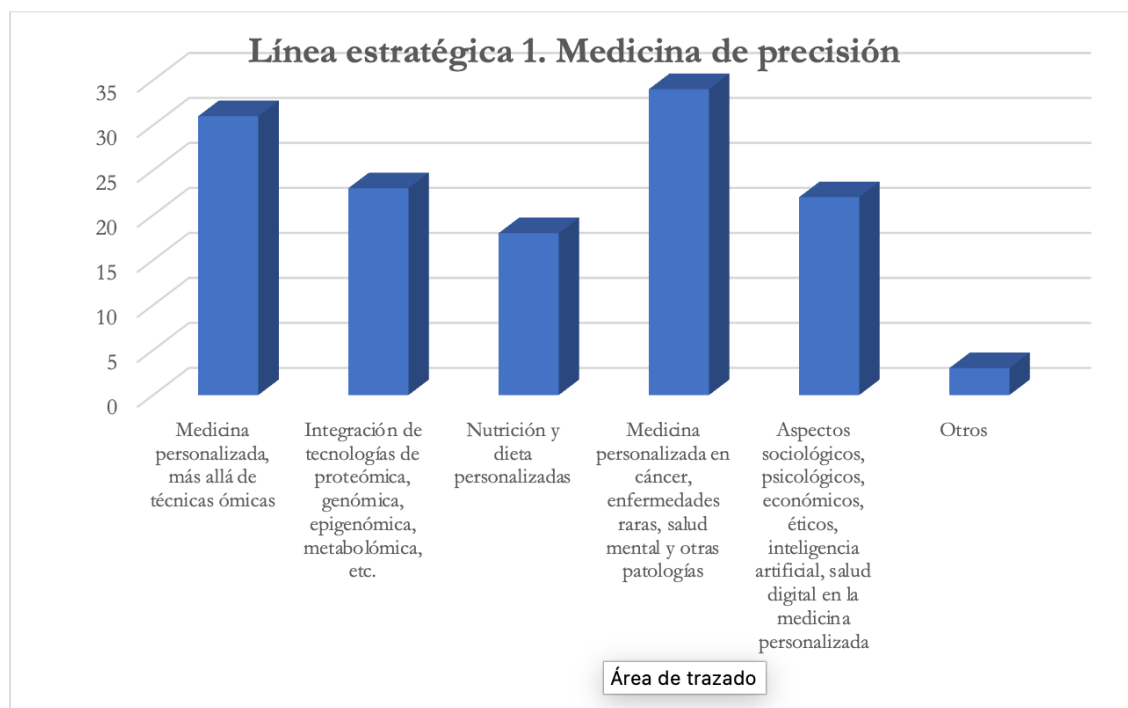
Below is a summary of the multiple responses in aggregate form:

5.1. CORE AREA 1. SCIENTIFIC CAPABILITIES. HUMAN CAPITAL AND AREAS OF LEADERSHIP.

The responses obtained from each IIS to the strategic lines proposed are indicated below:

STRATEGIC LINE 1. PRECISION MEDICINE

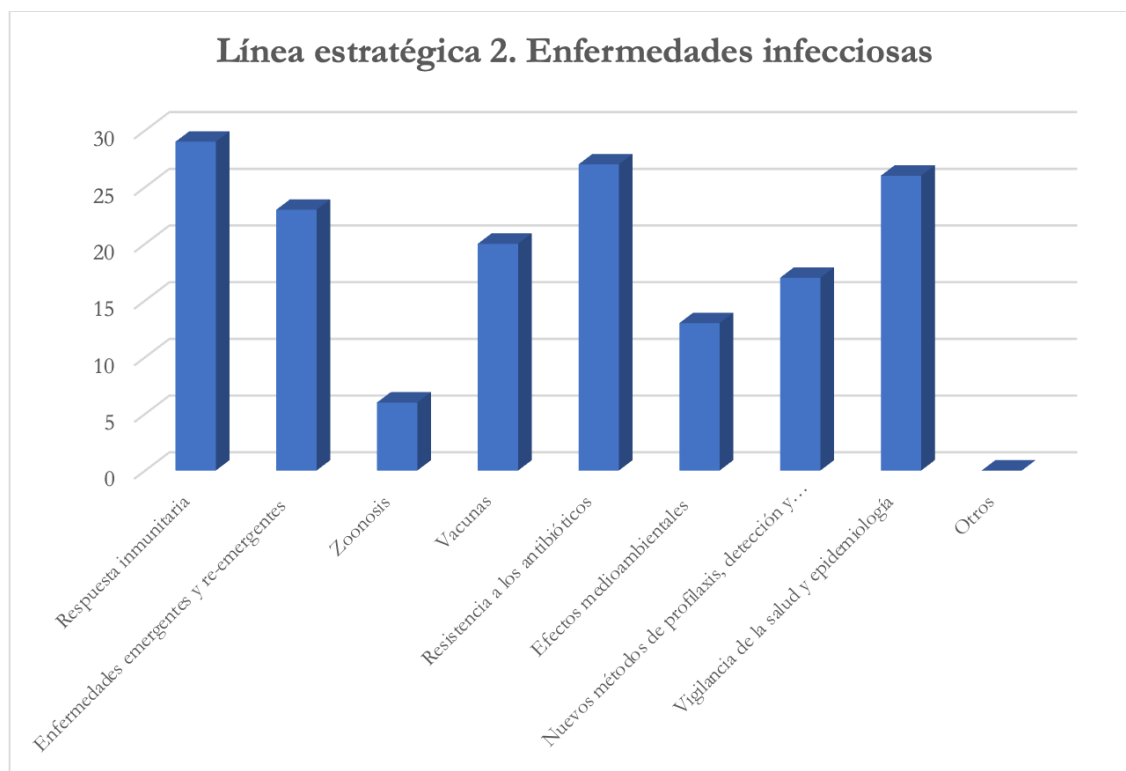
- Personalized medicine, beyond omic techniques
- Integration of genomics, proteomics, epigenomics, metabolomics technologies, etc.
- Sociological, psychological, economic, and ethical aspects, artificial intelligence, and digital health in personalized medicine
- Personalized nutrition and diet
- Personalized medicine in cancer, rare diseases, mental health, and other pathologies
- Other:
 - a. Precision and personalized medicine in critical patients and systemic autoimmune diseases – I3PT
 - b. Advanced technologies in personalized medicine: Robotics, Neuroimaging, Virtual Reality, 3D, etc. - IIS Biobizkaia
 - c. Personalized Medicine in Rare, Cardiovascular, and Endocrinological Diseases - IRYCIS



Precision Medicine stands out as an area of leadership in the Spanish R&D ecosystem, as 18 Institutes (more than 50% of the Institutes) are dedicating their research efforts to all of the strategic sub-lines presented. In particular, ***Personalized medicine in cancer, rare diseases, mental health and other pathologies is the sub-line in which the most IISs (34) are working, making it a major area of leadership in our country's scientific capabilities.***

STRATEGIC LINE 2. INFECTIOUS DISEASES

1. Immune response
2. Emerging and re-emerging diseases caused by fungi, bacteria, and viruses
3. Zoonoses
4. Vaccines
5. Antibiotic resistance, diseases caused by multidrug-resistant bacteria
6. Environmental effects (climate change, migration, globalization) on the emergence and spread of infectious diseases
7. New methods of prophylaxis, detection, and treatment
8. Health surveillance and epidemiology
9. Other:
 - a. Sepsis- IBSAL
 - b. Infectious diseases in children and newborns – IIS Biobizkaia



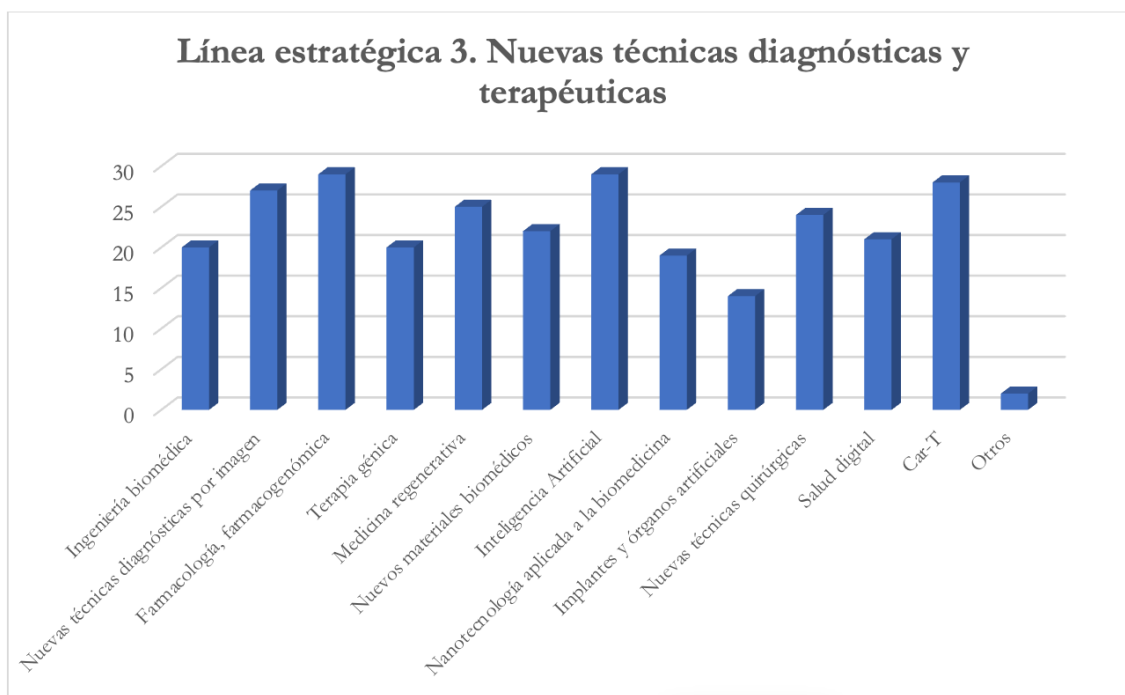
In infectious disease research, studies related to *Immune Response* (29) and *Antibiotic resistance, diseases caused by multidrug-resistant bacteria* (27) stand out, followed by *Health Surveillance and Epidemiology* (26), *Emerging and re-emerging diseases caused by fungi, bacteria, and viruses* (23) and *Vaccines* (20).

On the other hand, *Zoonosis* (6), followed by *Environmental effects (climate change, migrations, globalization) on the emergence and spread of infectious diseases*, are presented as areas with shortfalls in human capital within the Spanish R&D&I system.

STRATEGIC LINE 3. NEW DIAGNOSTIC AND THERAPEUTIC TECHNIQUES

1. Biomedical engineering
2. New imaging-based diagnostic techniques
3. Pharmacology, pharmacogenomics, new drugs, and therapies
4. Gene therapy
5. Regenerative medicine
6. New biomedical materials
7. Artificial Intelligence
8. Nanotechnology applied to biomedicine
9. Implants and artificial organs

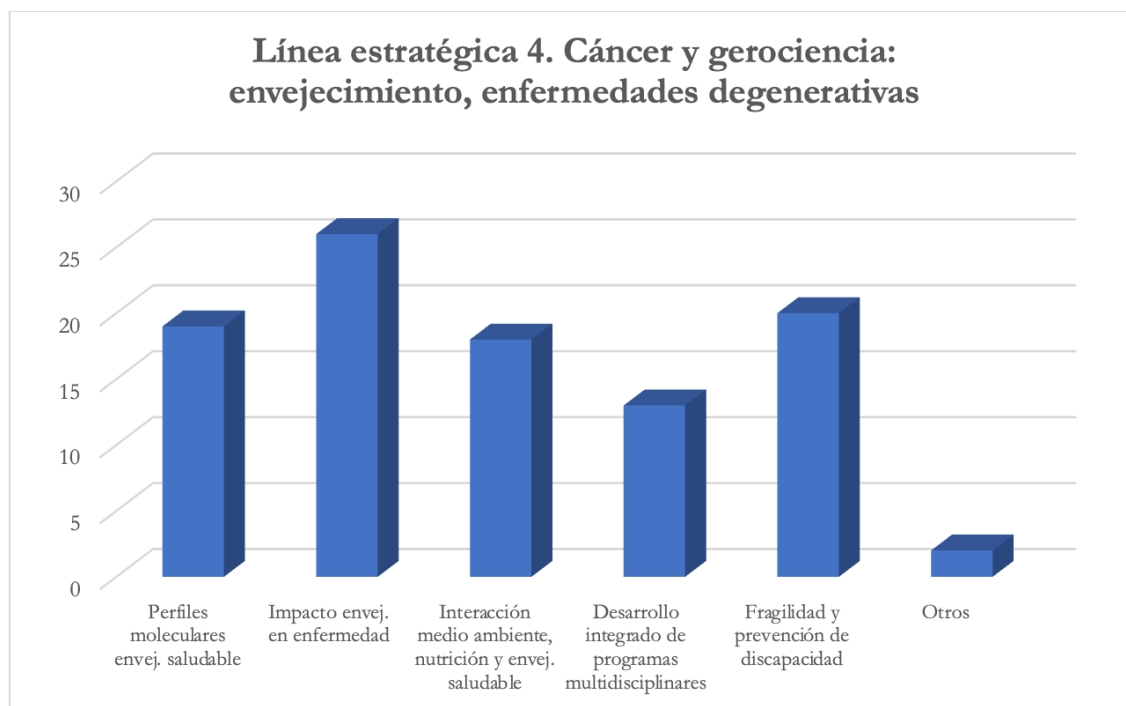
10. New surgical techniques
11. Digital health
12. Car-T
13. Other



Among the 12 lines into which Strategic Line 3 is subdivided, 17 or more IISs are dedicated to 11 of them. *Pharmacology, pharmacogenomics, new drugs, and therapies* (29) and *Artificial Intelligence* (29) stand out as major areas of knowledge, followed very closely by *Car-T* (28), while *Implants and artificial organs* (14) is the area with the lowest level of specialization among those represented.

STRATEGIC LINE 4. CANCER AND GEROSCIENCE: AGING, DEGENERATIVE DISEASES

1. Molecular profiles of healthy aging
2. Impact of aging on disease (neurodegenerative, cardiovascular, metabolic, cancer)
3. Interaction of environment, nutrition, and psycho-sociological factors in healthy aging
4. Integrated development of multidisciplinary programs from cellular and molecular biology of aging to systems biology and medicine
5. Frailty and disability prevention
6. Other:
 - a. Development of biomaterials for use in implants and prosthesis - IIS FJD
 - b. Neurodegenerative diseases - IMIB

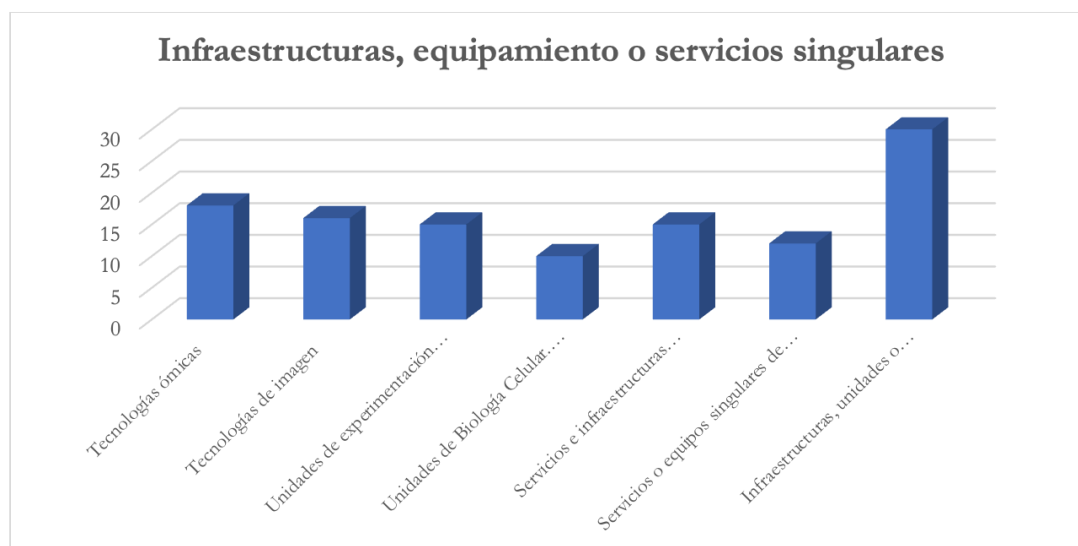


The *Impact of aging on disease (neurodegenerative, cardiovascular, metabolic, cancer)* is the most studied line of research among accredited IISs (26), followed by *Frailty and disability prevention* (20) and *Molecular profiles of healthy aging* (19).

5.2. CORE AREA 2. TECHNOLOGICAL CAPABILITIES/SERVICES

The questionnaire covered both general and unique infrastructure. However, we consider unique infrastructure, equipment, and services to be of greater importance when assessing strengths and collaborations.

The number of IISs that have some type of unique infrastructure, equipment, or service in each of the classifications is shown below.



Firstly, 30 of the 35 IISs that responded have units, platforms, or laboratories accredited by a recognized standard, which demonstrates the Spanish research ecosystem's interest in service quality. However, having more accredited platforms to enable greater expansion is an area to be improved.

Spanish health research has unique infrastructures in all the areas in which they have been classified, with *Omic technologies* standing out, with 18 unique teams or services, followed by *Imaging technologies* (16). On the other hand, there are 10 unique *Cell Biology* units or teams.

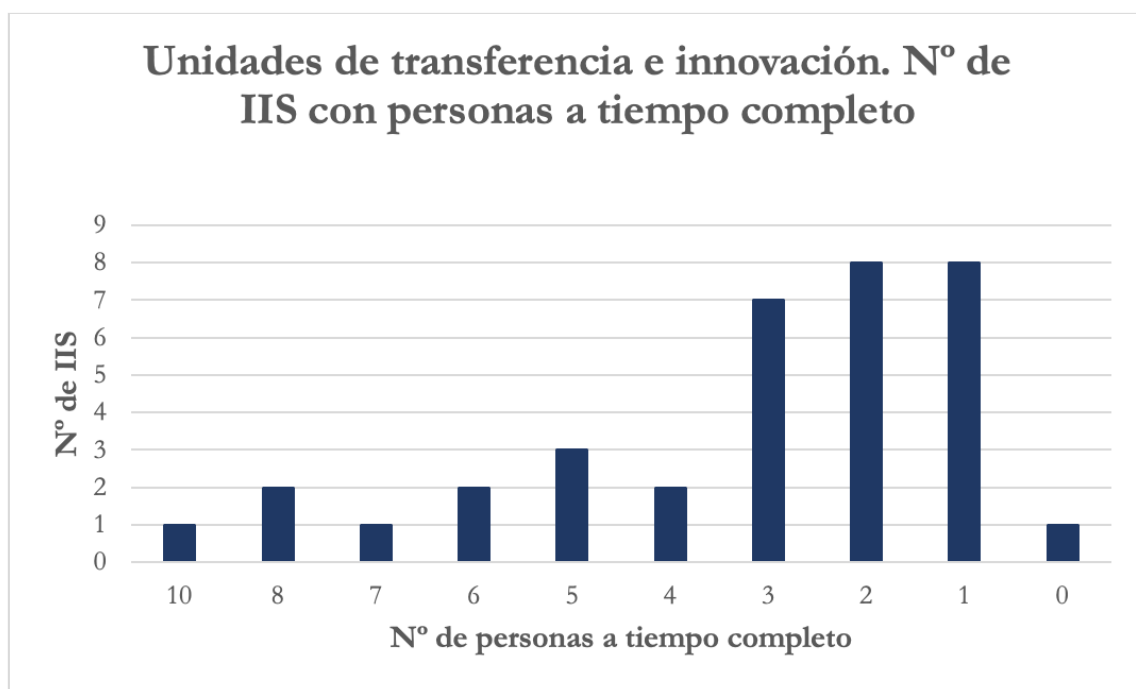
Of the unique infrastructure projects of particular note (4), two fall under the category of *Omic technologies* and two under *Imaging technologies*. Details about these unique infrastructures can be found in the Annex to this document.

5.3. CORE AREA 3. CAPABILITIES FOR TRANSFER TO SOCIETY/PATIENTS

A. TRANSFER UNITS

All IISs have staff dedicated to Transfer and Innovation. One IIS points out that it does not have full-time staff dedicated to these services.

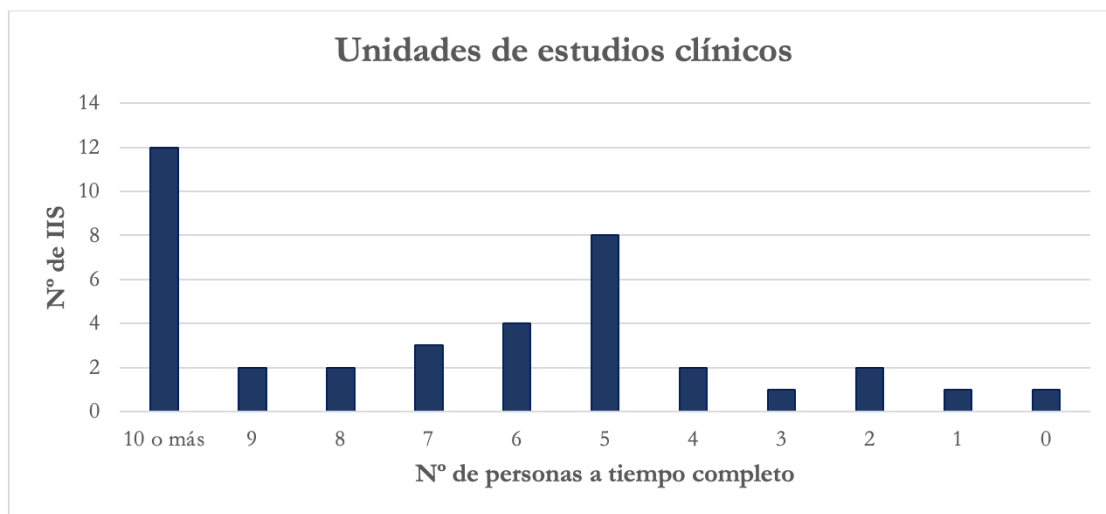
The following figure represents the number of IISs that have the number of people indicated on the x-axis dedicated full time to Transfer and Innovation.



B. CLINICAL STUDIES UNITS

34 of 35 IISs have staff dedicated to Clinical Studies. One institute points out that it does not have full-time staff dedicated to these services.

The following figure represents the number of IISs that have the number of people indicated on the x-axis dedicated full time to Clinical Studies. Some IISs may have more than 10 people on staff.

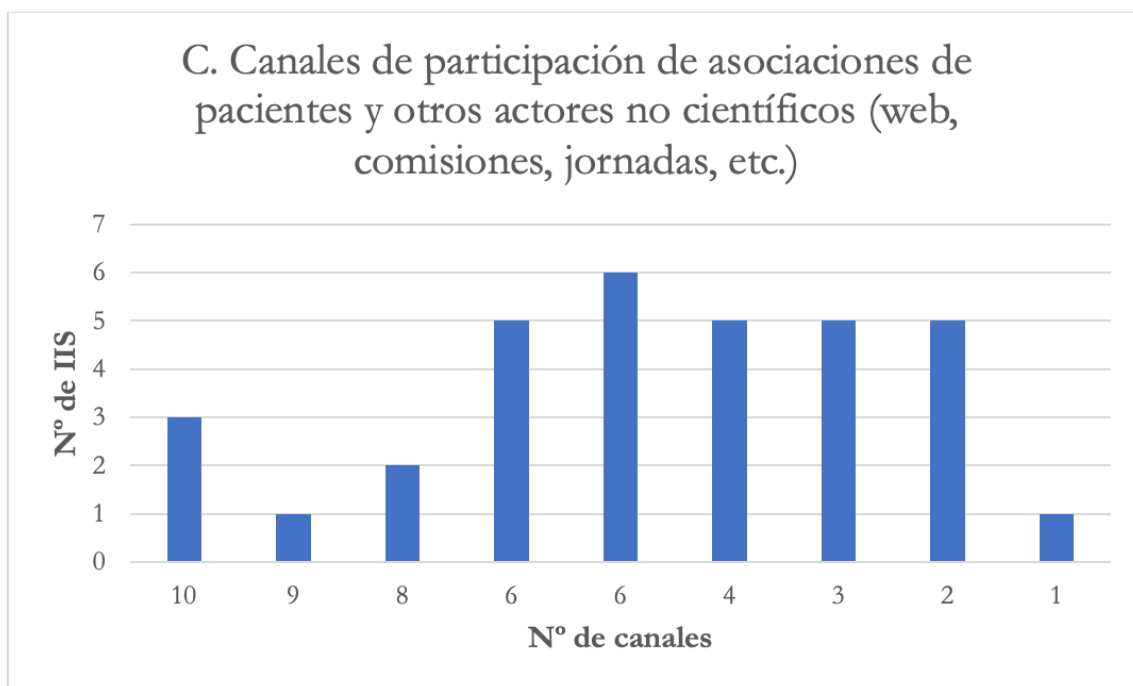


The results therefore demonstrate the considerable effort and dedication of the IISs in clinical research.

C. CHANNELS FOR THE PARTICIPATION OF PATIENT ASSOCIATIONS AND OTHER NON-SCIENTIFIC STAKEHOLDERS (websites, commissions, conferences, etc.)

All IISs have at least one channel of communication with patient associations and non-scientific stakeholders. Among the responses, communication through websites, the organization of specific conferences, and the participation of key non-scientific stakeholders in Commissions or Committees stand out.

The figure shows the number of IISs that have the number of channels indicated on the x-axis.

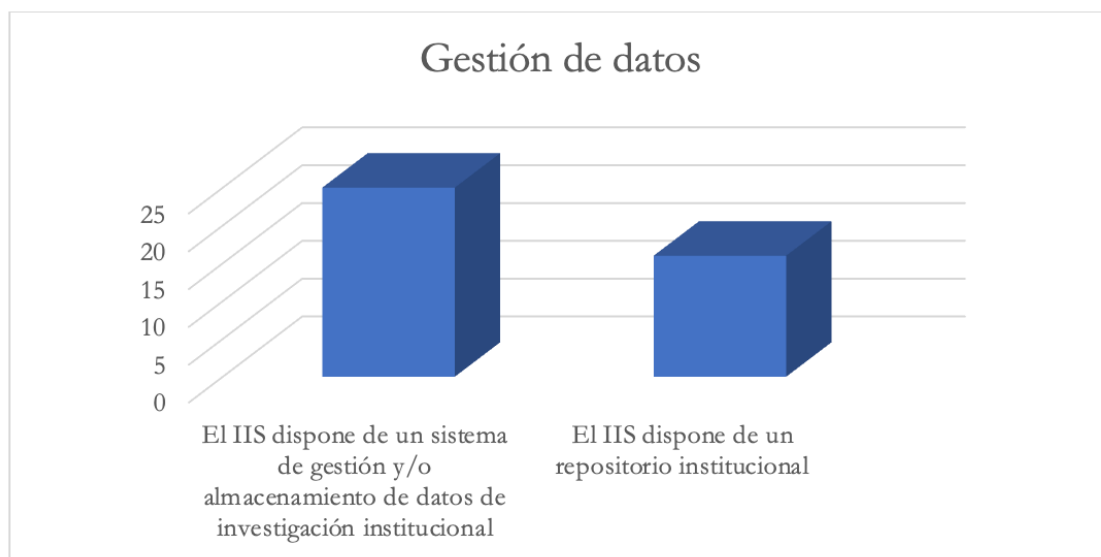


The channels used by each IIS are described in Annex IV.

D. DATA MANAGEMENT

With regard to the results obtained, 25 out of 35 have an institutional data management and/or storage system. With regard to institutional repositories, 16 IISs also have an institutional repository.

The following figure shows the number of IISs.

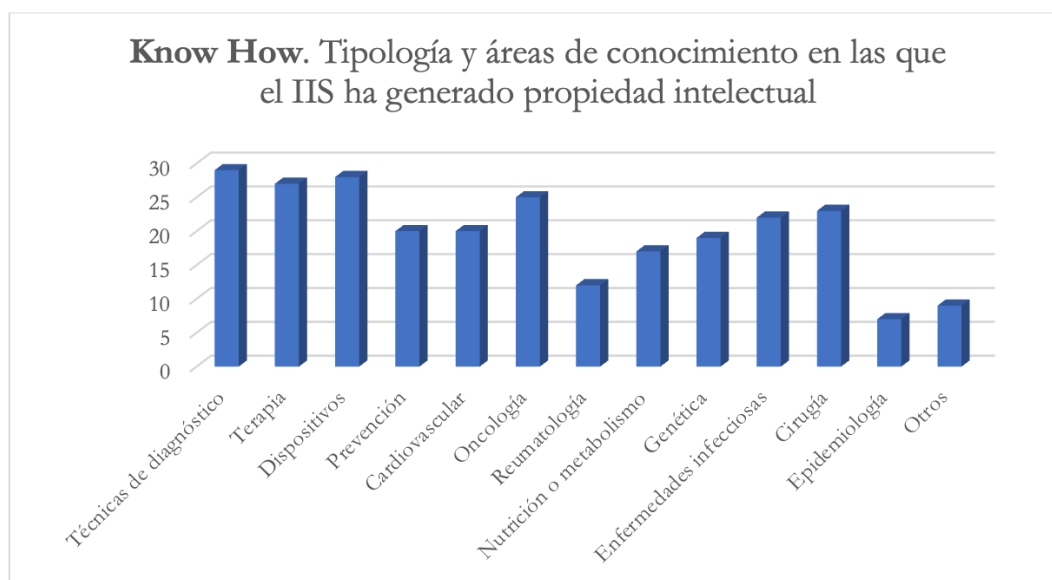


E. KNOW-HOW. Type and areas of knowledge in which the IIS has generated intellectual property.

The types and areas of knowledge that generate intellectual property in the IISs are classified as follows:

3. Diagnostic techniques
4. Therapy
5. Devices
6. Prevention
7. Cardiovascular
8. Oncology
9. Rheumatology
10. Nutrition or metabolism
11. Genetics
12. Infectious diseases
13. Surgery
14. Epidemiology
15. Other

In the healthcare R&D&I ecosystem, *Diagnostic techniques* generate the most innovation (29), followed by *Devices* (28) and *Therapy* (27). *Oncology* stands out in areas of knowledge.



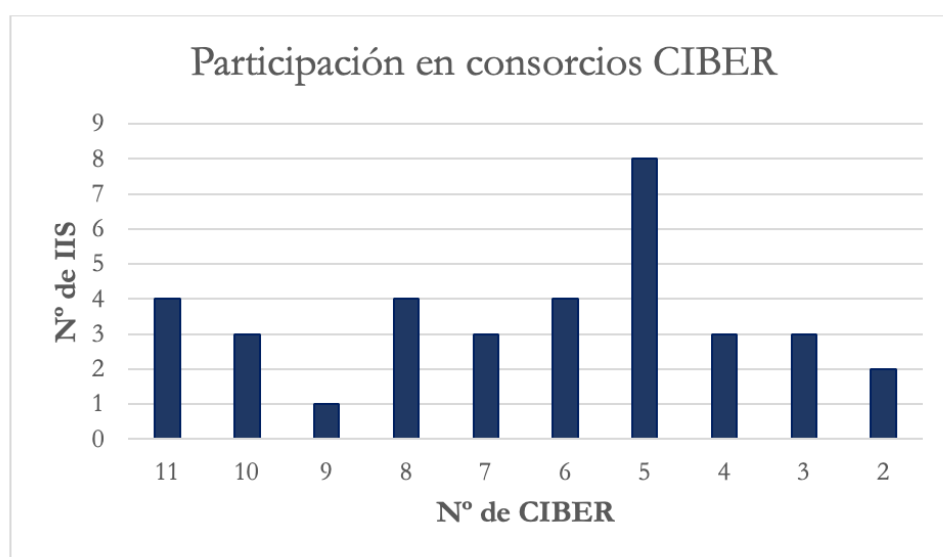
5.4. CORE AREA 4. COLLABORATION CAPABILITIES.

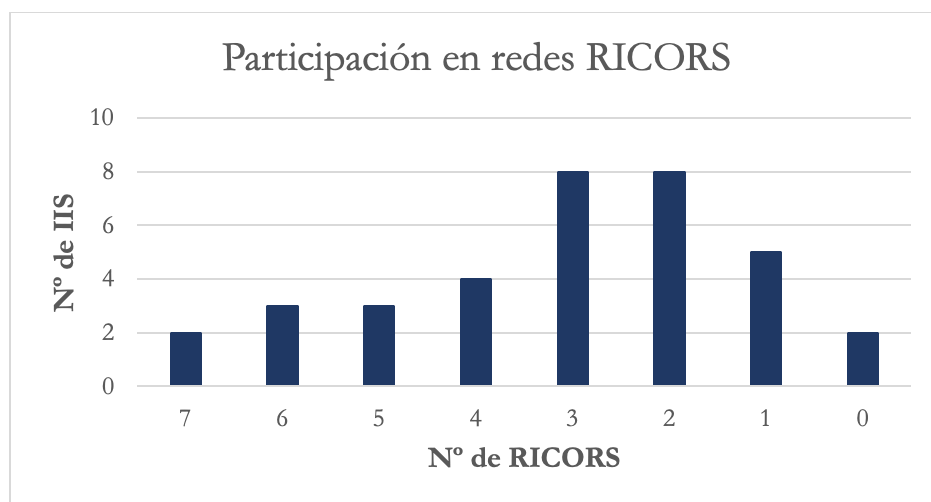
The types of collaboration for each IIS are classified by theme (CIBER, RICORS, etc.), international, and with relevant companies in the sector.

5.4.1. THEMATIC COLLABORATIONS

All IISs participate in CIBER consortia. Of these, 4 institutes participate in 11 of the 13 existing CIBERs. Regarding RICORS networks, 2 IISs participate in the 7 existing ones, while two others do not participate in any of them.

The following figure depicts the number of CIBER thematic consortia and RICORS networks in which each IIS participates.

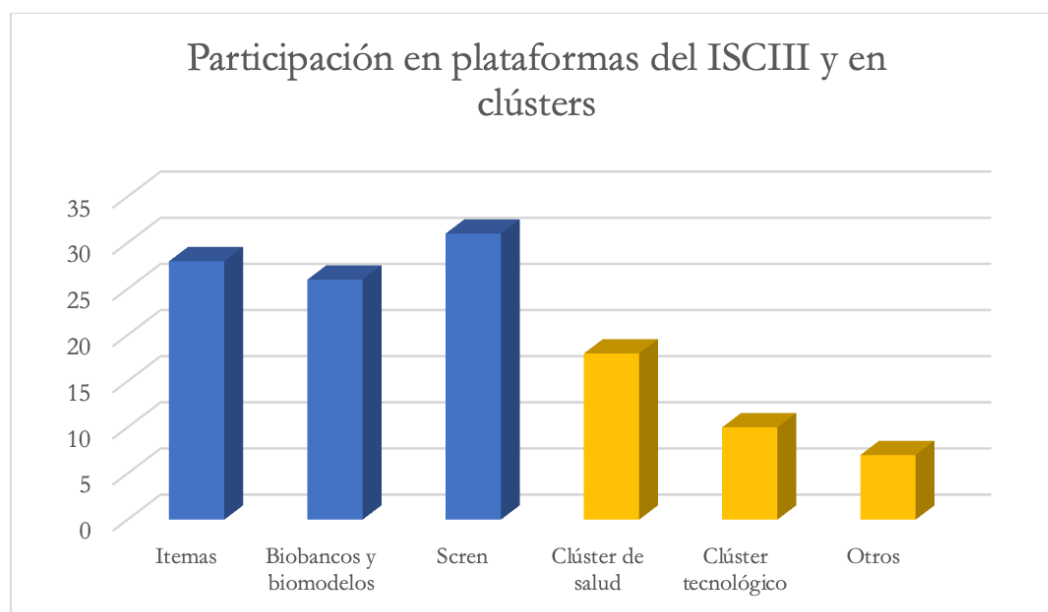




5.4.2. PARTICIPATION IN ISCIII PLATFORMS AND CLUSTERS

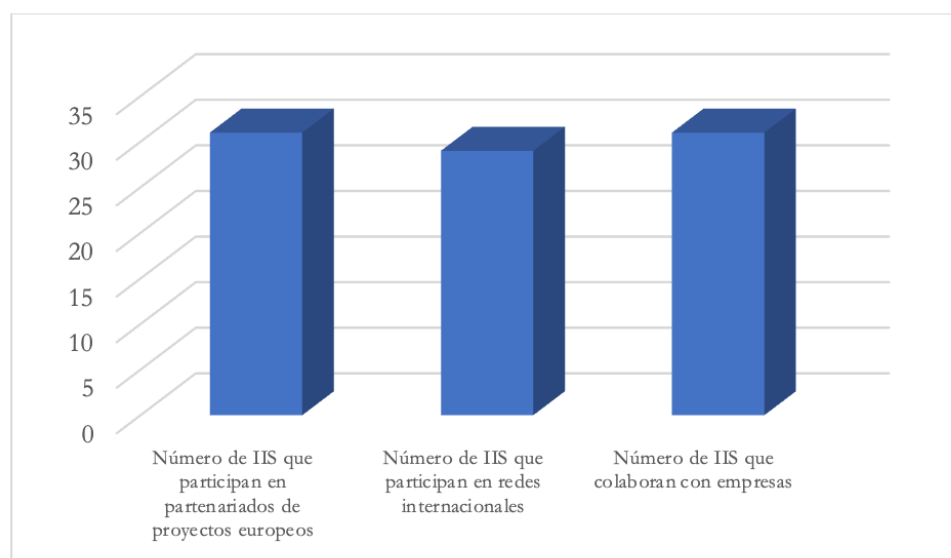
All accredited IISs participate in at least one ISCIII platform. Scren stands out as the platform with the most IISs (31), which once again highlights the great interest of the healthcare scientific community in Clinical Research.

On the other hand, most IISs (18) participate in health clusters, as shown in the following figure.



5.4.3. INTERNATIONAL AND BUSINESS COLLABORATIONS

Of the 35 IISs that participated in the survey, 31 are part of European project partnerships and 31 have collaborations with companies. The number of IISs participating in international networks is also notable (29).



6. CURRENT STATUS OF IISS AND PROPOSED AREAS FOR IMPROVEMENT BY ACCREDITED IISS

The following conclusions can be drawn from the analysis:

Strengths in the R&D&I ecosystem are identified in all of the defined Capability Core Areas, as detailed below.

- **Scientific Capabilities, including human capital and areas of leadership (CORE AREA 1)**

- The dedication of the IISS to line 1, Precision Medicine, stands out; of the five major themes analyzed, at least 18 IISs participate in each of them, reaching a participation of 97% in at least one of the fields of study proposed based on the 2021-2027 State Plan for Science, Technology, and Innovation.
- Line 2, New Diagnostic and Therapeutic Techniques, is a major strength in the Spanish R&D&I ecosystem. Most IISs (18 or more) are involved in 11 of the 12 sub-lines proposed, with IIS participation between 74% and 82% in three of them.
- In the field of Infectious Diseases (line 3), more than 50% of IISs are involved in five out of the eight topics, with three topics showing participation rates of between 68% and 77%. Line 4, Cancer, Geroscience: aging, degenerative diseases, has five main sub-lines, with three of them showing strength with 51 to 68% participation.
- There is room for improvement in various sub-lines of lines 2, 3, and 4, where participation does not reach 40%, dropping to 17% in zoonosis (strategic line 2).

- **Technological capabilities/services**

- A large number of IISs have at least one unit, platform, or service accredited by a recognized standard, which demonstrates the IIS's interest in Quality issues.
- The technologies for which most IISs have some unique infrastructure, equipment, or service are Omics, followed by Imaging Technologies. In addition, the unique infrastructure of particular note is located in these two areas.

- There is room for improvement in IIS infrastructures, provided that they need such technology for their studies.

- **Capabilities for transfer to society/patients**

- 30 of the IISs have five or more people dedicated exclusively to Clinical Studies.
- The vast majority of IISs have full-time staff dedicated to Transfer and Innovation tasks (34 out of 35).
- Most IISs have a system for managing and/or storing research data.
- The areas in which the most intellectual property is generated are Diagnostic Techniques, Therapy, and Devices. The most notable area of knowledge in innovation is Oncology.

- **Collaboration capabilities**

- All IISs participate in CIBER consortia and the vast majority participate in a RICORS network.
- Scien is the ISCIII platform with the highest participation among respondents. Participation in these platforms is good (more than 20).
- Most IISs have international collaborations, participate in international networks, and collaborate with companies in the sector.

The following aspects have been identified as proposals for action and should be considered areas for improvement:

1. Of the research sub-lines included in the 2021-2027 State Plan for Science, Technology, and Innovation, the following are considered deficient:
 - a. in strategic line 2 (Infectious Diseases), the study of *Zoonosis, Environmental effects (climate change, migration, globalization) on the emergence and spread of infectious diseases, and New methods of prophylaxis, detection, and treatment*;
 - b. in strategic line 3, *Implants and Artificial organs*; and
 - c. in strategic line 4, *Interaction of the environment, nutrition, and psychosocial factors in healthy aging and Integrated development of multidisciplinary programs from cellular and molecular biology of aging to systems biology and medicine*.
2. In the field of Cell Biology technologies, only eight unique teams or services have been identified throughout the national territory.
3. The availability of institutional repositories is limited.
4. Although the accreditation of IIS laboratories, units, or services is notable, it would be advisable to continue the commitment to quality services by increasing the number of accreditations.
5. There is room for improvement in the personnel dedicated to innovation in 37% of IISs, given that they include the dedication of one or two people full time, whenever necessary for the needs of the IISs.
6. The institutional repository section could be optimized by organizing consortia for several IISs to use the same institutional repositories, through cooperation agreements and joint funding. This would improve the capabilities of the set of institutes, being able to have more common repositories than ISCIII's REPISALUD.

7. It is proposed that the Carlos III Health Institute provide support in areas where most IISs share common weaknesses, as summarized in the previous points, such as research data management and its deposit in institutional repositories, or support in laboratory accreditation.
8. As for Collaboration Capabilities, the participation of all IISs in research networks should be encouraged.

7. APPLICATIONS OF THE CAPABILITIES MAP

Develop an interactive map of the capabilities of the Health Research Institutes accredited by the Carlos III Health Institute.

To this end, it is necessary to launch an interactive open-source web application that allows the scientific and technical capabilities of the Health Research Institutes accredited by the Carlos III Health Institute in Spain to be viewed and explored in a dynamic and detailed manner.

The purpose of the tool is to facilitate the strategic identification of potential partners through an advanced interactive map, supplemented by specific filters and an AI-based virtual assistant for specialized queries.



7.1. KEY FEATURES

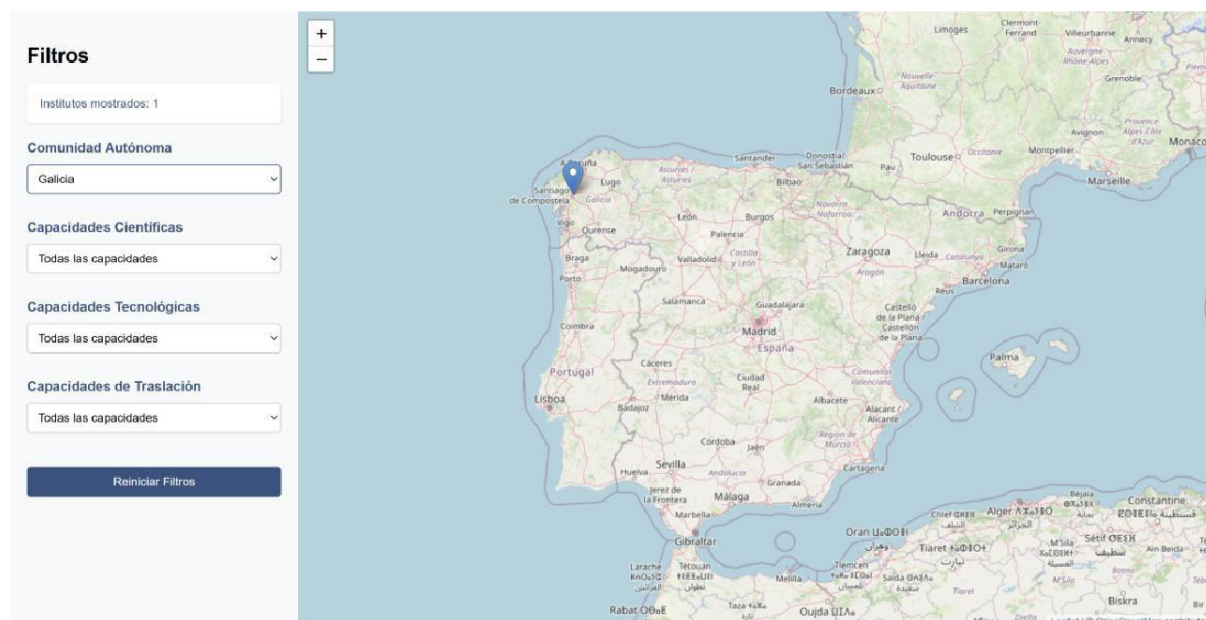
7.1.1. INTERACTIVE MAP DISPLAY

Geolocated markers that visually and immediately identify each IIS.

Interactive panels that show detailed information when a specific IIS is selected (institute name, key technical and scientific capabilities, relevant contact information).

7.1.2. ADVANCED FILTERS AND SEARCH TOOLS

The application will include specific filters aligned with the strategic lines defined by the 2021–2027 State Plan for Science, Technology, and Innovation. These filters will allow users to perform detailed searches based on the scientific, technological, translational, and collaborative capabilities of each Health Research Institute (IIS):



A. Scientific Capabilities:

Precision Medicine:

- Personalized medicine beyond omic techniques
- Personalized medicine in cancer, rare diseases, mental health, and other pathologies

Infectious Diseases:

- Immune response
- Antibiotic resistance and diseases caused by multidrug-resistant bacteria

New methods of prophylaxis, detection, and treatment

- New Diagnostic and Therapeutic Techniques:
- Biomedical engineering
- New surgical techniques
- CAR-T
- Cancer and Geroscience (Aging, degenerative diseases):
- The Impact of aging on neurodegenerative, cardiovascular, and metabolic diseases and cancer
- Interaction of environment, nutrition, and psycho-sociological factors in healthy aging

B. Technological Capabilities/Services:

- Omic technologies (mass spectrometry, next-generation sequencing)
- Imaging technologies (confocal microscopy, electron microscopy, Raman spectrometer)
- Animal experimentation units
- Cell biology units (flow cytometry, magnetic cell separation)
- Clinical research (Certified biobanks)

C. Capabilities for Transferring to Society/Patients:

- Transfer and innovation units
- Clinical studies units
- Channels of participation with patient associations
- Institutional management and storage of scientific data

Generation and management of intellectual property (surgery, oncology, infectious diseases, etc.)

D. Collaboration Capabilities:

- Participation in CIBER consortia (various specialties)
- Participation in RICORS networks
- Participation in ISCIII platforms
- International collaborations in specific projects and networks
- Partnerships with technology companies

BUILT-IN VIRTUAL ASSISTANT

It allows for natural language queries, making it easier to find centers with specific capabilities. Example of a typical query:

“Which research institutes have GMP-certified capabilities in advanced therapies such as CAR-T?”

Dynamic generation of detailed reports based on scientific and technical information extracted from PDF documents that are integrated and stored in the database.

7.2. EXPECTED IMPACT AND BENEFITS OF THE PROJECT

This platform will make a significant contribution to:

- Improving efficiency in identifying and fostering strategic collaboration among IISs.
- Enhancing the national and international visibility of the IISs.
- Facilitating transparency in the management and dissemination of scientific and technical capabilities.
- Promoting scalability and sustainability by relying on open and widely used technologies.

CONCLUDING REMARKS

Identifying the strengths of each IIS will increase their visibility and facilitate closer collaboration between IISs within the Spanish R&D&I system, establishing synergies that will lead to better proposals for both national and international collaborative projects, while also promoting the mobility of researchers at different stages of their careers.

Furthermore, showcasing the capabilities of the most established IISs will serve as inspiration for younger, smaller, or more recently accredited IISs.

The implementation will be done so as to be dynamic, with a simple, scalable, and secure deployment, and will facilitate future updates and maintenance.

The findings of the report on health research capabilities provide a comprehensive characterization of the research ecosystem, facilitating its integration into public policy-making and clinical service planning. The structured identification of gaps and strengths helps guide resource prioritization, define strategic funding lines, and support accreditation processes through standardized metrics. Overall, this analysis promotes a more efficient integration between research and clinical practice.

ARTIFICIAL INTELLIGENCE

WG5. Alliance of Institutes. 2025.

Coordination: IR-HUVH, IBSAL, AND IDISSC

Responsible parties: Dr. BEGOÑA DE BENITO, Dr. LUIS GARCÍA ÓRTIZ AND Dr. JULIO MAYOL.

It is divided into three subprojects:

SUBPROJECT 1: POSITION PAPER: ARTIFICIAL INTELLIGENCE IN HEALTHCARE RESEARCH

Objective: Establish a common position among Health Research Institutes regarding the use of artificial intelligence (AI) in the generation of scientific knowledge and the management of health data.

Who it is intended for: Researchers, institutions, funding agencies, policymakers, and citizens.

What it offers:

1. A description of the framework and commitment that should guide study design, data management, model development, and the communication of results
2. A roadmap with immediate actions, short-term objectives, and medium- to long-term goals.

Next scheduled review: [24 months from approval]

Subproject 1: Position Paper: Artificial Intelligence in Healthcare Research

EXECUTIVE SUMMARY

The Health Research Institutes of the Carlos III Health Institute hereby set forth their common position on the use of artificial intelligence in the generation of scientific knowledge and health data management. We are committed to developing AI that is patient-centered, transparent, equitable, and robust scientific evidence-based. This commitment is embodied in six fundamental ethical principles—beneficence and non-maleficence, equity and justice, transparency and explainability, data privacy and protection, responsibility, and human oversight—which will guide study design, data management, model development, and the communication of results. The roadmap includes immediate actions (creation of working groups, urgent training, data protocols), short-term objectives (common policies, pilot projects, federated infrastructure), and medium- to long-term goals (consolidation of best practices, scaling of validated solutions, international positioning). This position is coordinated with the specific subprojects of Working Group 5, dedicated to the regulatory and data framework, the operational guide for projects, and institutional implementation, and which elaborate in greater detail on the ethical, legal, and organizational requirements for the IISs.

We invite researchers, institutions, funding agencies, policymakers, and citizens to implement this common framework together. Citizen engagement will be essential to building the necessary trust in these technologies. Only through coordinated action can artificial intelligence fulfill its promise of improving people's health while respecting their fundamental rights.

1. INTRODUCTION: A STRATEGIC AND NECESSARY POSITION

Artificial intelligence enables the analysis of massive amounts of health data, generates precise predictions, accelerates the discovery of treatments, and supports complex clinical decisions. Spain has significant digital capabilities, and the European Union is promoting initiatives such as the AI Act and the European Health Data Space. However, this transformative potential comes with risks related to privacy, algorithmic bias, transparency, and reliability. The fragmentation of efforts and the lack of a common framework hinder the orderly adoption of this technology; for this reason, the Carlos III Health Institute has commissioned this consensus to guide the responsible use of AI and align the national strategy with international standards.

1.1. CONTEXT AND RELEVANCE

AI finds applications in all areas of health research: basic, clinical, translational, epidemiological, and health services research. The European Union promotes responsible innovation through the AI Act, which classifies systems based on risk and prohibits practices such as cognitive manipulation or social scoring. Healthcare systems are considered high-risk, which entails strict requirements. The European Health Data Space will facilitate cross-border access to medical records and the secondary use of data for research, while ensuring privacy protections. With its digital healthcare initiatives, Spain is well positioned to lead this implementation, although it must address challenges related to governance, funding, digital skills, data quality, and interoperability.

1.2. JUSTIFICATION OF THE CONSENSUS

AI can improve prevention, diagnosis, and treatment, but it can also amplify biases or produce opaque results. The GDPR and the LOPDGDD establish operational principles of lawfulness, transparency, data minimization, accuracy, time limitation, integrity, and confidentiality, requiring pseudonymization, privacy by design, and explicit informed consent for biomedical research. The AI Act considers systems in medical devices to be high-risk, requiring them to meet strict safety and performance requirements. Given this complex and evolving regulatory landscape, the institutes believe it is necessary to adopt a joint position that guides research and promotes ethical, responsible, and compliant use.

1.3. OBJECTIVES, SCOPE, AND TARGET AUDIENCE

The main objective is to provide a common reference framework for the responsible use of AI in healthcare research within the scope of the ISCIII. We aim to harmonize definitions, identify opportunities and challenges, establish ethical principles, explain the regulatory framework, and provide practical guides. The scope includes basic, clinical, translational, epidemiological, and health services research. The audience includes scientific bodies, researchers, technicians, managers, governance officials, ethics committees, funding agencies, health authorities, and interested citizens. In particular, funding agencies will find in this document reference criteria for incorporating explicit requirements regarding AI ethics, safety, equity, and governance into competitive calls for proposals and project evaluations.

1.4. DEVELOPMENT AND CONSENSUS METHODOLOGY

The consensus was developed through a deliberative process led by the Southern Galicia Health Research Institute and the San Carlos Health Research Institute. The ethical frameworks of the WHO and UNESCO, as well as current regulations on data protection, medical devices, biomedical research, and science, were reviewed, and national and international experiences were analyzed. The draft was shared with members of the Alliance of Institutes' AI working group to incorporate any contributions. In addition, the institutes commit to reviewing and updating this position approximately every two years, integrating regulatory changes, technological advances, and experience gained across the network.

2. KEY CONCEPTS FOR A COMMON UNDERSTANDING

Effective communication across disciplines requires a shared language. **Artificial intelligence** refers to computational techniques that enable systems to perform tasks that typically require reasoning, learning, perception, or adaptive interaction. **Machine learning** refers to algorithms that identify patterns in data and improve over time without explicit programming for each task. **Deep learning** is a subset based on multi-layered neural networks that represent information hierarchically. **Generative AI** describes models that produce novel content such as text or images. The term **big data** refers to datasets characterized by their large volume, diversity, and the speed at which they are generated. **Predictive systems** estimate the probability of future events based on historical data.

For consistency in terminology, all abbreviations are used after the full term has been defined in Spanish, and the official acronyms used in European and Spanish regulations are consistently maintained throughout the document.

In this consensus, **health research** encompasses complementary areas: basic research (fundamental biological mechanisms), clinical research (studies involving human subjects or biological samples), translational research (transferring findings to patients), epidemiological research (distribution and determinants of diseases in populations), and health services research (organization and efficiency of health systems). AI can be applied in all these areas, with specific methodological and ethical considerations in each case.

[See Table 1: Operational definitions of fundamental concepts]

3. STRATEGIC DIAGNOSIS: OPPORTUNITIES, CAPABILITIES, AND CHALLENGES

3.1. STATE OF THE ART

AI applications in healthcare research show transformative potential. In medical image analysis, algorithms achieve precision comparable to or exceeding that of human specialists in detecting pathologies. In genomics and precision medicine, AI identifies variants associated with complex diseases by analyzing millions of variations. In pharmacology, it significantly accelerates the discovery of compounds by predicting molecular properties and simulating interactions. Predictive systems are applied in epidemiology to anticipate outbreaks and model the progression of epidemics. In service management, they optimize resource allocation and improve hospital logistics. Although these applications have demonstrated technical feasibility under controlled conditions, many remain in the experimental phase and require rigorous clinical evaluation. The publication of guidelines such as SPIRIT-AI, CONSORT-AI, TRIPOD-AI, STARD-AI, and CHART reflects the recognition of the need for specific standards to ensure robust, transparent, and reproducible research.

3.2. OPPORTUNITIES AND CAPABILITIES IN THE SPANISH SYSTEM

The Spanish system possesses valuable assets: biobanks integrated into the National Network that provide well-characterized samples linked to longitudinal clinical data; clinical data networks within the SNS that hold significant potential once interoperability challenges are overcome; the Spanish Supercomputing Network; and data analysis centers that provide essential processing capability. The EHDS will link medical records across Europe, enabling the secondary use of pseudonymized data for research while prohibiting harmful uses. Spain is relatively well positioned in terms of healthcare digitization, although challenges remain: data governance requires greater flexibility, stable funding for infrastructure must be secured, digital skills need to be strengthened, the quality of clinical data must be improved, and technical and semantic interoperability requires sustained investment. There are specific examples of successful implementation in hospital and institute projects that have improved the detection of rare diseases and the analysis of radiological images, demonstrating not only technical potential but also the system's readiness.

3.3. CROSS-CUTTING CHALLENGES

Responsible development faces challenges that span multiple domains. **From a technical and methodological perspective**, data quality and representativeness are critical. Datasets may contain biases from multiple sources (selection, measurement, confounding) that propagate and amplify in the resulting models. The lack of standards for data preparation limits reproducibility. Training and validation require a rigorous methodology that includes a strict separation between development and evaluation data, appropriate cross-validation, and generalization testing on different populations.

In the ethical and social sphere, bias and equity are central concerns. AI can perpetuate inequalities if data and models are not evaluated with regard to gender, ethnic diversity, age differences, and socioeconomic determinants. A model trained predominately with data from the male population may perform worse in women; systems developed using data from urban tertiary care hospitals may not generally apply to rural settings. Privacy protection is governed by the GDPR and the LOPDGDD, which require data minimization, transparency, pseudonymization, and informed consent. Pseudonymization and anonymization present significant technical challenges: combining multiple seemingly innocuous variables can make re-identification possible. Social acceptance depends critically on trusting that AI respects fundamental rights, is used for the common good, and remains under the supervision of qualified professionals.

In the area of regulation and governance, coordination among institutions and the streamlining of regulatory processes are required. The AI Act imposes strict requirements on high-risk systems: formal risk management, rigorous data governance, comprehensive technical documentation, transparency, human oversight mechanisms, validated metrics for precision and robustness, and cybersecurity safeguards. The Medical Device Regulation stipulates that AI systems used as safety components must undergo conformity assessment and continuous post-market surveillance. Institutes must establish clear policies, ethics committees with expertise in AI, and specialized support units. Funding and training are critical factors: a shortage of specialized human resources and career mechanisms limit the pace and quality of development. The reform of the Science Act partially addresses these issues by strengthening stable funding, introducing flexible career paths, and establishing gender equality requirements.

[See Figure 1: Ethical Framework for AI in Healthcare Research]

4. ETHICAL AND REGULATORY FRAMEWORK FOR RESPONSIBLE ARTIFICIAL INTELLIGENCE

4.1. FUNDAMENTAL ETHICAL PRINCIPLES FOR INSTITUTES

The development of AI in healthcare research will be guided by six ethical principles that constitute operational commitments, not abstract aspirations. The **principle of beneficence and non-maleficence** stipulates that projects must maximize health benefits while actively minimizing the risk of harm, requiring careful assessment of whether the use of AI is appropriate compared to simpler alternatives, consideration of unintended consequences, and the design of safeguards.

Equity and justice require that we avoid perpetuating or exacerbating biases and inequalities. The technologies developed must benefit everyone without discrimination. This requires adequate representation of diverse populations in training data, disaggregated performance evaluation across different subgroups, and adjustments when unjustified disparities are detected. Equity in AI does not mean treating everyone exactly the same, but rather ensuring that no one is systematically disadvantaged.

Transparency and explainability implies that models must be understandable to professionals and, to the extent possible, to affected patients. Although certain deep learning models are inherently complex, there are explainable AI techniques that can shed light on which factors influence the predictions. Transparency extends to the data used, development methods, known limitations, and evaluation results. This openness facilitates critical scrutiny and builds the trust necessary for clinical adoption.

Data privacy and protection requires safeguarding the identity and rights of individuals whose data is used. Compliance with the GDPR requires implementing data minimization, adopting pseudonymization or anonymization techniques where applicable, establishing limited retention periods followed by secure destruction, and designing systems with privacy built in from the outset (privacy by design).

Responsibility and accountability implies that researchers and institutions take responsibility for results and can audit models to understand specific decisions. There must be clear chains of responsibility that identify who is responsible for each phase of system development and use. When errors or unintended consequences are detected, there must be mechanisms in place to correct them, learn from them, and communicate them appropriately.

Qualified human oversight means that critical decisions, especially those that directly affect people's health or rights, must be subject to the intervention and control of trained professionals. AI systems are tools designed to support human decision-making, not to replace it. Professionals must understand the capabilities and limitations of the systems they use, be able to question and override algorithmic recommendations when their clinical judgment warrants it, and be able to explain and justify their decisions to patients.

These principles are aligned with the ethical frameworks of the WHO and UNESCO, which emphasize the protection of human autonomy, the promotion of well-being and the public interest, the assurance of transparency and intelligibility, the promotion of clear responsibility, the guarantee of inclusivity and equity, and the promotion of AI that is responsive to real-world needs and sustainable in the long term.

4.2. APPLICABLE REGULATORY AND LEGAL FRAMEWORK

The **EU Artificial Intelligence Act** establishes a risk-based approach. It prohibits applications that pose an unacceptable risk (subliminal behavioral manipulation, exploitation of vulnerabilities, social scoring, real-time biometric identification in public spaces). High-risk systems—a category that includes healthcare applications—must meet strict requirements: risk management, data governance (high-quality, representative, unbiased training datasets), comprehensive technical documentation, transparency toward users, a design that enables effective human oversight, and demonstrated precision, robustness, and cybersecurity. The law recognizes that AI systems incorporated into medical devices must comply with the requirements of both regulatory frameworks (the AI Act and the Medical Device Regulation).

Law 14/2007 on Biomedical Research (Spain) upholds human integrity and dignity, guarantees autonomy and informed consent, prohibits discrimination, ensures confidentiality, and requires that biological materials be donated voluntarily. The **amendment to the Science Act** strengthens stable funding, introduces permanent contracts, establishes postdoctoral pathways, and requires institutions to implement equality plans and anti-harassment protocols.

The **GDPR and the LOPDGDD** establish binding principles of lawfulness, transparency, data minimization, accuracy, time limitation, integrity, and confidentiality. Specific informed consent is required for biomedical research. Data protection impact assessments are required when processing may pose a high risk to people's rights.

The **WHO** has published guidelines for multimodal models that highlight privacy risks, the need for impact assessments, privacy-preserving techniques (differential privacy, federated learning), and shared responsibility between developers and providers. **UNESCO** articulates the principles of proportionality, equity, autonomy, privacy, security, transparency, responsibility, sustainability, human oversight, and literacy.

The **European Health Data Space** aims to enable citizens to access and manage their medical records throughout the EU (primary use) and to allow anonymized or pseudonymized data to be used for research, innovation, and policy-making (secondary use), with an express prohibition on uses that could lead to harmful decisions or discrimination. The implementation will require a complex governance structure and pan-European technical infrastructure. Spain has an opportunity to take the lead, although it must address challenges related to governance, funding, technical capabilities, data quality, interoperability, and education.

In this context, the European Health Data Space (EHDS) distinguishes between a primary use of data, aimed at ensuring adequate cross-border healthcare, and a secondary use, which requires health data holders to make their data available for defined legitimate purposes beyond mere research, such as public health, policy planning, and evaluation.

Health Research Institutes recognize that participation in the EHDS requires robust accountability mechanisms, accessible communication channels for individuals and organizations wishing to submit queries or complaints, and clear documentation of responsibilities for each data flow and AI-based project.

5. GUIDE TO BEST PRACTICES IN THE LIFECYCLE OF RESEARCH WITH ARTIFICIAL INTELLIGENCE

Responsible AI development requires careful attention throughout the entire project lifecycle, from initial conception to the dissemination of results. Ethics must be built in from the design stage, not added later as

an administrative requirement. Studies should establish clear objectives that justify the use of AI over simpler methods, identify potential risks early on, and involve multidisciplinary teams that include data scientists, clinicians, epidemiologists, ethicists, and patient representatives.

The quality of the data fundamentally determines the quality of the models. Criteria must be established to ensure that the data is representative of the target population, to minimize errors and missing values, and to strictly comply with the GDPR and the LOPDGDD through data minimization, pseudonymization, and explicit informed consent. The management process must include comprehensive documentation of the data's source, clinical context, and transformations, along with mechanisms for monitoring equity and quality over time.

Model development should proactively mitigate bias through techniques such as sample reweighing, fair learning, or subgroup calibration. Rigorous validation requires independent datasets, and external validation in different populations or contexts is the gold standard for assessing generalization. Metrics should be evaluated in a disaggregated manner by relevant subgroups to identify disparities.

The experimental implementation requires ongoing oversight by committees that monitor the system's impact and ensure that it does not violate rights. Effective human oversight is essential: systems must provide understandable information, issue alerts when uncertainty is high, and allow for quick and easy human intervention.

The dissemination of results must adhere to standards of transparency and reproducibility (CONSORT-AI, SPIRIT-AI, TRIPOD-AI, STARD-AI, CHART). It is important to register protocols in public repositories, provide detailed descriptions of algorithms, data, and metrics, honestly report limitations and negative results, and facilitate access to models and code whenever possible. Authorship should reflect all substantial contributions, including those made by patients and citizens.

[See Table 2: Lifecycle best practices guide]

6. POSITIONING AND STRATEGIC RECOMMENDATIONS FOR INSTITUTES

6.1. STATEMENT OF GUIDING PRINCIPLES

The Health Research Institutes of the Carlos III Health Institute are committed to promoting artificial intelligence that is people-centered, evidence-based, transparent, equitable, and responsible. This commitment involves respecting people's fundamental rights and dignity in all our activities, ensuring the quality and robustness of our studies through rigorous methodology, valuing the diversity of data and clinical contexts, and promoting accountability through clear mechanisms of responsibility.

People-centered AI means that all technological, methodological, and implementation decisions will prioritize human well-being over technical or economic considerations. Each system will be designed with the actual needs of patients, healthcare professionals, and communities in mind. AI is not an end in itself, but a tool in the service of public health and scientific progress.

Grounding our work in scientific evidence means that all systems will be based on validated data, rigorous methodologies, and reproducible results. We reject speculative approaches or those driven solely by commercial interests that lack a solid empirical basis. We will promote a culture of research in which external validation, peer review, and open access publishing are standard practices.

Transparency is a fundamental principle. We will promote the development of explainable systems that make it possible to understand how conclusions or recommendations are reached. This transparency will extend to technical aspects of algorithms, institutional decision-making processes, project selection criteria, and funding sources, ensuring scientific integrity and public trust. We will balance transparency with legitimate considerations such as the protection of personal data, confidentiality in cases where partnerships require it, and security when disclosure could pose risks.

Equity requires special attention to potential sources of bias and discrimination. We will implement audit mechanisms to identify and correct algorithmic biases, ensuring that the benefits reach all segments of the population without exception. We recognize that systems can perpetuate or exacerbate existing inequalities if they are not designed with a critical awareness of health disparities related to gender, ethnicity, socioeconomic status, age, or geographic location. Therefore, the collection and analysis of disaggregated data—including variables related to ethnic and social diversity, socioeconomic status, and healthcare context—will be promoted, always with adequate safeguards for privacy and proportionality.

Responsibility involves establishing clear chains of accountability in which individuals are identified as responsible for each phase of a system's lifecycle, from design and development through implementation and monitoring. This includes the ability to track decisions, document processes, and address potential errors or unforeseen consequences. We will develop governance frameworks that define roles, responsibilities, and effective oversight mechanisms.

Respect for people's fundamental rights and dignity constitutes an absolute limit that no technological innovation can cross. We will ensure that all projects undergo rigorous ethical evaluations that consider not only potential benefits but also risks to individual and collective rights, including privacy, autonomy, informed consent, non-discrimination, and the protection of sensitive personal data.

We recognize the urgent need for inter-institutional collaboration and dialogue with society to build trust and legitimacy. The challenges posed by AI go beyond the capabilities of any single institution. The research requires convergence across multiple disciplines: medicine, computer science, statistics, ethics, law, and social sciences. This interdisciplinary approach can only be achieved through strategic alliances that enable the sharing of knowledge, resources, and infrastructure among institutes, universities, hospitals, regulatory agencies, and patient organizations.

Dialogue with society represents a commitment to the democratization of knowledge and citizen engagement in defining research priorities. We will develop public communication strategies that explain in accessible terms what AI is, how it is used in healthcare, what benefits it can offer, and what risks it entails. This dialogue will be two-way, creating genuine spaces for listening where citizens' concerns, expectations, and values inform research decisions. The participation of patient organizations will be particularly crucial.

We also recognize the importance of sustainability and the environmental impact of research. Training deep learning models consumes significant amounts of energy and generates considerable carbon emissions. We will adopt sustainable computing practices: optimizing algorithms, using energy-efficient infrastructure, prioritizing data centers powered by renewable energy, and considering environmental impact as a criterion in project evaluations. In line with this principle, strategic AI projects must estimate and monitor their energy consumption and carbon footprint, integrating these indicators into the prioritization, funding, and monitoring of their activities.

6.2. RECOMMENDATIONS FOR RESEARCH STAFF AND RESEARCH GROUPS

Researchers should develop skills in AI, ethics, and data protection through structured and ongoing training. We need programs that cover different levels, from introductory to advanced courses, with an emphasis on practical applications in healthcare. Ethics training should be integrated across all disciplines, developing an awareness for identifying potential dilemmas. Data protection requires specialized training in GDPR principles, anonymization and pseudonymization techniques, and legal responsibilities.

Collaboration with experts from various disciplines and with patients is essential for defining relevant questions. The most important questions often arise at the intersections between disciplines. We must create structures that facilitate these collaborations through multidisciplinary teams, shared spaces, interdisciplinary seminars, and evaluation systems that recognize interdisciplinary contributions. Patient engagement represents a paradigm shift: they move from being passive recipients to active participants and co-creators of knowledge, offering unique perspectives on which issues are priorities and which results truly matter.

It is essential to design studies with clear protocols using guidelines such as SPIRIT-AI and TRIPOD-AI, adopt best practices for data collection and management, and meticulously document each phase. An AI research protocol must specify objectives, population characteristics, data sources, preprocessing methods, AI techniques used, validation procedures, performance metrics, ethical considerations and data protection, and dissemination plans.

Teams must evaluate models using criteria of equity and reproducibility, subject projects to rigorous ethical review, and communicate findings transparently. Assessing equity requires going beyond aggregate metrics to examine performance across different subgroups through analyses of demographic parity, opportunity parity, and predictive parity. Reproducibility requires setting random seeds, thoroughly documenting hyperparameters and design decisions, using controlled computational environments, sharing full code, and publishing negative results. In uses in healthcare or clinical decision support, it is recommended to establish minimum quantitative performance thresholds (e.g., sensitivity, specificity, precision, F1 score, or Kappa coefficient) and document compliance with these thresholds prior to any deployment or scaling up.

Transparent communication involves reporting not only successes but also limitations, failures, and uncertainties, while avoiding "hype" and exaggerated claims. The principle of open science promotes open-access publications, the deposit of preprints, the sharing of research data with privacy safeguards, and the publication of source code. Gender equality and diversity should guide team composition and data selection, recognizing that diverse teams produce better science and that inclusion is a matter of both fairness and excellence.

6.3. RECOMMENDATIONS FOR INSTITUTIONAL IMPLEMENTATION IN INSTITUTES

Institutes must establish institutional policies that include ethical principles, evaluation procedures, and transparency requirements. These policies should be formal documents approved by governing bodies that establish the internal regulatory framework, not as generic statements, but as operational instruments that guide specific decisions and establish clear responsibilities. They must specify how projects will be reviewed prior to commencement, during development, and after completion, with clear criteria for determining which projects require a specific ethical evaluation for AI.

It is necessary to establish support units for data science and data protection to advise research groups. A data science unit should bring together experts in advanced statistics, machine learning,

data engineering, and high-performance computing, with responsibilities that include advising on study design, supporting the selection of analytical techniques, developing and implementing models, performing technical validation of results, training researchers, managing computational infrastructure, and developing reusable tools. This unit should work closely with groups such as partners involved in project conceptualization.

The data protection unit must include experts in data protection law, information security, and anonymization techniques, with functions that include advising on GDPR compliance, conducting data protection impact assessments, designing informed consent procedures, implementing security measures, managing incidents, providing training, and liaising with the data protection authority. It should act as a research facilitator by providing practical solutions such as consent forms, standardized anonymization procedures, and data processing agreements.

Institutions must ensure access to secure data and supercomputing infrastructure and promote interoperability with the EHDS. Secure data infrastructures must implement multiple layers of protection at the physical, technical, and organizational levels, including strict access controls, encryption of data at rest and in transit, multi-factor authentication, role-based access control, comprehensive auditing, and intrusion detection systems. Access to supercomputing is becoming increasingly essential; institutes must evaluate different models (in-house infrastructure, access to shared infrastructure, cloud services) while taking into account data volume and sensitivity, computational needs, technical expertise, budget constraints, and regulatory requirements.

Interoperability requires the active promotion of internationally recognized standards such as HL7 FHIR, DICOM, SNOMED CT, LOINC, and ICD. Institutes must prepare to participate in the EHDS by adapting their infrastructure, implementing interoperability standards, participating in governance processes, training staff, and contributing their data to the common European data space when appropriate. In particular, priority will be given to the use of data models and interoperability based on standards such as OMOP, HL7 FHIR, or Beacon, identifying a primary standard and complementary standards in emerging or innovative domains. When genetic or omic data are used, the institutes will maintain custody at the institution of origin, promote local processing using portable algorithms, and preferably share aggregated and validated results.

Investing in ongoing training and attracting talent is crucial. Training programs should be integrated into career plans that offer real-world opportunities for development, recognition of acquired skills, and career advancement. Attracting talent requires developing comprehensive strategies that emphasize the opportunity to work on issues with a direct social impact, intellectual freedom, a collaborative environment, training and development opportunities, job stability, and a healthy work-life balance. Gender equality and diversity should guide recruitment and promotion through proactive measures that set quantitative targets for female representation, implement processes to minimize gender bias, ensure pay equity, provide work-life balance measures, and promote female role models.

6.4. RECOMMENDATIONS FOR GOVERNANCE

Governance must be based on transparency, responsibility, and engagement. Transparency has many dimensions: at the technical level, it means that systems must be explainable; at the organizational level, it means that decision-making processes must be open; and at the institutional level, it means that institutes must publicly disclose their policies, the projects they have carried out, the results they have achieved, and

how they manage ethical issues. Responsibility implies that there are clear lines of accountability, with specific individuals identified as responsible for different decisions and actions. Engagement refers to the inclusion of various relevant stakeholders in governance processes, including patients and citizens, healthcare professionals, experts in ethics, law, and social sciences, and representatives of groups potentially affected by bias.

Institutes should strengthen their research ethics committees and establish specific AI committees that include data experts, clinicians, legal experts, patients, and citizens. Strengthening efforts should include training members on the ethical considerations of AI, bringing in experts with specific skills, developing specific procedures and criteria for the ethical evaluation of AI projects, and establishing monitoring procedures. The multidisciplinary composition of specific committees is essential, with patients and citizens serving as full members who can offer unique perspectives on what risks are acceptable and what benefits are truly valuable. These committees should include, as permanent members or ad hoc advisors, professionals with proven experience in data science and artificial intelligence, and have ready access to external advising in data ethics and governance.

The functions of these committees should include conducting an initial evaluation of projects, overseeing implementation through monitoring during the development, and proposing improvements by working constructively with researchers. Committees should be viewed as allies in the pursuit of ethical excellence, not as bureaucratic obstacles. In addition, the institutes will establish a permanent interdisciplinary forum on AI in healthcare to support projects, align criteria across committees and technical units, and facilitate rapid responses to complex queries.

Governance must be aligned with the AI Act and with WHO and UNESCO guidelines, which require avoiding prohibited practices, protecting autonomy, and ensuring human oversight. The AI Act establishes a risk-based approach with strict requirements for high-risk systems that institutes must comply with by implementing quality management systems, conducting conformity assessments, maintaining comprehensive technical documentation, and establishing surveillance systems.

Institutional policies must include mechanisms for periodic evaluation and accountability, as well as procedures for managing incidents. Periodic evaluations should address individual projects during their development, upon completion, and through post-implementation follow-up; research programs, assessing whether they generate valuable results, align with strategic priorities, use resources efficiently, and adhere to ethical principles; and policies and governance, examining whether they are effective and what improvements may be needed. Decisions regarding the procurement and contracting of AI solutions will include specific procedures for managing conflicts of interest with suppliers, including the public disclosure of prior ties, the traceability of interactions, and the independent evaluation of proposals.

Accountability means that institutes regularly report on AI research activities to various audiences through annual reports that include specific sections on AI activities. It should also include mechanisms that allow external stakeholders to request information, raise concerns, or file complaints. Incident management procedures must specify how incidents are reported through clear channels with guarantees against retaliation, how severity is evaluated, what immediate actions should be taken, how root causes are investigated, what corrective measures are implemented, and how incidents are communicated. Management should be based on a culture of learning rather than one of blame.

Coordination with funding agencies and health authorities is essential to ensure regulatory consistency and promote the adoption of standards. Institutes should maintain an active dialogue with funding

agencies to communicate their needs, promote the harmonization of requirements, and ensure that those requirements are appropriate and proportionate. Coordination with health authorities is equally essential for understanding applicable regulatory requirements, anticipating future changes, and contributing technical expertise to the development of appropriate regulations. The adoption of technical and methodological standards is essential; institutes must actively participate in processes for developing standard and promote their adoption once they have been established. This coordination will include the gradual incorporation of explicit requirements regarding AI ethics, security, equity, and sustainability into calls for proposals, regulatory guidelines, and project evaluation guidelines.

[See Table 3 in the Annex: Summary of Responsibilities by Stakeholder]

7. ROADMAP FOR IMPLEMENTATION (2025-2030)

Effective implementation requires a timeline with clear priorities and achievable objectives across three progressive phases. The proposed scheduling aligns with the entry into force of the EU Artificial Intelligence Act, so that the institutes can gradually adapt their structures, processes, and resources to the new regulatory obligations.

7.1. IMMEDIATE ACTIONS (0-12 MESES)

The first twelve months should focus on laying the organizational and knowledge foundations. Establish multidisciplinary working groups at each institute to conduct a comprehensive diagnosis of the current situation by taking a detailed inventory of existing capabilities, identifying needs and gaps, and pinpointing opportunities that can be capitalized on. This diagnosis must be coordinated at the national level to provide a comprehensive overview of the entire network.

Develop urgent training programs on AI, ethics, and data protection for research and technical staff. AI training should address both conceptual and practical aspects, with an emphasis on specific applications in healthcare. Ethics training should go beyond a superficial introduction to address specific dilemmas. Training in data protection should provide practical knowledge of the GDPR and national regulations.

Establish consent and data management protocols in accordance with the GDPR and the LOPDGDD. Consent protocols specific to AI projects must clearly explain what AI is, what data will be collected, how it will be processed, what inferences will be generated, how privacy will be protected, and what rights participants have. Management protocols must address the entire lifecycle by specifying collection procedures, documentation standards, security measures, anonymization or pseudonymization procedures, access rules, and backup procedures.

Define specific ethical review procedures for AI projects that supplement standard procedures with additional considerations. Develop expanded application forms that include specific sections on the system's technical description, training data, development and validation procedures, performance metrics, equity analysis, explainability, human oversight, and a monitoring plan.

Initiate dialogue with agencies responsible for the EHDS to prepare for infrastructure integration, understand technical and organizational requirements, influence the design from the perspective of research needs, and establish partnerships with other European institutes.

7.2. SHORT-TERM GOALS (1-3 YEARS)

The one- to three-year period represents a phase of consolidation and expansion. Implement common policies and guidelines across all institutes through a participatory process that involves representatives from all institutes, with broad consultation, pilot testing at some institutes, and refinements based on experience. Develop collaborative pilot projects that allow for testing models in different clinical settings and assessing their impact. Projects must include a rigorous evaluation not only of technical performance but also of actual clinical impact, usability, acceptability, efficiency, and equity. In this phase, priority will be given to a rigorous evaluation of the integration of AI into real-world clinical settings, using metrics related to impact, security, equity, acceptability, and efficiency to inform decisions regarding continuity or scaling up.

Create secure, federated data infrastructures that enable distributed data analysis without physical centralization. Federated infrastructures offer advantages in terms of privacy protection and facilitate collaboration among institutions that face restrictions on sharing data directly. They must be supplemented with robust security measures, including encryption, strong authentication, granular access control, operational auditing, and advanced techniques such as multi-party secure computation or differential privacy.

Strengthen advanced training and the recruitment of multidisciplinary profiles through structured professional development programs that provide clear career advancement paths. Promote participation in European initiatives and international consortia through proactive strategies to identify relevant opportunities, prepare competitive proposals, and effectively manage funded projects.

Evaluate projects using metrics related to equity, clinical impact, and social return. Equity metrics assess whether the system operates fairly for all groups. Clinical impact metrics assess whether a system actually improves health outcomes or the quality of care. Social return metrics assess the broader value that a project generates for society. Develop evaluation frameworks that integrate these multiple dimensions in a coherent manner.

7.3. MEDIUM- TO LONG-TERM GOALS (3-5+ YEARS)

The three- to five-year horizon and beyond represents a phase of readiness. Consolidate best practices so that they become institutionalized and the standard way of working through comprehensive documentation, systematic training for all new staff, quality assurance mechanisms, and an organizational culture that values adherence to best practices.

Scale up validated solutions by expanding systems that have been shown to be effective, secure, and acceptable in pilot projects to larger populations and more diverse contexts. Scaling up requires careful consideration from a technical, organizational, regulatory, and economic level. Recognize that not all validated solutions will be suitable for scaling up; develop clear criteria based on evidence of effectiveness, security, equity, acceptability, feasibility, and sustainability.

Systematically assess the clinical and public health impact of AI systems through systematic evaluation that is planned from the outset, conducted on an ongoing basis, includes comparisons with standard practice, and considers not only intended effects but also potential unintended effects. Integrate models backed by robust evidence into healthcare by requiring that systems be designed with the context of use in mind from the outset, undergo rigorous evaluation before widespread implementation, and ensure that systems always operate under effective human oversight.

Consolidate data infrastructures and participation in the EHDS will enable institutes to position themselves as international leaders. Established infrastructure must be technically robust, interoperable, well-

governed, and sustainable. Active participation in EHDS means that institutions are not only technically prepared but are also actively using it in projects and contributing their data to the common European data space.

Establish frameworks for collaboration with industry and ensure responsible technology transfer. The frameworks should establish clear principles and procedures that protect the public interest and ensure that collaborations are mutually beneficial and ethically appropriate, addressing which types of collaboration are acceptable, how conflicts of interest will be managed, how patient data will be protected, how results will be shared, and how intellectual property will be managed.

Keeping a close eye on technological developments is essential given the extremely rapid pace of change. Institutes should establish mechanisms to stay up to date on relevant developments by participating in conferences, keeping abreast of the literature, joining professional networks, and establishing committees to periodically review the state of the art. Monitoring should provide regular updates on policies and strategies, identify and manage emerging risks, and identify emerging opportunities.

[See Figure 2: Roadmap for Implementation 2025-2030]

8. RESOURCES, TRAINING, AND COLLABORATION

Advances in AI require a convergence of human skills, material resources, and strategic partnerships. This development requires human talent with specialized training in data science, statistics, computer science, bioethics, management, ethics, and law. Training programs should be integrated into career plans and promote interdisciplinary collaboration, translated into real-world opportunities for professional development and career advancement. The IISs will deploy structured continuing training programs in AI, ethics, and data governance, organized by skill level and equally accessible to research, clinical, technical, and management staff.

Gender equality and diversity should guide the selection and promotion of staff through concrete measures such as objective and transparent criteria, a balanced composition of evaluation committees, the promotion of diverse reference models, and work-life balance policies. Institutions must develop secure data infrastructures and accessible supercomputing centers, adhering to the highest security standards and ensuring accessibility through equitable and transparent policies.

Participation in the EHDS will facilitate access to standardized and pseudonymized data, expanding the volume and diversity of available data while ensuring compliance with European standards for quality, interoperability, and privacy protection. Collaboration with universities, hospitals, technology centers, and companies is essential for sharing knowledge and resources. Public-private alliances must be governed by principles of transparency and mutual benefit, with clearly defined and communicated terms, ensuring that the public interest prevails and that the results benefit society.

Citizen engagement strengthens legitimacy and facilitates the collection of high-quality data. Patients should be informed and have a say in the design of projects. When citizens are clearly informed about the objectives, methods, and implications, and have the opportunity to express their opinions and concerns, this builds the trust that is essential for the acceptance and success of the solutions developed. Active participation allows for the incorporation of experiential knowledge and perspectives, ensuring that solutions effectively address the real-world needs of end users through surveys, focus groups, and the onboarding of representatives into governance bodies, thereby ensuring that citizens' voices are heard at every stage. Specific mechanisms

for public participation will be promoted, such as patient advisory committees, project co-design processes, and public queries to guide priorities and evaluation criteria.

9. FUTURE LIMITATIONS AND LINES

AI research applied to healthcare is taking place in a constantly evolving environment that calls for epistemological humility. We recognize that any position statement should be viewed as a living document subject to ongoing review. We know part of the way, but we are unaware of many of the challenges we will face, and we need to learn systematically through experience, emerging evidence, and interdisciplinary discussion.

Critical gaps in knowledge remain. Although AI models show promising results in controlled studies, there is little evidence of their actual impact in everyday clinical practice. Systems must be evaluated in complex, diverse, and dynamic environments that reflect real-world healthcare. We are largely unaware of how these systems influence the work of researchers and clinical professionals. Equity is another key challenge: algorithmic bias can reproduce and amplify structural inequalities in subtle ways that are not always obvious. We need more sophisticated methodologies that allow us to assess how different definitions of equity translate into practical consequences and how to balance the tension between maximizing overall precision and ensuring equitable performance.

The generation of synthetic data is emerging as a promising resource, but it raises technical and ethical questions that require further research into when it preserves relevant statistical properties of real data, how to ensure that it does not allow for re-identification, and how data protection regulations apply to synthetic data. Research must address the discussion over authorship and authenticity in results generated by AI. Questions are being raised as to whether AI is merely an instrument or whether its contribution warrants explicit recognition. The proliferation of deepfakes and manipulated data threatens the integrity of scientific evidence. Institutes must establish clear policies on the use of generative AI, set transparency standards, and strengthen mechanisms for validating data and images.

The development of multimodal models opens up new opportunities but also increases privacy risks because they can infer sensitive information from combinations of data. The WHO warns of the need for rigorous impact assessments and the adoption of advanced techniques such as differential privacy or federated learning. This inherent complexity poses limitations in terms of explainability, undermining its acceptance in research and clinical practice.

Future lines include the development of audit and certification methodologies that build trust, the exploration of synergies with emerging technologies such as quantum and neuromorphic computing, and the assessment of the environmental impact of AI research. Training large models can consume as much energy as the annual consumption of several households. Adopting sustainable computing practices is both an environmental responsibility and a matter of economic efficiency. Institutes must develop energy efficiency metrics, prioritize more efficient algorithms whenever possible, use infrastructure powered by renewable energy, and consider environmental impact as a criterion in project evaluations. These lines will prioritize audit and certification methodologies for AI systems in healthcare, as well as the creation of an online guide modeled after PROSPERO and PRISMA for the registration, monitoring, and review of AI projects, and the development of a data asset catalog based on the HealthDCAT-AP application profile.

This position commits to periodic, structured, and participatory reviews that incorporate scientific advances, regulatory developments, and technological changes. We propose establishing a biennial review cycle in which an ad hoc working group would analyze the validity of the recommendations, identify areas requiring updates, and propose modifications to be submitted for broad consultation. Only through continuous updating, with a critical yet constructive perspective focused on the common good, can AI research in healthcare establish itself as a driver of responsible innovation that is genuinely people-centered. These reviews are scheduled to take place approximately every two years, unless regulatory or technological circumstances warrant bringing the update forward.

10. CONCLUSIONS AND CALL TO ACTION

Artificial intelligence offers a genuine and exceptional opportunity to improve health research and, ultimately, people's health. This opportunity will only come to fruition if we approach this transformation with the seriousness, rigor, and responsibility it demands. This document establishes a common framework developed through a broad deliberative process that harmonizes definitions, identifies opportunities and risks in a balanced manner, outlines shared ethical principles, explains the regulatory framework in an accessible way, and proposes specific best practices along with actionable recommendations.

The Health Research Institutes of the ISCIII reaffirm our institutional commitment to patient-centered AI that is grounded in robust scientific evidence and is transparent, equitable, and responsible. These are not abstract slogans but operational commitments that will translate into specific institutional policies, rigorous ethical evaluation procedures, technical and regulatory support structures, and sustained investments in training and infrastructure. We invite researchers to adopt specific methodological guidelines, to collaborate in a genuinely interdisciplinary manner, to incorporate ethical considerations from the initial design stage, and to communicate their findings transparently. We invite institutions to create effective support structures, establish clear policies, make sustained investments, and actively promote gender equality and diversity. We invite funding agencies to promote stable policies and funding, incorporate equity and social impact criteria into their evaluations, require robust data management plans, and support the development of shared infrastructures. We invite policymakers to develop balanced regulatory frameworks, invest in interoperable and secure digital infrastructures, facilitate participation in European initiatives, and promote dialogue among all stakeholders. We invite society to actively participate in the discussion on how we want AI to develop, demand transparency, share their views on which issues should be prioritized, and trust that science conducted in public institutions is guided by a commitment to the common good, although this trust must be continually earned through a demonstration of responsibility.

Only through coordinated and sustained action by all relevant stakeholders can artificial intelligence fulfill its promise to make a significant contribution to people's well-being and innovation in healthcare. The road ahead will not be easy or straightforward. We will face technical challenges that will require methodological innovation, ethical dilemmas that will demand careful deliberation, and tensions between different legitimate values that will require prudent balancing. But if we remain true to the principles outlined in this document, if we keep the well-being of patients and society as our constant guide, and if we humbly learn from both our successes and our mistakes, we can move forward with confidence toward a future where artificial intelligence truly serves the health and well-being of all people.

SUBPROJECT 2: NATIONAL SURVEY: MAP OF THE STATE OF BIG DATA AND AI RESEARCH AT IISS

During this year, a survey was designed to map the state of research on Big Data and AI at accredited Health Research Institutes in Spain.

Available in Annex 2 of this document, which includes survey forms or templates.

Legal Notice and Scope

This document provides **operational guidelines** for **AI** and **big data** projects in healthcare. **This does not replace** current regulations; in the event of a discrepancy, the **MDR (EU) 2017/745**, **IVDR (EU) 2017/746**, **AI Act**, **GDPR/LOPDGDD**, **RD 192/2023**, and the guidelines of **AEMPS/MDCG**. The term **ICPS** is used here to refer to **clinical investigation with a medical device** (regulated studies). **Clinical use** refers to routine use outside the framework of research.

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Executive summary

This guide provides a practical and verifiable framework for designing, evaluating, and implementing artificial intelligence (AI) and big data projects in healthcare within the Spanish SNS. Its objective is to help research teams, clinical managers, and support units make informed decisions by aligning projects with current scientific, ethical-legal, and organizational requirements, and by accelerating their translation into clinical practice.

Who it is intended for

- Researchers and research groups that develop or implement AI/big data models.
- Clinical Research Units (CRUs) and support platforms that assist with the studies.
- Cross-functional committees and units (ethics, data protection, information security, quality).
- External allies (medtech/pharma companies, tech SMEs, and health authorities).

What it offers

- A **regulatory map applied to the case**: identification of regulations, guidelines, and relevant roles; timeline of obligations under the AI Act and medical device regulations, where applicable.
- A **roadmap by technology readiness level (TRL)** with minimum deliverable requirements per milestone and gateway criteria.
- A transparent **evaluation and scoring model**, with minutes, a block-by-block scoring sheet, and funding/monitoring conditions.

- Templates, checklists, and standardized outputs to be attached to reports, SOPs, PIS/IC, and regulatory dossiers.
- **Interoperability and data governance** guidelines (quality, traceability, catalog, secure exchange with networks/consortia).
- Essential requirements for **cybersecurity and data protection** by design, with minimum technical and organizational controls.
- Prioritized **training** recommendations for teams (data protection, responsible AI, medical devices, and CTIS).

SUBPROJECT 3: GUIDE TO TECHNICAL AND REGULATORY REQUIREMENTS FOR BIG DATA AND ARTIFICIAL INTELLIGENCE (AI) PROJECTS IN HEALTHCARE

1. PURPOSE AND SCOPE

Purpose of the guide: to integrate, within a single framework, the technical, ethical, and regulatory requirements applicable to Artificial Intelligence (AI) and Big Data projects in healthcare, in a practical and verifiable manner, to facilitate their design, evaluation, authorization, and safe deployment within the National Health System (SNS). The guide aims to standardize criteria among researchers, evaluators, and oversight bodies, reduce regulatory uncertainty, and promote clinical value and the protection of people.

Scope: It applies to research, validation, and clinical deployment projects within the SNS that use health data and/or AI algorithms, including both software qualified as a medical device and projects the software for which is not intended to be or considered a medical device but employs advanced analytics.

- **Lifecycle covered:** Conception and design → data preparation and governance → development and validation (internal/external) → clinical evaluation → implementation in a clinical setting → post-deployment monitoring, maintenance, and decommissioning.
- **Types of projects:**
 - Research Project (RP) – algorithmic research and development using retrospective/prospective data (TRL 1–3);
 - Clinical Investigation with a Medical Device (ICPS; regulated studies, TRL ≥4). *When a device is used routinely outside of a clinical trial, this is referred to as **clinical deployment** (not ICPS).*
- **Areas and settings:** clinical and support units, translational research, multicenter networks, and federated learning scenarios.
- **Data types:** electronic health records (EHRs), medical images (including DICOM), signals, omic data, clinical reports, Patient-Reported Outcome Measures / Patient-Reported Experience Measures (PROMs/ PREMs), and administrative or operational data.

Limitations and exclusions: Non-health-related applications (e.g., well-being/fitness without a medical purpose), commercial or advertising communications, and basic research involving animal models are excluded from the scope. This guide does not replace current regulations; in the event of any discrepancy, the applicable regulations in the EU and Spain shall prevail.

What the guide requires: The guide requires: (i) a **regulatory framework applicable to the case**, with the qualification (including as a medical device, if applicable), the class, and key obligations (MDR/IVDR, AI Act), as well as MDCG/AEMPS references and the definition of roles; (ii) **deliverables by TRL** and the corresponding documented **pass verdict**; (iii) **interoperability and data governance**, including catalogs, standards, quality measures, and secure exchange mechanisms; (iv) **cybersecurity by design**, including risk analysis and treatment, minimum technical and organizational controls, continuity, and incident response; and (v) **evaluation and scoring**, with minutes, block-by-block scoring sheet, funding conditions, and a follow-up log.

Note: The following sections provide verifiable requirements and annexes containing checklists and templates. The numbering and internal references facilitate their use in calls for proposals and evaluations conducted by the ISCIII and other agents.

2. TARGET AUDIENCES AND INTENDED USES

2.1. TARGET AUDIENCES

- Clinical researchers and experts in data analysis and AI, as well as project leaders and scientific directors of **AI** and big data projects in healthcare.
- Clinical care teams (doctors, nurses, and other healthcare professionals) and support teams (pharmacy, radiology, laboratory, anatomical pathology, medical records, etc.).
- Innovation and digital transformation units, data offices, and hospital information technology (**IT**) departments; those responsible for interoperability and standards (e.g., **HL7 FHIR**, **DICOM**, **openEHR**, **OMOP**, **IHE**, though not limited to these).
- Data Protection Officers (**DPO**), data controllers and processors, and security/cybersecurity teams.
- Research Ethics Committees (**CEIm**) and ethical governance bodies.
- Authorities and regulatory agencies (e.g., **AEMPS**) and regional health services.
- Technology manufacturers and suppliers (including software as a medical device).
- Evaluators and public and private funders responsible for calls for proposals from the **ISCIII**, public procurement of innovation processes, etc.).
- Patients and patient associations, with regard to engagement, information, and co-evaluation of clinical value; Patient Safety and Quality of Care Committees, responsible for validating mitigation plans and monitoring incidents in clinical practice (in line with MDR GSPR, and national patient safety regulations); and Health Technology Assessment (HTA) Units and Quality Agencies, whose reports are decisive for the adoption, funding, and scaling of AI projects in the SNS (e.g., RedETS, EUnetHTA).

2.2. INTENDED USES:

- **Project design:** Support the definition of clinical and business objectives, target population, variables, and endpoints, as well as lifecycle planning (from conception and design through post-deployment monitoring).

- **Data governance and regulatory compliance:** developing data protection and security policies in accordance with the GDPR and the LOPDGDD, including legal guidelines, Data Protection Impact Assessments (DPIAs), data minimization, access control, traceability, and retention/disposal policies.
- **Development and technical validation:** Establish minimum data quality criteria, performance metrics (including calibration), internal and external validation, and strategies for bias management.
- **Regulation and ethics:** Determine whether the software qualifies as a medical device, its risk class, and the required documentation; prepare the project submission for assessment by the Research Ethics Committee (CEIm) and, where applicable, by the Spanish Agency of Medicines and Medical Devices (AEMPS).
- **Interoperability and clinical integration:** Guide integration with the Electronic Health Record (EHR), standards such as HL7 FHIR, DICOM and other systems, while also ensuring clinical user experience (UX) and security requirements.
- **Evaluation and funding:** Apply criteria and scoring for research projects (RP) and clinical investigation with a medical device (ICPS), taking into account feasibility, technology readiness level (TRL), and support for investment and funding decisions.
- **Implementation and operation:** Plan pilot projects, user training, management of the change, post-deployment monitoring (detection of drift, security, performance), and controlled action plans.
- **Scalability and sustainability:** Facilitate multicenter scale up, cooperation (including federated learning), maintenance, and economic evaluation (e.g., total cost of ownership TCO, return on investment ROI, and incremental cost-effectiveness ratio ICER).

3. KEY TERMINOLOGY AND DEFINITIONS

This section defines the key terms needed to interpret the requirements of the guide. Abbreviations are explained the first time they appear. Each definition includes, where relevant, the regulatory or technical context that governs its application in AI and big data projects in healthcare.

3.1. COMMONLY USED ACRONYMS:

- A. Regulatory, ethical, and data protection (EU/Spain)

AEPD: Spanish Data Protection Agency.

- **EDPB/CEPD:** European Data Protection Board / [Comité Europeo de Protección de Datos](#).
- **MDCG:** Medical Device Coordination Group.
- **EUDAMED:** European database of medical devices.
- **UDI:** Unique Medical Device Identifier.
- **ON/NB:** Organismo Notificado/Notified Body.
- **PMS/VPC:** Post-Market Surveillance/Vigilancia poscomercialización.

- **PMCF**: Post-Market Clinical Follow-up.
- **GSPR**: General Safety and Performance Requirements (MDR).
- **ISO 13485**: Quality management systems for medical devices.
- **ISO 14971**: Risk management for medical devices.
- **ISO 14155**: Clinical investigation of medical devices in human subjects (GCP).
- **IEC 62304**: Software lifecycle for medical devices.
- **NIS2**: European cybersecurity directive for critical sectors.
- **ENS**: National Security Plan.

- **B. Interoperability and clinical standards**
- **HL7 v2 / CDA**: HL7 Version 2 Messaging / Clinical Document Architecture.
- **IHE**: Integrating the Healthcare Enterprise (integration profiles).
- **openEHR**: Open clinical information model.
- **OMOP CDM (OHDSI)**: The OHDSI Consortium's Common Data Model.
- **PACS / RIS / LIS**: Picture/ Radiology/ Laboratory Information System.
- **SNOMED CT / LOINC / ICD-10-ES / ATC / RxNorm**: Clinical and pharmaceutical terminology.
- **CDS Hooks / SMART on FHIR**: Integration of decision support and FHIR-based apps.
- **ONNX**: Open Neural Network Exchange (model portability).

- **C. Data, security, and operation**
- **ETL / ELT**: Extract-Transform-Load / Extract-Load-Transform.
- **RBAC / ABAC**: Role-based / attribute-based access control.
- **IAM / SSO / OIDC / OAuth2 / TLS / PKI**: Identity management, single sign-on, and authentication/ encryption protocols.
- **SIEM / SOC**: Security Incident Management / Security Operations Center.
- **SBOM**: Software Bill of Materials.
- **CVE / CWE**: Common vulnerabilities and weaknesses.
- **SAST / DAST**: Static / dynamic safety analysis.
- **RPO / RTO**: Recovery point objective / recovery time objective.
- **CI/CD**: Continuous integration and continuous deployment.
- **SLA/SLO**: Service Level Agreement / Objective.
- **RACI**: Responsibility Matrix (Responsible, Accountable, Consulted, Informed).
- **DTA**: Data Transfer Agreement.

- **DSA:** Data Sharing Agreement.
- **DPA:** Data Processing Agreement.
- **JCA:** Joint Controller Agreement.
- **UX:** User experience.
- **D. AI, metrics, and evaluation**
 - **AUC-ROC / AUPRC:** Area under the ROC / PR curve.
 - **F1 / PPV / NPV:** Classification performance metrics.
 - **ECE / Brier:** Expected calibration error / Brier score.
 - **KPI/KPIs:** Key performance indicators.
 - **HTA:** Health Technology Assessment.
 - **BIA:** Budget Impact Analysis.
 - **QALY / DALY:** Quality-adjusted life years / disability-adjusted life years.
- **E. Purchase and financing**
 - **PPI:** Public Procurement of Innovation.
 - **ROI / TCO / ICER:** Return on investment / total cost of ownership / incremental cost-effectiveness ratio.

3.2. KEY DEFINITIONS:

- **A. Artificial Intelligence and related systems**

AI System (AI Act): A system based on statistical, logical, or computational techniques that, based on objectives defined by humans, is capable of inferring, predicting, classifying, recommending, or making decisions that have an impact on physical or virtual environments. The AI Act stipulates that, in the area of healthcare, these systems are generally considered **high-risk**, which entails stricter requirements regarding risk management, human oversight, transparency, and security.

- **B. Data and privacy**

Big Data in healthcare: Massive, heterogeneous, multimodal, and/or longitudinal healthcare datasets (e.g., EHRs, medical images, omic data, signals, free-text data) that require specific architectures and processes for governance, quality, security, and analysis.

Personal health data: Information relating to the physical or mental health of an identified or identifiable individual (including inferred data). The processing of this data requires a stronger legal basis and advanced security measures in accordance with the General Data Protection Regulation (GDPR) and the Organic Law on Data Protection and the Guarantee of Digital Rights (LOPDGDD).

Pseudonymization: The processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is protected by appropriate technical and organizational measures (Art. 4(5) GDPR). The AEPD clarifies that pseudonymized information is still **personal data**, since it can be re-identified using additional information, which must be stored separately and properly protected

Anonymization: The process of converting personal data into data that cannot be used to identify any individual. Anonymization must be irreversible within reasonable limits, through the implementation of technical and organizational measures that prevent re-identification. Anonymized data falls outside the scope of the GDPR (Recital 26).

- C. Project types and readiness

RP Project (Research/Development): Initiatives focused on the development and proof of concept of algorithms using retrospective or prospective data, with no direct impact on clinical practice. This corresponds to Technology Readiness Levels (TRL) 1–3.

ICPS Project (Clinical investigation with a medical device): A study regulated under the Medical Devices Regulation (MDR/IVDR) and Spanish regulations, authorized by a Research Ethics Committee (CEIm) and, where applicable, by the Spanish Agency of Medicines and Medical Devices (AEMPS). Its goal is to generate clinical evidence regarding a medical device, including software as a medical device (SaMD). It may require technical integration into the clinical setting, but its use is limited to the context of research and study procedures and does not constitute routine practice within the department.

Clinical deployment (operation): Routine use of the system in clinical practice outside the context of research. It requires post-deployment monitoring (Post-Market Surveillance, PMS, and Post-Market Clinical Follow-up, PMCF, where applicable) and an operational governance model. This is not considered clinical investigation with a medical device (ICPS).

Software for medical use (SaMD): Software that, on its own, serves a medical purpose. When intended for diagnosis, prevention, monitoring, or clinical decision support, it may qualify as a medical device and be subject to the Medical Device Regulation (MDR/IVDR) and applicable national regulations.

Legal manufacturer: A natural or legal person responsible for the design, manufacture, CE marking, technical documentation, and post-market surveillance of an MD (including software).

Data Protection Impact Assessment (DPIA): A systematic analysis to identify and mitigate risks that the processing of personal data may pose to people's rights and freedoms, in accordance with Article 35 of the GDPR. It is mandatory for high-risk treatments, such as those involving AI in healthcare.

Legal basis for processing: The legal basis that authorizes the processing of personal data (e.g., public interest mission, scientific research, legal obligation, or consent where applicable), in accordance with the special categories of data set forth in Article 9 of the GDPR.

- D. Key technical concepts

Data quality: The extent to which data are complete, accurate, consistent, timely, and representative of the target population; this includes the handling of missing values, outliers, and selection bias.

Internal/external validation: Internal validation estimates the model's performance on the

development data (using splitting or resampling); external validation measures it on different centers or populations to assess its generalizability.

Generalization: The model's ability to maintain performance and calibration outside the training set, in different contexts and populations.

Calibration: The agreement between estimated probabilities and observed frequencies; essential for risk-based clinical decision-making.

Algorithmic bias and equity: A systematic deviation in performance or utility among subgroups (e.g., by sex, age, ethnicity, or center), which requires measurement, mitigation, and monitoring.

Explainability: The ability to justify why a model makes a specific decision.

Interpretability: The ability to understand a model's internal structure. For example, linear regressions, which are interpreted in terms of their coefficients.

Traceability and logging: The ability to reconstruct the data history, model versions, parameters, thresholds, decisions, and changes throughout the lifecycle.

Effective human oversight: Mechanisms that enable qualified professionals to understand, intervene in, override, and take responsibility for AI-supported decisions.

Significant change (model/software): A modification that may affect safety or clinical performance (e.g., incorporation of new data, change in target population or architecture), and that requires change control and, where applicable, re-evaluation or re-regulation.

Post-deployment monitoring: Continuous monitoring of performance, security, incidents, drifts, and actual usage, with maintenance, recalibration, and decommissioning plans.

Drift:

- **Data drift:** A change in the distribution of the input data relative to the training set.
- **Concept drift:** A change in the relationship between variables and the clinical objective.

Both of these issues can degrade the model's performance if they are not detected and corrected

MLOps: A set of practices for developing, validating, versioning, deploying, and maintaining AI models in a reproducible and secure manner, including automation, change control, auditing, and governance.

Interoperability (HL7 FHIR, DICOM): The ability to exchange and interpret clinical data in a secure and structured manner. HL7 FHIR is used for clinical resources, and DICOM is used for images and their metadata.

- [E. Interoperability and operation](#)

Electronic Health Record (EHR): A corporate system that stores and manages a patient's longitudinal clinical information.

Patient-Reported Outcome Measures (PROMs)/ Patient-Reported Experience Measure (PREMs): Outcomes reported by patients (PROMs) and experience perceived by patients (PREMs), useful as outcome variables (endpoints) and for evaluating the clinical impact.

ModelCard / DataSheet: Standardized documentation templates for documenting models and

datasets, including origin, population, limitations, metrics, risks, intended and prohibited uses, and maintenance requirements.

Federated learning: A training and validation paradigm in which data remains at the source, with only model parameters or updates being shared within a defined governance and security framework.

Patient safety: A principle and set of measures designed to prevent harm resulting from the use of the system, including risk management, alerts, safeguards, and clinical usability validation.

Economic evaluation: Analysis of total cost of ownership (TCO), return on investment (ROI), and incremental cost-effectiveness ratio (ICER) to support implementation and scale up decisions.

Clinical UX: Design of secure, intuitive, accessible, and efficient interfaces and workflows, validated with users and aligned with the EHR; includes alert management, privacy, and security.

General-purpose AI (GPAI): AI models or systems of general application, capable of performing a **wide range of tasks** and of **being integrated** into other applications. The **AI Act** establishes specific requirements regarding **documentation, transparency, and responsible use** when AI is used as the basis for other systems.

Service Level Indicator (SLI): **Quantitative metric** that measures an aspect of the service (e.g., **p95 latency, availability, error rate**) and serves as the basis for defining service level agreements (SLAs) and **service level objectives (SLOs)**.

4. APPLICABLE REGULATORY FRAMEWORK

This guide is aligned with the European framework (MDR/IVDR and the AI Regulation) and with the Spanish national framework (AEMPS, Royal Decree 192/2023, and data protection—GDPR/LOPDGDD). This document outlines key obligations and their implementation timeline.

4.1. MDR/IVDR AND THE QUALIFICATION OF AI SOFTWARE AS A MEDICAL DEVICE

- **Qualification and classification:** Software intended for medical purposes (diagnosis, prevention, monitoring, decision support, etc.) may **qualify as a medical device (MD)** under the **MDR (EU) 2017/745** or the **IVDR (EU) 2017/746**, with obligations regarding clinical/performance evaluation and risk management. The **MDCG** maintains specific guidelines for software (e.g., **MDCG 2020-1** on the clinical evaluation of software). [European Commission / Guidance - MDCG endorsed documents and other guidance](#)
- **Spain – Competent authority and licenses:** The **AEMPS** is the competent authority. **Royal Decree 192/2023** regulates, among other things, prior operating licenses for facilities, notified bodies, reprocessing, and the monitoring of radioactive materials in Spain. [AEMPS - Medical device legislation](#)
- **National support guidelines:** The AEMPS publishes operational guides (e.g., **Guide for the marketing of medical devices in Spain, 2025**), which are useful for manufacturers, importers, and distributors. [Guide for the marketing of MDs in Spain](#)

4.2. EUROPEAN AI REGULATION (AI ACT) AND INTERACTION WITH THE MDR/IVDR

Scope and timeline: The **AI Act** took effect on **August 1, 2024**. The prohibitions and requirements regarding AI literacy apply **as of February 2, 2025**; governance rules and obligations for **GPAI** apply **as of August 2, 2025**; for **high-risk AI systems integrated into regulated products** (e.g., MDs under the MDR/IVDR), full application is extended **until August 2, 2027**. [AI Act European Commission - Artificial Intelligence in healthcare](#)

High health risk: AI systems that are **safety components** of regulated products (including medical devices) are considered **high-risk** and must comply with requirements for **risk management, governance, and data quality, technical documentation, traceability, and event logging, transparency, and human oversight**, which are typically integrated into the medical device conformity assessment procedure. [European Commission - Artificial Intelligence in healthcare](#)

4.3. THE SPANISH NATIONAL FRAMEWORK AND DATA PROTECTION

AEMPS and Royal Decree 192/2023: In Spain, the AEMPS enforces the MDR/IVDR and Royal Decree 192/2023 regarding licensing, surveillance, manufacturing (including in-house where applicable), and distribution, with specific procedures and registries at the national/regional levels. [AEMPS - Medical device legislation](#)

GDPR and LOPDGDD: The GDPR (EU) 2016/679 regulates the processing of health data, which falls under the special categories of personal data. The legal basis for processing must always be found in **Article 6 of the GDPR** (e.g., Art. 6(1)(e) task carried out in public interest, or Art. 6(1)(A) consent in certain cases), in conjunction with the provisions of Member States' laws. **Article 9 of the GDPR** does not in itself constitute a legal basis, but rather sets out exceptions to the general prohibition on processing special categories of data; in health research, the exception under Art. 9(2)(j) (scientific research purposes) is typically applied, together with the safeguards under Art. 89(1) (e.g., pseudonymization). The LOPDGDD supplements and implements this regulation in Spain. [Regulation \(EU\) 2016/679 of the European Parliament and of the Council, 27 April 2016, Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights.](#)

Rights and safeguards: The following must be assessed: **DPIA/EIPD**, data minimization, access controls, retention, and the exercise of rights. The **AEPD** provides specific guidance on health data. [European Data Protection Board, Spanish Data Protection Agency](#)

4.4. INTERNATIONAL TECHNICAL REFERENCE STANDARDS

In addition to European and national regulatory frameworks, there are international technical standards that guide the development and evaluation of AI-based medical devices:

- **ISO 13485:** Quality management for medical devices.
- **ISO 14971:** Risk management for medical devices.
- **IEC 62304:** Medical software lifecycle.
- **ISO 14155:2020:** Good Clinical Practice in investigations with medical devices.
- **ICH E6(R3) – Good Clinical Practice:** Currently in the process of being adopted internationally, it

updates the Good Clinical Practice and will apply across the board to clinical trials, including those involving AI-based medical devices. Its incorporation strengthens the global harmonization of ethical, regulatory, and methodological requirements.

Practical note: In RP (TRL 1–3) and ICPS (TRL ≥4) projects, document the **software qualification**, the **risk class**, the **legal basis** for data, the **clinical/performance evaluation plan**, and the **AI Act compliance** (high risk), aligning the technical dossier with the MDR/IVDR and, where applicable, with the AI Act implementation milestones.

4.5. CYBERSECURITY AND RESILIENCE IN HOSPITALS.

Cybersecurity is a critical factor in the implementation of AI and big data systems in healthcare, given that hospitals are part of the nation's critical infrastructure and are frequent targets of cyberattacks. System security measures must ensure the confidentiality, integrity, and availability of clinical data, as well as the clinical continuity in the event of an incident.

Projects must meet the requirements of the [National Security Plan \(ENS\)](#) and the [NIS2 Directive](#), including prevention, detection, response, and incident recovery plans. In addition, specific contingency protocols that consider the coordination with the healthcare center's security teams and with the relevant computer security incident response teams (CSIRT) are expected to be defined.

In this context, it is advisable to align hospital cyber resilience plans with the capabilities developed at the European level. The [Cyber Solidarity Regulation \(EU\) 2025/38](#) establishes the **European Union Cybersecurity Reserve**, a mechanism that provides Member States with specialized resources for detection, analysis, and response to serious incidents affecting critical infrastructure, including healthcare infrastructure.

Similarly, the **European Committee of the Regions** has highlighted the importance of **regional cybersecurity support centers**, designed as decentralized hubs that provide direct support to hospitals and biomedical research centers with limited in-house capabilities. These centers coordinate with national authorities, ENISA, and European Security Operation Centers (SOCs), ensuring real-time surveillance and enhanced response capabilities.

Integrating these European capabilities into institutional hospital cybersecurity plans provides **redundancy, specialized support, and scalability** in the event of large-scale incidents. At the same time, it places AI and big data projects in healthcare within a framework of **cyber resilience aligned with the European digital strategy**, thereby strengthening the confidence of professionals, managers, and patients in the safe use of these technologies.

Expected output of section 4: Regulatory map applicable to the case (GDPR/LOPDGDD; MDR/IVDR where applicable; AI Act; NIS2 and ENS; EHDS; CRA; relevant IEC/ISO standards). System qualification and category (if it is a medical device), operator role (legal manufacturer / deployment manager), and compliance strategy (GSPR, clinical/performance evaluation, post-market surveillance); AI Act timeline for the project, with milestones and applicable obligations (transparency, high risk, technical documentation, monitoring, registration); List of referenced MDCG/AEMPS guidelines and traceability of their application to the project (links and version); Alignment with cyber resilience: ENS/NIS2 plan, coordination with the competent CSIRT, and, where applicable, integration with the EU Cybersecurity Reserve and regional support centers.

5. PROJECT TYPES AND TECHNOLOGY READINESS LEVELS (TRL)

We distinguish between two families of projects based on their purpose and readiness level: **RP** (research and development, **TRL 1–3**) and **ICPS** (clinical investigation with a medical device, **TRL ≥4**). The **TRL** scale is adapted here to **AI in healthcare** to guide milestones, deliverables, and pass verdicts. This adaptation allows readiness levels to be aligned with evaluation and funding criteria, as well as with applicable regulatory frameworks (MDR/IVDR, AI Act, GDPR/LOPDGDD), thereby facilitating regulatory traceability and the planning of healthcare deployment.

5.1. TYPES OF PROJECTS

RP (Research/Development): Generation and testing of algorithmic concepts using retrospective or controlled prospective data. The primary focus is on methodology, data quality, performance, and initial generalization. There is no actual clinical use or direct impact on patients. During the RP phase, neither the medical device regulations nor the AI Act apply, unless the software already performs critical functions in healthcare. It is recommended to document the **intended use** and the **legal basis for data processing**, especially when personal data is used.

ICPS (Clinical investigation with an MD): A study regulated by CEIm/AEMPS where applicable, aimed at generating clinical evidence regarding the MD/SaMD. Executing the protocol may require technical integration within the hospital, but its use is limited to the scope of the study. This phase must include a **post-deployment monitoring plan (PMS/PMCF)**, change control, and operational traceability, as well as compliance with **patient safety** requirements and the assurance of **effective human oversight**.

Clinical deployment (operation): Routine use outside of a trial or study. Clinical deployment is implied in TRL 8–9 as a phase following ICPS. In this guide, TRLs have been **specifically adapted to the context of AI in healthcare**, incorporating technical, regulatory, and clinical requirements. Each level must be documented with **verifiable artifacts** that support progression to subsequent phases.

5.2. AI-ADAPTED TRLS IN HEALTHCARE: MILESTONES AND MINIMUM DELIVERABLES

Technology readiness levels (TRLs) have been **specifically adapted to the field of AI** in healthcare, incorporating technical, regulatory, and clinical evidence. Each level must be documented using **verifiable artifacts** (protocols, reports, validations, regulatory approvals) that clearly trace progress toward subsequent stages.

The following describes the **nine technology readiness levels (TRLs)** adapted for AI projects in healthcare, along with the milestones and minimum deliverables required for each phase.

TRL 1 – Basic principles observed. Preliminary clinical and methodological knowledge; definition of the problem and potential **endpoints**.

Evidence: review of the state of the art, clinical hypothesis, outline of **intended use**.

TRL 2 – Concept formulated. Conceptual design of the algorithmic approach and data plan.

Evidence: high-level RP protocol, variable schema, inclusion/exclusion criteria, governance plan, and preliminary **DPIA**.

TRL 3 – Proof of concept. Initial development using research data; basic internal validation.

Evidence: curated dataset (dictionary and lineage), primary metrics, overfitting control, initial bias analysis, reproducible documentation.

TRL 4 – Minimum viable product (controlled environment). Executable version with technical and data **SOPs**; robust internal validation and initial **external validation**.

Evidence: traceable (versioned) software package, initial **ModelCard** and **DataSheet**, risk, security, and cybersecurity plan.

TRL 5 – Technical validation in a relevant environment. Testing using data from different centers and under conditions close to clinical practice (without influencing decisions).

Evidence: multicenter external validation, **calibration** analysis, performance by subgroups, and bias mitigation, interoperability plan.

TRL 6 – Pilot shadow mode (shadow testing) in a clinical setting. Integration with systems (EHR/FHIR/DICOM) and operation in parallel with the clinical workflow, without replacing professional judgment.

Evidence: usability evaluation, response times, and clinical workload; logging (and alerts; predefined **change plan**).

TRL 7 – Supervised use with limited clinical impact. Controlled deployment in pilot units with effective human oversight.

Evidence: ethical/organizational approval, patient safety indicators, clinical **override** procedure, support and maintenance agreement.

TRL 8 – Preparation for regulated/operational adoption. Complete technical documentation and quality processes for sustained operation; if applicable, dossier for **CE marking** and compliance with the requirements of the **AI Act** for high-risk devices.

Evidence: robust risk management, **post-market plan** (or post-deployment monitoring plan), contracts, and **SLA/SLO**.

TRL 9 – Scaling up operations and continuous improvement. Operational system that is stable, monitored, and undergoing controlled improvements.

Evidence: real-time metrics, **drift** and recalibration, periodic audits, the **MLOps** cycle, and an annual review.

5.3. PASS VERDICTS AND RESPONSIBILITIES

- **RP → ICPS (≥ TRL 4):** This requires external validation, subgroup bias analysis, an updated **DPIA**, an interoperability plan, and a defined human oversight mechanism.
- **Pre-clinical use (TRL 6–7):** In **ICPS**, this corresponds to pilot studies and “**shadow/supervised use**” **within the study**; any clinical decision is governed by the protocol and defined human oversight.
- **Sustained operation (TRL 8–9):** This requires a post-deployment monitoring plan, change control, and evidence of user training. These typically correspond to **clinical deployment** (post-marketing) with **PMS/PMCF** where applicable.

Each transition between TRLs must be supported by documented deliverables, and gateways can be used as objective evaluation criteria in public calls for proposals.

5.4. CORRESPONDENCE WITH EVALUATION AND FUNDING

Differentiated evaluation: The criteria and scoring are applied differently in **RPs** (scientific and data quality, methodology, generalizability) and **ICPS** (safety, interoperability, clinical impact, sustainability).

Illustrative minimum readiness: **RP** must reach **TRL 3** to be eligible for scaling up; **ICPS** should be at **TRL 6–7** for clinical pilot studies and at **TRL 8–9** for stable deployment.

This TRL adaptation is applicable to AI projects in healthcare and serves to align technical, ethical, and regulatory milestones with investment and adoption decisions. In addition, TRLs make it possible to establish **readiness thresholds for public funding, ethical and regulatory evaluation, and clinical deployment planning**. It is recommended that each TRL be linked to the **RP/ICPS evaluation forms included in the annexes**, so that there is consistency between the technological progression and the evaluation criteria applied.

Expected output of section 5: Declared and justified TRL level (RP: TRL 1–3; ICPS: TRL ≥ 4). Achieved and traceable minimum TRL-based evidence (to transition from RP to ICPS: initial external validation, subgroup bias analysis, updated DPIA, and basic evidence of cyber resilience commensurate with the risk). Readiness roadmap with TRL milestones, “significant change” criteria, and an initial cyber resilience plan for the transition to ICPS. Documented pass verdict (minutes of the relevant committee/body) and reference to the attached RP/ICPS evaluation forms.

6. REQUIREMENTS REGARDING HEALTH DATA AND GOVERNANCE

This section sets forth the **verifiable criteria** that must be met regarding the gathering, processing, protection, and use of health data in AI projects. Its objective is to ensure **quality, representativeness, regulatory compliance**, and the **sustainability of the data** throughout the entire system lifecycle, from its conception to its decommissioning.

6.1. QUALITY, REPRESENTATIVENESS, AND BIAS MITIGATION

Data quality is essential to ensuring that AI systems operate reliably and safely in their intended clinical setting. The data must suitably reflect the **target population** and the **clinical setting** in which the system will be evaluated or deployed.

- To this end, it is necessary to clearly define the **inclusion and exclusion criteria**, analyze **missing values**, check for **duplicates**, ensure **temporal consistency**, and rigorously standardize **units and clinical codes**. In addition, the use of **stratified sampling** is recommended to ensure that relevant subgroups, such as sex, age, center, or comorbidities, are suitably represented.
- **Algorithmic equity** must be addressed by measuring performance across subgroups, identifying selection and information biases, and implementing mitigation strategies (reweighting, collecting additional data, or redesigning the model). These strategies should be reviewed with clinical professionals to ensure their feasibility.

- Before moving on to regulated phases, at least one **external validation** must be conducted at a different center or in a different population, demonstrating **transferability** across settings through a comparative analysis of clinical, demographic, and operational conditions.
- **Expected deliverables:** A dictionary of variables with lineage, a report on quality and representativeness, a bias analysis with metrics by subgroup, and documentation of the decisions made to mitigate bias.

6.2. LIFECYCLE MANAGEMENT AND DATA MANAGEMENT PLAN (DMP)

The **data management plan (DMP)** is the document that defines how the data used in an AI project in healthcare will be organized, protected, versioned, and retained. Its development and implementation makes it possible to ensure **data traceability** from initial capture through to final deletion, ensuring at all times **technical quality**, **regulatory compliance**, and **operational sustainability**. Where appropriate, this plan should align with the **FAIR principles**, facilitating responsible reuse and interoperability between systems.

Key components of the DMP:

- **Inventory and source:** It must include a comprehensive catalog of data sources, identifying the responsible parties, legal basis, and specific purposes; **accredit the legitimate origin of the data** (avoiding informal practices such as directly extracting data from Excel sheets in medical records without safeguards); and be accompanied by traceability of all transformations performed (ETL/ELT) and the versioning of the datasets.
- **Metadata and standardization:** Rely on recognized clinical information models and standardized terminologies; log variable dictionaries, data cleansing rules, and semantic mappings to ensure consistency and interoperability.
- **Retention and disposal:** Define retention policies that align with the purpose and applicable regulations; establish procedures for secure disposal; and maintain records accrediting the destruction of data.
- **Roles and responsibilities:** Develop a matrix (e.g., RACI) that identifies the data owner, the data custodian, the data protection officer, the security team, and the data science team.
- **RP vs. ICPS:** In RP projects, priority is given to the **reproducibility** of results and **controlled sharing**; ICPS projects require **clinical continuity**, **robust operational traceability**, and **data sustainability** for their maintenance in real-world clinical settings.

Expected deliverables: Approved and versioned DMP; version control for datasets; change log including date, responsible party, reason for the change, and affected version; formal data handover document accrediting the data's legitimate origin; backup and disaster recovery plan with defined recovery point and recovery time objectives (RPO/RTO)

6.3. SECURITY, PRIVACY, AND COMPLIANCE (GDPR/LOPDGDD)

Data processing in AI projects in healthcare must be guided by the principles of **security, privacy, and regulatory compliance**, ensuring the protection of patients' rights and the trust of healthcare professionals. This section sets forth the **verifiable criteria** that must be met with regard to the **appropriate legal basis**, **data minimization**, **transfer management and third parties**, and the **implementation of technical and organizational measures** that ensure the confidentiality, integrity, and traceability of the system.

In addition to the GDPR/LOPDGDD, the project must align with an **Information Security Management System (ISMS)** compliant with **ISO/IEC 27001**, supported by controls from **ISO/IEC 27002**, and with **ISO/IEC 27701** for privacy management.

- **Legal basis and data minimization:** Use an **appropriate legal basis** and the corresponding special category; in the case of algorithm training, it is generally not feasible to rely on informed consent due to the required sample sizes. In Spain, the **Seventeenth Additional Provision of the LOPDGDD** permits the reuse of pseudonymized data for research purposes without the need for consent, provided that the established conditions are met. In addition, collect only the data necessary to achieve the objectives and maintain a clear separation between identifying information and clinical data.
- **Pseudonymization/anonymization:** Pseudonymization and anonymization techniques must be applied in accordance with the purpose of the processing. Anonymization, in particular, must **prevent re-identification** in a reasonable and irreversible manner, in accordance with Recital 26 of the GDPR. In addition, the residual **risk** of re-identification must be **assessed**, and the keys that would allow the pseudonymization to be reversed must be adequately protected through specific technical and organizational measures.
- **Access control and registration:** Access to data must be restricted in accordance with the principle of least privilege. This involves implementing robust authentication mechanisms, logging all access and query actions using **logging** systems, and retaining those logs with integrity guarantees. Encryption must be applied both in transit and at rest, with secure management of cryptographic keys and appropriate segmentation of execution environments to prevent unauthorized access.
- **Encryption:** Data must be protected using **robust encryption both in transit and at rest**, using algorithms and key lengths aligned with current international recommendations. **Key management** must be carried out securely, with regular rotation, storage in hardware security modules (HSMs) whenever possible, and strict access controls. In addition, **environment and network segmentation** must be ensured, preventing the mixing of sensitive data with other systems and applying **logical and physical isolation** techniques that reinforce the confidentiality and integrity of the information.
- **Transfers and third parties:** When processing involves international transfers or the participation of third parties, it is mandatory to assess the **data processors and joint controllers**, formalize an **appropriate contractual arrangement**, and establish clauses that ensure **regulatory compliance**. In addition, **specific safeguards** must be implemented to ensure data protection throughout its entire lifecycle. In the case of cloud service providers, the assessment must take into account the **physical location of the data**, compliance with the **National Security Plan (ENS)** and the **NIS2 Directive**, as well as a detailed review of the **contractual clauses regarding confidentiality, availability, and traceability**.
- **DPIA/EIPD:** A **data protection impact assessment (DPIA/EIPD)** must be conducted whenever the processing is likely to involve a **high risk to people's rights and freedoms**. This analysis must identify risks, include **appropriate mitigation measures**, and be updated in the event of any **significant change** in the processing, system architecture, or intended use. The DPIA must be **signed by the relevant data controllers** and form part of the **project technical dossier**, and it must be subject to periodic review throughout the entire lifecycle.
- The project must have a **Cyber Incident Response Plan (CIRP)** that includes **drills** at least once a year, activation criteria, and **RACI** roles (**R**esponsible (who performs the task), **A**ccountable (who makes

the final decision), Consulted (who should be consulted) and Informed (who receives information on progress)) and contact with the **reference CSIRT (Computer Security Incident Response Team)**. Include **legacy management** (patches, segmentation/isolation, trade-offs) and **incident logging/reporting** in accordance with NIS2/ENS and national regulations.

Deliverables: The deliverables to be provided in this section include the record of processing activities, the data protection impact assessment report, applicable security policies, standard operating procedures (SOPs), the results of audits or penetration tests where applicable, and minutes accrediting the training and awareness of staff involved in data processing. In addition, in connection with the ISMS, Statement of Applicability (SoA), asset inventory, ISMS risk analysis and mitigation, role-based access controls, logging/auditing, encryption in transit and at rest, backup management (RPO/RTO), and periodic restoration testing.

6.4. FEDERATED LEARNING AND MULTICENTER COLLABORATION

Federated learning is a technique that allows AI models to be trained and validated without the need to centralize data. Unlike the traditional approach, in which data is collected on a single server for processing, **federated learning transfers the model to each participating institution**. At each node, the model is trained locally using the available data, and only model updates, such as parameters or updates, are shared with an aggregation server or other nodes, depending on the defined architecture. This strategy makes it possible to **protect privacy, reduce the risk of personal data exposure, and facilitate collaboration** across entities that cannot share their data for legal, ethical, or technical reasons.

In the healthcare sector, this methodology is particularly **useful for working with sensitive data** such as clinical, genomic, or medical imaging data. Furthermore, it aligns with data protection principles, such as data minimization, purpose limitation, and proactive responsibility, by ensuring that the information remains under the control of the data controller and is not transferred outside its environment. However, **federated learning is not the same as anonymization**: model updates can leak information if appropriate technical and organizational measures are not implemented. Therefore, it must be designed in accordance with the principles of privacy by design and privacy by default, with a data protection impact assessment that covers the entire lifecycle, inter-institutional governance, and a specific threat model.

For this technique to be viable, **the architecture of the federated system must be precisely defined**. This involves describing the nodes where the data resides and where local training takes place, the aggregator that consolidates updates, and the secure, audited communication channel that connects all participants. Clear policies must be established regarding the frequency and size of updates, participation criteria, and procedures in the event of node failures. In addition, each environment must be isolated and secured through **hardening**, which consists of implementing security hardening measures such as disabling unnecessary services, enforcing strict access controls, and configuring systems securely. The architecture must ensure fault tolerance, automatic retries, and a complete, traceable log of events for auditing purposes.

Protecting privacy and ensuring the robustness of the federated system requires additional measures. These include **secure aggregation techniques** that prevent the exposure of individual contributions, **differential privacy** options to limit reconstruction from updates, and defenses against inference and poisoning attacks, such as update verification, **clipping**, and **robust aggregation**. These measures reduce the risk of data leakage and model manipulation by malicious participants, but must be balanced against their impact on performance and convergence, documenting the decisions made.

The governance of federated learning must be formalized through clear agreements that define each entity's responsibilities in determining the purposes and means of processing, in accordance with Articles 26 and 28 of the GDPR. It is essential to establish **Data Transfer Agreements (DTAs)** and Service Level Agreements (**SLAs**) that specify levels of security, availability, and traceability. In addition, a technical committee and an ethics committee should be established with defined functions, including the validation of results, rules for updating the model, and publication criteria. When federated learning supports a medical device or software as a medical device, governance must align with the requirements of the MDR/IVDR and the AI Act for high-risk systems.

Federated evaluation must be based on **harmonized metrics**, with analyses conducted by center and consolidated, and must include variability across nodes, data heterogeneity, and bias detection. It is necessary to justify the contribution weighting scheme and monitor its calibration and performance by subgroup at each site, in accordance with quality and equity criteria. In addition, it is recommended that specific tests be conducted to detect potential data leakage before consolidating versions of the global model.

Finally, the deliverables that the project must provide include an **architecture diagram, orchestration policies** (updates, node failures, security, and hardening), the minutes of the technical and ethics committee meetings detailing the decisions made, and a federated performance report by site and consolidated, including analyses of heterogeneity and biases. When applicable, the regulatory framework and the integration of the MDR/IVDR and AI Act requirements must be included in the dossier.

Scope: Enable training/validation without moving raw data, while preserving privacy and ensuring inter-institutional governance.

- **Architecture and orchestration:** Definition of nodes, aggregator, and secure communication channel; establishment of update and node failure policies; implementation of measures for **system isolation and security hardening**, including the **disabling of unnecessary services, access control**, and the **application of secure configurations** on each node.
- **Privacy and robustness:** Secure aggregation techniques; **differential privacy** options and defense against inference/poisoning attacks where applicable.
- **Governance and agreements:** Joint responsibility/data processing agreements; DTA and SLA; establishment of a **technical committee** and an **ethics committee** with **defined functions**, including the review and validation of results, the **model update rules** and the **publication criteria**.
- **Federated evaluation:** Harmonized metrics; evaluation by center and global evaluation; analysis of heterogeneity and biases across nodes.

Evidence: Architecture diagram; orchestration policies; committee minutes; federated performance reports by site and consolidated.

6.5. DATA AND MODEL DOCUMENTATION (DATASHEET AND MODEL CARD)

Structured documentation of data and models is essential to ensuring the **transparency, traceability, and responsible use** of AI systems in healthcare. This process provides insight into the origin, characteristics, and limitations of both the datasets and the models, making it easier for technical, clinical, and regulatory teams to evaluate them and ensuring that decisions are based on verifiable information.

- **DataSheet (dataset):** This must describe the dataset used, including its origin and collection period, the inclusion and exclusion criteria applied, the cleansing and labeling processes, the variables and coding used, as well as the representativeness of the dataset with respect to the target population. It must also specify any known limitations and the conditions of access and use, so that any reuse takes place within a controlled framework and in accordance with applicable regulations.
- **ModelCard (model):** This must document the trained model, specifying the clinical objective and intended use, the target population, the version and release date, the data and preprocessing processes used, and the performance metrics (including calibration). In addition, it must outline the results by relevant subgroups, the risks identified, and the safeguards implemented, as well as permitted and prohibited uses. Finally, it must include monitoring and maintenance requirements, specifying how performance will be monitored in production and the criteria for updating it.
- **Updates and change control:** It is critical to maintain consistency among data, models, and services deployed. **Synchronized versioning** between the dataset and the model must be ensured using objective criteria to identify significant changes (e.g., impact on safety, performance, or the target population). In addition, a **version lot** must be maintained to document the correspondence between the dataset, model, and service deployed, including the **date, person responsible, reason for the change, and digital fingerprint**. In addition, a **communication plan** should be established to ensure that users and evaluators receive clear and timely information about any relevant changes.

Expected deliverables: Complete, up-to-date DataSheet and ModelCard files, dated and signed by the responsible parties; version logs that document the correspondence between the dataset, model, and deployed service, including a change log and digital fingerprints (hashes) to verify integrity; a controlled repository with defined permissions and traceability of publications/commits; and a **standard operating procedure (SOP)** detailing acceptance criteria, a checklist for pre-release verification, a rollback procedure in case of incidents, and the individuals responsible for each phase of the deployment.

Expected output for Section 6: Completed verification checklist; approved data management plan; quality and representativeness report; data protection impact assessment (where applicable); federated learning artifacts (if applicable); versioned DataSheet and ModelCard files; synchronized version log for dataset–model–service (with change log and hashes); link to a controlled repository with publication traceability; and current release and deployment SOP.

7. TECHNICAL REQUIREMENTS FOR THE AI SYSTEM

Define verifiable requirements for the design, validation, explainability, monitoring, and safe operation of the AI system in healthcare, ensuring clinically relevant performance, traceability, and controlled maintenance.

7.1. MODEL DESIGN AND VALIDATION

The **model design and validation** are critical steps in demonstrating that an AI system fulfills its **intended use** and that the results are **reliable, safe, and clinically relevant** in the clinical context where it will be applied. It is not enough for the model to work in a laboratory setting; it must provide **evidence applicable to clinical practice**, be safe for patients, and show **generalizability** to different populations and healthcare organizations.

Minimum requirements:

- **Clinical and technical specification:** A precise definition of the clinical objective, the target population, and the endpoints, along with real-world usage scenarios. The assumptions and limitations of the model must be clearly stated to clarify under what conditions it is reliable and under what conditions it is not.
- **Robust experimental design:** Proper separation of training, validation, and test sets; prevention of data leakage; control of overfitting; and use of documented and reproducible protocols (e.g., cross-validation).
- **Relevant metrics:** In addition to overall accuracy, sensitivity, specificity, F1, AUC-ROC, AUPRC, balanced accuracy, and operational metrics such as response times or failure rates should be evaluated. Whenever possible, they should be accompanied by confidence intervals.
- **Calibration and clinical utility:** Evaluation of overall and subgroup calibration (Brier score, ECE, calibration intercept and slope, reliability diagrams), with recalibration where applicable. Clinical utility must be demonstrated through decision-curve analysis (net benefit) and, where applicable, with other evidence such as impact on decision-making, reduction of preventable events, or analysis of benefit-harm thresholds and trade-offs. Thresholds and acceptance criteria must be specified in advance.
- **External validation and generalization:** At least one validation study conducted at different centers or in different populations prior to any clinical use, analyzing transferability by relevant subgroups (sex, age, comorbidities, center).
- **Bias management and equity:** Measuring performance differences by subgroups, documenting potential selection or information biases, and implementing mitigation measures (reweighting, collecting new data, model adjustments).
- **Robustness and stress testing:** Evaluate and document performance under conditions involving missing or inconsistent data, noise and signal degradation, coding/semantic mapping errors, out-of-distribution (OOD) scenarios, and, when the risk warrants it, adversarial disruptions; establish acceptance thresholds, tolerances, and mitigation/rollback measures.
- **Interpretability and explainability:** Consider at the design stage what level of explainability is required for each role (clinicians, data teams, auditors), thereby avoiding additional work later on and facilitating clinical acceptance.
- **Reproducibility and traceability:** Version control for data, code, and artifacts (including random seeds, dependencies, and containers), so that any audit or re-evaluation can replicate the results.
- **Update plan and significant changes:** Definition of objective criteria for identifying changes that require revalidation (e.g., incorporation of new data that alters the target population, modifications to the model architecture, or a significant loss of calibration). These changes must be traced, communicated to users, and, if they affect safety or the intended use, subject to ethical or regulatory review.
- **Clinical impact and efficiency:** Link technical validation to intermediate or final clinical outcomes, changes in decisions, processing times, and potential benefits for patient safety. Where applicable, include a cost-effectiveness or budgetary impact assessment.

Expected deliverables: detailed validation protocol; performance report with confidence intervals; subgroup analysis and calibration; robustness and stress test results; reproducibility notebook; evaluation SOP; update plan with criteria for significant change; and, where applicable, a plan to measure clinical impact and efficiency in later phases.

7.2. EXPLAINABILITY AND TRACEABILITY

Explainability and **traceability** are fundamental pillars for ensuring that AI systems in healthcare are **understandable, auditable, and secure**. Explainability allows users to understand why the model generates a particular prediction or recommendation, while traceability ensures that every decision and every version of the system can be reconstructed in the event of an audit, incident, or regulatory review. A system that cannot explain its decisions or demonstrate how and when it was modified should not be considered suitable for use in clinical settings.

Minimum requirements:

- **Role-based explainability:** It must be tailored to the user's profile.
 - Clinical professionals need to see the most relevant factors that have influenced the outcome of a specific case, along with warnings about limitations and, where possible, confidence indicators.
 - Data science teams require technical information, such as the relative importance of variables, the stability of explanations, and the model's sensitivity to changes in the data.
 - Evaluators and auditors need to understand the model's assumptions, limitations, and risks in order to verify its suitability for the clinical and regulatory context.
- **Techniques and safeguards:** Explanations can be obtained using intrinsically interpretable models or through post-hoc methods (e.g., SHAP, LIME). In both cases, it is essential to validate the **stability of the explanations** and clearly indicate their scope of validity, thereby preventing their use out of context.
- **Logging and traceability:** Each inference must be logged with a **unique identifier**, the **version of the model and the pipeline**, the **parameters and thresholds** applied, and the **input/output** in an anonymized format or represented by digital fingerprints (hashes) that ensure integrity without exposing personal data. The **final decision** and, where applicable, the **associated human intervention** must also be recorded, in accordance with the oversight requirements of the AI Act.
- **Change log:** Chronological documentation of all modifications to the model must be maintained, including the expected impact and verification results prior to deployment. This version control system must be linked to a secure repository with defined permissions and publication traceability (commits), so that it is always clear which version was active and under what conditions.

Overall, explainability and traceability are not optional features, but essential requirements for trust, patient safety, and regulatory compliance. A system that cannot explain its decisions or demonstrate how and when it was modified should not be considered suitable for use in clinical settings.

Expected deliverables: Role-based explainability guide; documented examples of explained cases; logging policy and record retention; version record with change control and traceability in a secure repository.

7.3. MONITORING, DRIFT, AND RECALIBRATION

Once deployed in a clinical setting, the AI system must undergo **continuous oversight**. Monitoring is not optional: it is the only way to ensure that **performance** and **safety** are maintained under real-world conditions, where data, processes, and clinical practice may differ from the initial validation scenarios. Without proper monitoring, the model may degrade over time, compromising patient safety and the reliability of decisions.

Minimum requirements:

- **Monitoring plan:** It must include clinical metrics (overall performance and performance by subgroups such as gender, age, comorbidities, center) and service metrics (latency, availability, error rate, resource consumption). The rate of manual interventions (clinical overrides), which are early indicators of a lack of confidence in the system, should also be recorded. These indicators should be displayed on a dashboard updated in real time and reviewed periodically by a responsible committee.
- **Drift detection:** One of the main risks during the operational phase.
 - **Data drift:** Changes in the distribution of input variables (e.g., variations in clinical protocols or data coding).
 - **Concept drift:** Changes in the relationship between variables and clinical outcomes (e.g., new disease variants that alter correlations). Both of these issues can degrade performance without users even noticing. It is necessary to implement detection mechanisms based on statistical tests and the monitoring of key indicators, with predefined alert thresholds and clear response procedures.
- **Recalibration and maintenance:** When significant degradation is detected, the system must have procedures in place for statistical recalibration and model updating. Before releasing any changes, a **pre-release evaluation** must be performed on recent data and, whenever possible, in a **shadow mode** setting, where the updated model runs in parallel without affecting clinical practice until its reliability is verified.
- **Incident management:** Each incident must be classified by severity, documented, and resolved in accordance with Service Level Agreements (SLAs) and Service Level Objectives (SLOs). There must be a reliable rollback procedure to restore the previous version in the event of a failure, as well as a communication plan to inform users and supervisory bodies.
- **Significant changes:** Objective criteria must be defined to identify modifications that require revalidation and, where applicable, a new ethical or regulatory review. Examples: changes in the target population, in the model architecture, or in the intended use.

Expected deliverables: Real-time monitoring dashboard; periodic reports on drift and performance; records of recalibration and updates; incident log with severity classification; and standard operating procedure (SOP) for incident response, including rollback and communication criteria.

Continuous monitoring, early detection of drift, and recalibration are not one-off tasks, but ongoing processes that ensure **patient safety**, **professional confidence**, and **regulatory compliance**.

7.4. SOFTWARE SECURITY AND LIFECYCLE (MLOPS)

Ensuring software security and a controlled lifecycle is key to making AI systems in healthcare reliable, auditable, and sustainable. This objective is achieved by applying best practices in engineering, cybersecurity, and regulatory compliance throughout all phases (development, testing, deployment, and operation), assessing AI-specific threats (adversarial attacks, data poisoning, leakage, or inference), and establishing effective defenses (anomaly detection, update validation, SBOM, SAST/DAST, and orchestrated responses from the SOC). To this end, MLOps practices are employed that integrate automation, traceability, and governance into model management.

The software lifecycle shall comply with **IEC 81001-5-1** and shall be coordinated with **IEC 62304** and **ISO 14971** (requirement ↔ risk ↔ control ↔ verification traceability). An **SBOM per version** (in **CycloneDX** or **SPDX** formats), vulnerability management (**CVE** with **CVSS** criteria), and a **patch and communication policy** for updates.

Minimum requirements:

- **Secure development:** Security by design; strict version control; systematic code review; unit and integrated testing for each release; dependency pinning; automatic vulnerability scans; updated software bill of materials (SBOM).
- **Model Lifecycle Management (MLOps):** Data and model versioning (dataset and model registry) with hashes and metadata; experiment traceability; **validation before promotion**; **canary/shadow** deployment strategies with automatic rollback; model update policies with acceptance and rollback criteria.
- **Environments and Deployment:** Environment segregation (development, testing, production); immutable containers for reproducibility; infrastructure as code; CI/CD with explicit approvals, automatic controls, and an audit log for every change.
- **Secrets and data:** Secure management of credentials and keys; least privilege; robust encryption in transit and at rest; backup policies and **periodic restoration tests** with defined and evidenced **RPO/RTO**.
- **Observability:** Centralized metrics, logs, and traces; anomaly detection and automated alerts; **continuous performance monitoring, calibration, and data/model drift** with defined thresholds and actions.
- **Cybersecurity and robustness:** Host and runtime hardening; disabling unnecessary services; security updates; risk-proportionate penetration testing; where applicable, **robustness testing against data or model manipulation** (adversarial/poisoning).
- **Vulnerability management and disclosure:** A management process based on **ISO 30111** and responsible disclosure in accordance with **ISO 29147**; public channel (VDP); response SLA (**MTTD/MTTR**); criteria for notification and communication to centers/users; **coordinated vulnerability disclosure** and incident log integrated with the cyber resilience dashboard.
- **Operational documentation:** Deployment and rollback SOP; business continuity plan; **RACI matrix** of roles and responsibilities; training programs for users and administrators; **model card** for the system, including limitations and scenarios not recommended.

Expected deliverables

Versioned deployment package; **current SBOM**; results of unit, integration, and security tests (**SAST/DAST**); cybersecurity reports and penetration test reports; model **experiment and validation log**; **canary/shadow** and rollback deliverables; **dependency scan** report; **hardening** plan and deliverables; **drift/calibration monitoring** with thresholds; change review minutes in accordance with **IEC 62304**; continuity plan; operating manual; deliverables of backups and **restoration tests**; VDP log (cases and times).

Overall, software security and lifecycle management through MLOps are not isolated tasks, but rather ongoing processes that ensure the reliability, traceability, and resilience of the system in real-world clinical settings.

Expected deliverables for section 7: Validation protocol and report, explainability guide and **logging** policy, monitoring plan with thresholds and recalibration procedures, change log, **SOP for MLOps**, **SBOM**, and security/testing deliverables.

8. INTEROPERABILITY AND INTEGRATION IN THE CLINICAL SETTING

Ensure that the **AI** system integrates in a secure, efficient, and maintainable manner with the **EHR**, imaging systems (**PACS/RIS**), laboratory, pharmacy, and other clinical setting components, using open standards and robust integration patterns.

8.1. FUNCTIONAL INTEGRATION REQUIREMENTS

For an AI system to deliver real value in clinical practice, it is not enough for it to operate in isolated environments: it must be integrated in a **secure, efficient, and maintainable** manner with the electronic health record (EHR) and with other healthcare systems (PACS/RIS for medical imaging, LIS for laboratory, pharmacy, admissions, etc.). This integration must be based on **open standards** and robust patterns that ensure **interoperability, traceability, and operational sustainability**.

Minimum requirements:

- **Data sources and usage:** Clear identification of the source systems (EHR, LIS, RIS/PACS, pharmacy, admissions) and the relevant entities (episodes, problems, diagnoses, procedures, medications, lab results, reports, images, and physiological signals). This definition prevents hidden dependencies and ensures a complete and consistent data flow.
- **Publication of results:** Outputs must be generated in structured or semi-structured formats (such as JSON) and, where necessary, accompanied by reports that are readable by professionals. They must be linked to the corresponding clinical episode/encounter and explicitly include the **model version** and the **thresholds applied** in the inference, ensuring traceability and patient safety.
- **Integration patterns:** A combination of synchronous and asynchronous mechanisms.
 - On-demand queries: **REST** services.
 - Automatic updates: Messaging/events (e.g., **FHIR Subscriptions**, queues).
 - Clinical decision support: **CDS Hooks** and **SMART on FHIR** to launch applications directly from the EHR, while maintaining a seamless experience within the clinical work.
- **Latency and availability:** Definition of Service Level Objectives (**SLOs**) per workflow (e.g., inference < X s, availability $\geq Y\%$). **Degraded modes** that ensure that clinical care can continue in the event of system unavailability, thereby preventing disruptions in care, must be considered.

Expected deliverables: Logical architecture and flow diagrams; a catalog of interfaces, endpoints, and events; target timing specifications; and technical integration documentation.

8.2. STANDARDS AND SEMANTIC MODELING

Technical and semantic interoperability must ensure that data can be **exchanged, understood, and reused consistently** across centers, providers, and countries, both for **primary clinical use** and for **secondary use** in research, advanced analytics, evaluation, and federated data spaces. This requirement is essential within the framework of the **European Health Data Space (EHDS)** and its national implementation, and must cover clinical data, imaging, biobanks, and genomics, along with cataloging and governance mechanisms.

Minimum requirements:

- **Clinical messaging and persistence models:**
- **HL7 FHIR:** Structured exchange of resources such as demographics, episodes, observations, procedures, medications, and clinical documents; national profiles where available.
- **DICOM:** Intake and publication of images and metadata, including structured reports (DICOM SR); reference to series and studies from the EHR.
- **IHE (XDS, XCA, MHD):** Integration of heterogeneous systems using proven data exchange profiles.
- **openEHR / ISO 13606:** Models for structured clinical persistence and semantic traceability, with reusable archetypes and a clear separation between the clinical model and templates.

Clinical terminology and vocabulary:

- **SNOMED CT** for problems and procedures.
- **LOINC** for notes and laboratory results.
- **ICD-10-ES** for administrative classification.
- **ATC / RxNorm** for drugs, depending on the context.
- **UCUM** for units of measurement.
- **Orphanet/ORDO** for rare diseases, **ICF** for functionality and disability.
- All of these terminologies require consistent, maintained, and versioned mappings, along with automated compliance validators.

Models for secondary use and federation:

- **OMOP Common Data Model (OHDSI):** Analytical harmonization in multicenter settings, with a cohort ecosystem and reusable tools; it is recommended to document the ETL process and the FHIR ↔ OMOP bridges.
- **HealthDCAT-AP:** Cataloging and discovery of data assets, aligned with the European DCAT-AP and FAIR principles.
- **MIABIS (BBMRI-ERIC):** Standardized description of collections, samples, and processes in biobanks.

Genomics and omic data:

- **GA4GH frameworks:** Phenopackets for phenotypes, htsgget/refget for sequencing, Beacon v2 for federated discovery, DUO (Data Use Ontology) for terms of use.
- **HL7 FHIR Genomics:** Clinical integration of genetic findings.
- **VCF / HGVS:** Standardized representation of variants.
- These specifications enable interoperability in distributed environments and align clinical genomics with clinical practice.

Mapping and version governance: Maintain documented and versioned equivalence tables, including criteria for compatibility and traceability; record which version of the terminology or profile was in effect for each exchange or analysis.

Expected deliverables: A guide to implemented FHIR/DICOM profiles; documented terminology dictionaries and mappings; applied data models (openEHR, OMOP, MIABIS, *FHIR Genomics*); conformity validations; and documentation of compatibility with the EHDS Regulation, TEHDAS, and European frameworks (*Beyond 1 Million Genomes*, GDI). All of this must be accessible in a **controlled repository**, with version history and commits.

8.3. SECURITY, IDENTITY, AND ACCESS CONTROL

Identity protection and **secure access management** are essential to ensuring **confidentiality, integrity, and traceability** in the use of AI systems in healthcare. These mechanisms not only prevent unauthorized access, but also help demonstrate regulatory compliance and reduce clinical and legal risks.

Minimum requirements:

- **Authentication and SSO:** Integration with the corporate identity management infrastructure, so that users authenticate themselves using robust mechanisms aligned with the institution's policies. The use of standard protocols such as **OpenID Connect (OIDC)** and **OAuth2**, which enable federated authentication and granular permission control, is recommended. Credentials must be managed using **access tokens** with the minimum necessary scope, subject to **controlled rotation and expiration** policies.
- **Authorization:** Apply principles of segregation of duties using models such as **Role-Based Access Control (RBAC)** or **Attribute-Based Access Control (ABAC)**, assigning permissions based on role (clinician, researcher, technician) or contextual attributes. In exceptional circumstances, access may be granted through “**break-glass**” mechanisms, provided that the action is documented and justified.
- **Encryption:** All information must be protected in **transit (TLS)** and at **rest** using robust algorithms. Password management must be carried out in secure environments, with regular rotation and strict access controls. **Network segmentation** and **microsegmentation of critical services** enhance security, reduce the attack surface, and limit the impact of incidents.
- **Traceability and auditing:** Every access, query, or inference must be recorded in a **logging** system that tracks who performed the action, when, for which patient or medical record, and using which version of the model. Logs must be kept intact and confidential, protected against tampering, and retained in accordance with regulations and internal policies, ensuring their availability for audits, regulatory reviews, or incident investigations.

Segmentation, identities, and security telemetry

The deployment will implement **network segmentation by zones/roles**, **strong authentication** and **federated identity** where applicable, along with **centralized telemetry** (logs, metrics, and traces) and **evidence retention**. The configuration and operation must be consistent with the **SGSI (ISO/IEC 27001)** adopted for the project, and must be reported periodically to the **cyber resilience scorecard (10.7)**.

Expected deliverables: Role-based permissions matrix; identity management policy

(including MFA where applicable); deliverables of encryption in transit and at rest; segmentation/microsegmentation configuration; examples of audit logs with model version and reference to patient/episode; documentation of **log retention and protection policies**; and traceability of access reviews and **break-glass** events.

Taken together, **security, identity, and access control** are not merely technical requirements, but essential prerequisites for **trust**, the **protection of patients' rights** and the **sustainability of AI projects in clinical settings**.

8.4. CLINICAL WORKFLOW, USABILITY, AND PATIENT SAFETY

The integration of an AI system into clinical practice should not disrupt the clinical workflow or increase the workload of professionals. On the contrary, it should be integrated **seamlessly into existing processes**, adding value without creating additional risks. The design must ensure that AI is used at the **appropriate stage of the clinical journey**, supporting clinical decision-making without disrupting team dynamics.

Minimum requirements:

- **Workflow analysis:** Creation of BPMN diagrams or use of other equivalent tools to identify the AI's entry and exit points, the responsibilities of each stakeholder, and the associated times. This makes it possible to anticipate bottlenecks, define responsibilities, and ensure that the system is used at the appropriate clinical stage.
- **Presentation of results:** Results should be presented in a clear, understandable, and contextualized manner, including messages with correct units, warnings about limitations, and indicators of uncertainty where applicable. They must be accompanied by **links to scientific evidence or clinical guidelines**. The system must allow **clinicians to override settings**, with a record and justification, ensuring **effective human oversight** as required by regulations.
- **Preventing alert fatigue:** Prioritizing relevant notifications and implementing safe muting mechanisms. The trigger thresholds must be **configurable under governance**, avoiding both alert overload and the omission of critical alerts.
- **Usability and human factors:** The design must be **consistent with the EHR**, accessible, and validated through testing with representative users prior to deployment. These tests should assess comprehension, ease of use, impact on cognitive load, and confidence in the recommendations.
- **Patient safety:** Identification of potential hazards associated with the use of the system and establishment of preventive controls, such as visible warnings, double-checking of critical decisions, and **manual fallback** mechanisms in the event of a failure. There must be a clear procedure for **incident reporting and management** to act rapidly in the case of adverse events.

Expected deliverables: Prototypes and screenshots integrated into the EHR, a usability testing report, a documented risk analysis and mitigation plan, along with incident logs and corrective actions.

Overall, the integration of AI into clinical workflows should **improve the quality of care without compromising safety or efficiency**. A system that does not adapt to the actual context or that introduces additional risks should not be considered suitable for use in clinical settings.

8.5. RUNTIME AND DEPLOYMENT ENVIRONMENT

Defining **where the system runs** and **how it is kept operational** is essential to ensuring **security, efficiency, and service continuity**. The runtime environment must minimize risks, optimize performance, and enable controlled management of changes and updates, ensuring that the system meets clinical and regulatory requirements.

Minimum requirements:

- **Topology:** Specify whether the system will run **on-premises**, in the **cloud**, or in a **hybrid model**, as this decision affects latency, security, and scalability. **Data paths** must be documented with clear diagrams, identifying security zones (DMZ, VPC, VPN) that protect information flows. When dealing with medical images or real-time signals, proximity to **PACS** and **EHR** is key to reducing latency. When necessary, **edge computing** can be used, running the model close to the source of the data to avoid large data transfers and reduce response times.
- **Containerization and CI/CD:** Artifacts must be **immutable**, digitally signed, and accompanied by an updated **SBOM (Software Bill of Materials)**. **Continuous integration and deployment (CI/CD)** processes must include automated testing, security scanning, explicit approvals, and secure deployments (**blue/green** or **canary releases**) that allow new versions to be validated without interrupting service. There must be a proven **rollback** procedure in place to restore the previous version in the event of a failure.
- **Observability:** The system must include **centralized metrics, logs, and traces**, with correlation identifiers to track each transaction. Monitoring dashboards should display queue status, response times, and errors, and trigger **automatic alerts** linked to the **SLOs (Service Level Objectives)** defined for each workflow.
- **Capability and performance:** Anticipate high-demand scenarios through **proper resource sizing**, queues with **backpressure** mechanisms, **autoscaling** for CPU/GPU, and **load and resilience testing** that includes **p95/p99** metrics, which are essential in clinical settings to ensure response times even under extreme conditions. In addition, **failover** tests should be conducted to verify service continuity in the event of a failure.

Expected deliverables: Deployment diagram with routes and security zones; documented CI/CD pipelines; results of load, resilience, and fault recovery tests; and an updated **operational SOP** with procedures for deployment, rollback, and business continuity.

Overall, a **well-designed runtime environment** ensures the system's **stability, security, and scalability**, facilitates its maintenance, and reinforces its **compliance with regulatory and quality requirements** in healthcare.

8.6. INTEROPERABILITY TESTING AND VERIFICATION IN A CLINICAL SETTING

Before an AI system is used with patients, it is essential to verify that the **integration works exactly as designed**. These tests are not a mere formality, but rather a **guarantee of safety and reliability**, and they must be repeated periodically during operation to ensure that changes or updates do not introduce risks.

Minimum requirements:

- **Synthetic and test data:** Use of realistic test sets for unit and integration testing. When using real data, it must be anonymized to protect privacy. These initial tests allow the detection of errors in the logic without compromising sensitive information.
- **End-to-end testing:** Validation of representative clinical scenarios, including both typical cases and edge cases, as well as deliberate errors. The goal is to verify that the system responds properly under all anticipated conditions and that any failures are handled safely, without interrupting clinical care.
- **Shadow mode environment:** Running the system in parallel with the actual clinical workflow, without impacting medical decisions, prior to activation. This allows makes it possible to evaluate the performance and stability under real-world conditions, identify potential issues, and fine-tune the settings without compromising patient safety.
- **Version-based validation:** Each new version of the model or service must undergo a formal validation process, including **clear acceptance criteria**, verification of **functional invariants**, and documentation of results. This control prevents minor changes from leading to clinically significant errors.

Expected deliverables: Documented test plan and results, checklist for version approval, and **go/no-go** decision records supporting the authorization of deployment.

Taken together, interoperability and validation tests establish a **framework of trust** for the system's evolution: every step toward clinical use must be supported by **documented evidence and formal reviews**, ensuring safe and sustainable deployment in clinical settings.

8.7. MULTICENTER OPERATION AND PORTABILITY

For an AI system to scale beyond the center where it was developed, it is necessary to ensure that its deployment in other hospitals is **secure, efficient, and traceable**. Portability is not about copying a model, but rather about ensuring that **interfaces, clinical workflows, and technical dependencies** adapt to heterogeneous environments without compromising interoperability or patient safety.

Minimum requirements:

- **Interoperability contracts:** Documents that specify how systems communicate (interfaces, data formats, standards, and semantic rules). They must be **stable and versioned**, with **backward compatibility** to prevent an update from breaking integrations in hospitals that have not yet migrated.
- **Model portability:** Packaged in standard formats (**ONNX, inference service containers**) that allow execution in different environments without modifying the code. Complete documentation of **dependencies** (libraries, versions, frameworks) and an updated **Software Bill of Materials (SBOM)** for security audits, aligned with regulations such as **NIS2** and the **ENS** must be included.
- **Local configurability:** Mechanisms that allow for the adjustment of parameters specific to each center (terminology, clinical thresholds, clinical workflows) **without the need to retrain** the model, whenever possible. This reduces implementation costs and ensures consistency with the intended use.
- **Site Catalog:** A record of deployments at each hospital, documenting implemented profiles, terminology mappings, applied exceptions, version history, and local validation results. This catalog facilitates audits and the reconstruction of deployment history.

- **Distributed validation:** In scenarios involving **federated learning** or multicenter validation, it is recommended to conduct node-specific tests, analyzing data heterogeneity and performance by subgroup, to demonstrate that the system maintains safety and efficacy across diverse environments.

Expected deliverables: Portable model package, multicenter deployment guide, site catalog with validation records and documented differences, updated SBOM, and local approval documents.

Overall, **multicenter operations and portability** are not secondary tasks, but rather necessary conditions for the **sustainability and scalability** of AI systems in healthcare. A model that cannot be transferred in a controlled and safe manner is unlikely to have a real impact on the **National Health System**.

8.8. GOVERNANCE OF INTEGRATION AND AGREEMENTS

The integration of an AI system into the clinical ecosystem does not end with its initial deployment. To ensure that it is **sustainable over time**, it is necessary to establish a **governance framework** that ensures the **continuity of service**, the **orderly management of changes**, and **coordination among all parties involved**. Without this framework, any technical update, organizational change, or incident could pose a risk to **patient safety** and **interoperability**.

Minimum requirements:

- **Technical Integration Committee:** The body responsible for overseeing the system's operation, prioritizing improvements, and resolving issues. It must include clinical, technical, and security profiles, meet at set intervals, and monitor the **SLAs (Service Level Agreements)** and **SLOs (Service Level Objectives)** regarding availability, response times, and service quality.
- **Contracts and annexes:** Formalization of agreements that define the responsibilities of each party. They must include **DTAs (Data Transfer Agreements)**, **joint controller or data processor** agreements, and specific annexes regarding **security, availability, and continuity plans**. This contractual framework ensures regulatory compliance, traceability, and institutional protection.
- **Management of changes:** Every modification (technical, functional, or organizational) must be planned during **maintenance windows** that minimize the clinical impact. It is necessary to notify users of any changes, provide training when they affect clinical practice, and update technical and clinical documentation.

Expected deliverables: Minutes of the technical integration committee meetings, signed agreements, approved continuity plan, records of communicated changes, and updated documentation following each modification.

Overall, the **governance of integration** is not merely an administrative formality, but rather an **essential mechanism for maintaining security, interoperability, and trust** in the system throughout its entire lifecycle. A project that lacks this framework runs the risk of becoming unsustainable and jeopardizing its adoption.

Expected deliverables for Section 8: Catalog of standard interfaces and profiles, terminology mappings, security and audit policies, prototypes integrated into EHR, test plan and results, deployment diagram and operational SOPs, as well as signed agreements and an active, traceable integration governance framework.

9. ASSESSMENT AND MATURITY: CRITERIA AND GRADING

The **evaluation of AI projects in healthcare** must be **objective, verifiable, and commensurate with the level of technological readiness**. For this reason, this guide establishes different criteria for two types:

- **RP (research and development projects, TRL 1–3).**
- **ICPS (clinical investigation with a medical device, regulated studies, TRL ≥4).**

The evaluation combines **five key dimensions**:

1. **Scientific and technical quality**, which ensures methodological soundness and clinical relevance.
2. **Ethical and regulatory compliance**, essential for the protection of patients' rights and safety.
3. **Interoperability and integration**, which determines technical feasibility in real-world clinical settings.
4. **Secure operations and cyber resilience (cybersecurity)**, which includes monitoring, risk management and traceability, threat protection, vulnerability management, access control, hardening, and secure configuration, as well as business continuity and incident recovery.
5. **Clinical and economic value**, which guides sustainability and adoption within the National Health System.

The **total score** is **36 points for RP** and **48 points for ICPS**, with **elimination criteria** that prevent approval when essential elements are missing (e.g., legal basis in accordance with the GDPR/LOPDGDD, mitigation of risks to patient safety, or, in the case of ICPS, absence of basic cybersecurity/cyber resilience controls and external validation prior to clinical use). Only **documented deliverables** are considered; unsubstantiated claims cannot be evaluated.

The **“Feasible and fundable”** category is reserved for projects that, in addition to achieving the highest relative score, demonstrate a realistic alignment with available resources. The remaining projects that exceed the minimum thresholds may be considered **“Feasible”**, maintaining a significant scientific and clinical value, although they will not be given funding priority.

Illustrative thresholds:

- **Feasible:** ≥ 24 points for RP and ≥ 28 points for ICPS.
- **Feasible and fundable:** ≥ 30 points for RP and ≥ 40 points for ICPS.

These thresholds are illustrative and may be **adjusted depending on the call for proposals and the availability of resources**.

9.1. EVALUATION METHODOLOGY (COMMON RP/ICPS)

Scale per item (0–3): 0 = no evidence; 1 = insufficient or speculative; 2 = adequate, with improvements pending; 3 = robust and verifiable.

Required deliverables: Documents, protocols, results, tables, and appendices (unsubstantiated claims will not be scored). For cyber resilience (cybersecurity), the following will be evaluated, as appropriate: policies and controls, event logging and auditing, vulnerability management, resistance testing, and incident response and recovery plans.

Calculation by blocks: Mean of items in the block × weight of the block (points).

Knock-out criteria:

- Lack of a **legal basis** and measures under the **GDPR/LOPDGDD** where applicable.
- Unmitigated risks to **patient safety**.
- In **ICPS**: lack of **external validation** prior to clinical use or absence of a **monitoring plan**.
- In projects that qualify as **MD**: lack of **risk management** and minimal regulatory documentation.
- **Insufficient cyber resilience in relation to risk/TRL** (e.g., absence of basic controls, lack of logging and auditing, absence of an incident response plan or vulnerability management).

9.2. SCORING FOR RP (TRL 1–3) – 36 POINTS

Bloque	Puntos	Contenido evaluable (ejemplos)
1. Diseño científico y relevancia clínica	8	Problema y endpoints clínicos; población diana; justificación y estado del arte; hipótesis y beneficios esperados.
2. Datos: calidad y representatividad	10	Procedencia y linaje; diccionario y metadatos; limpieza; missingness ; representatividad; plan de sesgos y subgrupos; controles de acceso a datasets y segregación de entornos (desarrollo/prueba) proporcionales al riesgo.
3. Metodología y rendimiento	8	Particiones y control de fuga; métricas (incl. calibración); validación interna; reproducibilidad (versionado/semillas); robustez y pruebas de estrés (datos faltantes, OOD, degradación de señal y, si procede, perturbaciones adversarias).
4. Ética y protección de datos	4	Base jurídica; DPIA/EIPD (si aplica); minimización; ciberresiliencia proporcional al riesgo/TRL: control de accesos y privilegios mínimos, registro y auditoría, gestión básica de vulnerabilidades, cifrado en tránsito/en reposo cuando proceda.
5. Plan de madurez y transferencia	4	Hoja de ruta a TRL 4–6 ; validación externa planificada; criterios de “cambio significativo”; plan inicial de ciberresiliencia para la transición a ICPS (hardening, pruebas de resistencia/penetración programadas y continuidad/recuperación)
6. Innovación y alineación estratégica	2	Novedad, transferencia potencial, encaje con estrategias del SNS/ISCIII .

Illustrative thresholds (RP, 36 points):

- **Not feasible:** < 24 points.
- **Feasible:** 24–29 points.
- **Feasible and fundable:** ≥ 30 points.

RP Comments: To proceed to ICPS, at least initial **external validation**, subgroup-based bias analysis, and an updated **DPIA** is required. In addition, **cyber resilience** deliverables (policies and controls, logging/auditing, and an incident response plan) commensurate with the risk.

9.3. SCORING FOR ICPS (TRL ≥4) – 48 POINTS

Bloque	Puntos	Contenido evaluable (ejemplos)
1. Valor clínico y seguridad del paciente en investigación	10	Relevancia clínica y <i>endpoints</i> del estudio; salvaguardas del protocolo; procedimientos de <i>override</i> ; gestión de incidentes y reporte; medidas de ciberresiliencia orientadas a seguridad del paciente (detección, contención y recuperación ante incidentes; registro y auditoría)
2. Regulación y conformidad (MDR/IVDR + AI Act + CEIm/AEMPS)	10	Cualificación y clase (si PS); GSPR y gestión de riesgos; plan de evaluación clínica/desempeño; autorizaciones CEIm y, cuando proceda, AEMPS; encaje AI Act (alto riesgo); controles de ciberseguridad conforme a MDR Anexo I (seguridad/performancia), gestión de vulnerabilidades y referencias aplicables (p. ej., IEC 62304/81001-5-1, ISO/IEC 27001) cuando proceda
3. Interoperabilidad e integración para el estudio	8	Integración con HCE/FHIR/DICOM necesaria para el protocolo; trazabilidad por sujeto/episodio; pruebas <i>end-to-end</i> en entorno de investigación; usabilidad para investigadores/ <i>clinicians</i> ; seguridad en la integración (autenticación/autorización, cifrado en tránsito, segregación de entornos y hardening), con pruebas end-to-end que incluyan casos de seguridad.
4. Monitorización, MLOps y control de cambios	8	Métricas del estudio y del servicio; <i>drift</i> y recalibración (si aplica durante el estudio); <i>changelog</i> y bloqueo de versiones para protocolo; CI/CD controlado; observabilidad y telemetría de seguridad (logging/auditoría centralizada), gestión de vulnerabilidades y dependencias (incl. SBOM), y checks de seguridad en el pipeline CI/CD.
5. Datos y equidad	6	Calidad/representatividad del <i>dataset</i> del estudio; análisis por subgrupos; mitigación de sesgos; <i>DataSheet/ModelCard</i> ; controles de acceso y privilegios mínimos, cifrado en reposo/cuando proceda y segregación de datos sensibles.
6. Sostenibilidad y escalabilidad	6	Recursos del estudio (soporte, seguridad, formación); plan de transición a posestudio (PMS/PMCF o despliegue asistencial); gobernanza multicéntrica si procede; plan de ciberresiliencia y continuidad (backup/restore, ejercicio de respuesta a incidentes, responsabilidades y escalado)

Illustrative thresholds (ICPS, 48 points):

- **Not feasible:** < 28 points.
- **Feasible:** 28–39 points.
- **Feasible and fundable:** ≥ 40 points.

The thresholds may be adjusted based on the call for proposals and the availability of resources.

9.4. EVALUATION PROCEDURE AND MINUTES

Project evaluations must be conducted using **consistent criteria, full traceability, and multidisciplinary participation**, ensuring that decisions are **objective, reproducible, and transparent**.

Minimum requirements:

Panel and roles: The evaluation committee must include, at a minimum, a **clinician from the field**, a **data/AI specialist**, an **interoperability expert**, and a **regulatory or ethics expert**. It is recommended to add a **cybersecurity/cyber resilience profile**. All members must sign a **declaration of conflicts of interest** to ensure impartiality.

- **Execution:** The process is based on a **document review** and, where applicable, a **brief presentation** by the applicant team. Each evaluator scores the work independently using the scale defined in the guide; the results are then discussed in a **joint session** to reach a consensus. The review must explicitly cover aspects of cyber resilience (controls and policies, vulnerability management, logging/auditing, and incident response/recovery plans), with findings and risks classified by criticality.
- **Checklists and traceability:** **Checklists** (annexes) are used, and the evidence supporting each score is documented. The records must include the **revised versions** and the **spreadsheet detailing the scores**, ensuring that any audit can reconstruct the process. A record of cybersecurity findings and their traceability (risk, responsible party, target date, and status), as well as of stress tests, where applicable, will be maintained.
- **Conditions:** The panel may propose **funding conditions** related to deadlines and responsible parties, such as completing an external validation, resolving safety findings, or providing a multicenter agreement. With regard to cyber resilience, measures such as system hardening, correction of critical vulnerabilities, incident response exercises, or evidence of penetration/stress tests commensurate with the risk may be required. These conditions must be documented in the minutes.
- **Tiebreaker:** In the event of a tie, priority is given to projects with a **higher TRL**, **better documented clinical impact**, **better cost-impact ratio**, and **lower regulatory risk**, thereby maximizing the value and viability of public investment. All other factors being equal, priority will be given to lower operational/cybersecurity risk and greater control readiness.

Expected deliverables: Signed minutes of the evaluation committee, completed checklists, a final score sheet broken down by sections, and a record of funding conditions (if applicable), a cyber resilience review report with findings and a remediation plan, and audit records/evaluation logs.

Overall, this procedure not only defines how to score applications but also establishes a **governance framework** that strengthens **transparency, accountability, and trust** in evaluation and funding decisions, **including cyber resilience**.

9.5. ASSESSMENT RESULTS AND DOCUMENTATION

Once the evaluation process is complete, it is essential to produce **clear, comprehensive, and traceable documentation** that reflects the decisions made, the conditions established, and the elements necessary for follow-up. This documentation not only serves as an internal record, but also provides **transparency and auditability** for future reviews.

Minimum requirements:

- **Summarized report:** This must include the **score obtained for each section**, the **threshold reached** (not viable / viable / viable and fundable) and an analysis of the **main strengths and weaknesses** of the project. It will explicitly include the **cyber resilience** status (controls implemented, findings, and outstanding risks) where applicable.
- **Action Plan:** When the project is on the verge of viability or faces critical issues, a plan must be developed that defines **specific milestones**, **assigned personnel**, and **defined deadlines** to increase the project's readiness and facilitate its progress toward subsequent phases. With regard to cyber resilience, the plan will include prioritized remediation measures (e.g., hardening, vulnerability management, logging/auditing, resistance testing/recovery) with target dates and acceptance criteria.
- **Follow-up record:** An up-to-date record must be maintained for **periodic reassessments** to verify the completion of pending actions and evaluate the impact of significant changes. The log must also track cyber resilience actions and their status (open/in progress/closed), retaining verification evidence. This process ensures that the imposed conditions are met before new phases or final funding are approved.

Expected deliverables: Signed assessment report, action plan (where applicable), updated follow-up and reassessment log, cyber resilience annex with findings, remediation plan, and evidence of closure, where applicable.

Taken together, these results and documents are essential for demonstrating **traceability, equity, and transparency** in decision-making, thereby strengthening confidence in the evaluation process and in the prioritization of public resources, including cyber resilience

Expected output of section 9: Signed minutes of the evaluation committee, including the decision and comments (RP or ICPS). Block-based scoring sheet (RP: 36; ICPS: 48) with the elimination criteria applied and an explanation of the scores. Funding conditions and/or requirements for rectification prior to the advancement (deadlines, responsible parties, and required deliverables). Monitoring log: Action plan, milestones, and traceability, with reference to the **RP/ICPS evaluation forms** and the attached deliverables.

10. PRACTICAL IMPLEMENTATION AND MANAGEMENT OF THE CHANGE

Ensure an orderly, secure, and measurable implementation of the **AI** system in the clinical setting, minimizing clinical and organizational risks and maximizing effective adoption.

10.1. GOVERNANCE AND LEADERSHIP OF THE CHANGE

The implementation of an AI system in the clinical setting cannot be treated as a mere technical deployment. It requires a **clear governance structure** that defines who makes decisions, how risks are managed, and what mechanisms ensure coordination among the various stakeholders. Without this framework, implementation can lead to uncertainty, resistance, and risks to **patient safety**.

Minimum requirements:

- **Sponsorship and roles:** Secure **clinical and administrative sponsorship** to support the project and align it with the center's strategic objectives. Key roles must be designated: a **product owner** as the functional lead, a **patient safety officer**, the **Data Protection Officer (DPO)**, **IT and interoperability** leads, and **quality and regulatory** roles. This structure ensures that decisions are balanced across clinical, technical, and regulatory criteria.

- **Implementation committee:** A supervisory body that reviews milestones, risks, and dependencies, and makes critical decisions on whether to proceed or halt the project (**go/no-go**). It must meet at regular intervals and maintain **documented minutes** of agreements and actions.
- **RACI Matrix:** A formalization of responsibilities for each task, specifying who is **Responsible**, who is **Accountable**, who should be **Consulted**, and who should be **Informed**. This tool is essential for critical areas such as training, testing, support, communication, and monitoring.
- Define incident escalation: **Regional CSIRT (if one exists)** → **INCIBE-CERT** (private sector/non-state-administered healthcare) or **CCN-CERT** (public sector/state-administered healthcare) → national **single point of contact** → **ENISA/CSIRT Network** and **EU Reserve** where applicable.

Security and corporate liaison:

The project will appoint a **project security manager** with operational authority and serving as a functional liaison to the corporate **Chief Information Security Officer (CISO)**. Their responsibilities include: ensuring compliance with applicable policies and frameworks, coordinating risk assessments and remediation plans, validating technical/organizational controls prior to each milestone, overseeing incident management and reporting to the reference **CSIRTs** when appropriate, and maintaining the updated **RACI** (owners, responsible parties, consulted parties, and informed parties). The escalation chain and substitution in case of absence will be documented.

Expected deliverables: Minutes of the implementation committee meetings, updated **RACI matrix**, risk log with assigned responsible parties, and a **communication plan** detailing how the various stakeholders will be informed.

Overall, **governance and leadership of the change** are not mere formalities, but rather key factors for an implementation that is **secure, orderly, and accepted by professionals**. A project without a clear structure runs the risk of failing, even if the technology is sound.

10.2. ANALYSIS OF PREPARATION AND ORGANIZATIONAL IMPACT

Before implementing an AI system in a clinical setting, it is essential to understand how it will affect **processes, workloads, and professional roles**. This analysis makes it possible to anticipate risks, plan mitigation measures, and ensure that the technology is integrated in an **orderly, efficient, and secure** manner.

Minimum requirements:

- **Process mapping (BPMN):** creating diagrams that identify the AI's **entry and exit points, responsibility hand-offs**, and the **associated durations** for each task. This makes it possible to identify bottlenecks and redesign workflows to ensure clinical continuity.
- **Clinical workload and times:** Estimation of **variations in task duration** resulting from the use of the system. A model that increases times without adding value may be met with resistance; therefore, strategies that maintain efficiency must be developed.
- **Impact on roles and resistance:** An analysis of how the introduction of AI affects the responsibilities of each professional profile. It is essential to identify **key adopters**, identify **cultural or organizational barriers**, and design supporting measures (training, awareness, and participation in decision-making) that promote acceptance.

- **Clinical policies:** Definition of clear rules regarding **responsibilities, overrides with justification** and procedures for **documenting decisions in the EHR**. These policies are necessary to ensure **effective human oversight** and to comply with regulatory traceability requirements.

Expected deliverables: An updated clinical process diagram, a report on the impact on times and workloads, and a mitigation plan that includes organizational, training, and communication measures to facilitate the safe adoption of the system.

Overall, the analysis of organizational readiness and impact is a key tool for **minimizing resistance, ensuring efficiency, and building confidence** among professionals in the implementation of AI systems in healthcare.

10.3. TRAINING, CERTIFICATION, AND USER SUPPORT

The implementation of an AI system in the clinical setting will only be effective if professionals understand how it **works**, its **limitations**, and the **safeguards** that accompany it. Training is not an optional extra, but an essential requirement for ensuring **patient safety** and **confidence in the tool**.

Minimum requirements:

- **Profile-based plan: Mandatory, certified, and periodic training** in cybersecurity is established for all clinical and technical staff involved in the project, with a record of completion. The plan will include, at a minimum: digital hygiene, secure credential management, **phishing/deepfakes and their verification**, data protection in clinical and research settings, **incident management and reporting** (including drills), and best practices in AI/MLOps (SBOM, version control, data and model management). **Annual refresher sessions** and ad-hoc training will be provided following significant changes or incidents, with a **final evaluation** and **traceability** of results.
- **Formats:** A combination of hands-on workshops, simulations based on real-world scenarios, contextual help, and quick-reference guides. This blended approach makes both the initial learning curve and consultation during clinical practice easier.
- **Certification and refresher training:** Formal record of **completion of training**, with **periodic refresher sessions** to keep skills up to date, especially when changes are made to the system.
- **Support:** Establishment of an operational channel for **incidents and questions**, with defined response times, supplemented by an **FAQ catalog** that addresses common inquiries and reduces uncertainty regarding clinical use.

Expected deliverables: Approved training plan, materials used, attendance records, assessment results, individual certifications, and documentation of the active support channel.

Overall, **training, certification, and user support** are critical components for ensuring the **secure, effective, and sustainable** adoption of AI systems in healthcare.

10.4. PILOT PROJECTS AND PHASED DEPLOYMENT

Before rolling out an AI system across an entire clinical setting, it is essential to **mitigate risks through incremental validation**. Pilot projects allow us to test the system's performance under real-world conditions, identify issues early on, and refine processes before a full-scale deployment.

Minimum requirements:

- **Pilot unit selection:** Selection based on objective criteria such as the **relevance of the use case**, the **volume of activity**, the **commitment of the clinical team**, and the ability to ensure **traceability of data and results**. A well-chosen unit makes it easier to gather solid evidence and identify barriers early on.
- **Shadow mode (TRL 6):** Initial implementation in parallel with clinical workflow, without influencing medical decisions. This approach allows for the evaluation of **performance, security, and usability metrics** without compromising patient care, while validating technical integration and user experience.
- **Progress criteria:** Definition of minimum thresholds for **performance, security, and professional acceptance**. Progression to subsequent phases must be documented through a formal **go/no-go** decision record, ensuring traceability and transparency.
- **Controlled scale up:** Phased deployment by **service, shift, or center**, accompanied by **structured feedback** and a **mitigation plan** that resolves issues before continuing with the expansion.

Expected deliverables: Approved pilot protocol, results report, decision record on advancement, and scale up plan with a timeline, responsible parties, and success criteria.

Taken together, **pilot projects and phased deployments** are a key mechanism for ensuring a **secure, efficient, and widely accepted implementation** by professionals prior to the full scale up of the AI system in healthcare.

10.5. TECHNICAL CHANGE AND VERSION MANAGEMENT

Once the AI system is up and running, **changes** are inevitable: model updates, threshold adjustments, functional improvements, or bug fixes. However, any uncontrolled modification may pose risks to **patient safety, interoperability, or traceability**. Therefore, the management of changes must be a **structured, documented, and auditable process**.

Minimum requirements:

- **Versioning visible in the EHR:** Each inference must explicitly record the **model version** and the **thresholds applied**, ensuring traceability for audits, regulatory reviews, and incident analysis.
- **Significant change:** define objective criteria to determine which modifications require revalidation (e.g., incorporation of new data, alteration of critical parameters, changes to the model architecture). In these cases, a **formal revalidation process** must be carried out prior to deployment, within a planned **maintenance window**.
- **Safe rollback:** Have a **proven rollback procedure** in place that allows a quick and controlled restoration of the previous version if the update causes errors or unexpected results. This rollback must be accompanied by **notification to users** and a record of the incident.
- **Sandbox and approval:** All updates must be tested in advance in a **sandbox/approval environment**, using an **acceptance checklist** to verify functionality, security, and compatibility with clinical workflows. Only after passing these tests is deployment to production authorized.

Expected deliverables: A **change log** documenting each modification; version verification reports; and complete records of **deployment and rollback**.

Overall, the **structured management of technical changes and versions** ensures that the system evolves in a **secure, transparent, and compliant manner**, thereby maintaining the trust of both professionals and patients.

10.6. OPERATIONAL PATIENT SAFETY AND ETHICS

The implementation of an AI system in clinical settings must be guided by a fundamental principle: **preventing harm and ensuring responsible use**. Technology does not replace clinical responsibility; rather, it complements it. Therefore, it is necessary to establish controls that ensure **patient safety** and **compliance with ethical principles**.

Minimum requirements:

- **Hazard analysis and controls:** Identification of potential risks and definition of preventive measures, including clear warnings regarding limitations, definition of **usage limits**, and **double-checking** mechanisms for critical decisions.
- **Incident management:** Establishing a procedure to **classify events by severity**, investigate their **root cause**, implement **corrective actions**, and report incidents to the competent authorities and, where applicable, to affected users, in accordance with applicable regulations.
- **Effective human oversight:** The system must allow the professional to **override** any recommendation, with traceability and documented justification. This control ensures that the **final decision always rests with the clinical team**.
- **Transparency:** Professionals must receive clear information about the **operation, limitations, and criteria** of the system. Where applicable, patients should also be informed about the use of AI in their care, in accordance with the principles of **autonomy and informed consent**.

Expected deliverables: An approved security plan; an up-to-date incident log with analysis and resolution; and **periodic audits** to verify the implementation of controls and the effectiveness of corrective measures.

Taken together, operational patient safety and ethics form the **foundation of trust** necessary for the sustainable adoption of AI systems in healthcare.

10.7. METRICS, RESULTS, AND SCORECARD

Implementing an AI system doesn't end with its deployment. To ensure its **value, security, and sustainability**, it is necessary to continuously measure its **adoption**, its **clinical performance**, and its **organizational impact**. This monitoring makes it possible to identify deviations, correct problems, and demonstrate the **return on investment**.

Minimum requirements:

- **Adoption and use:** Measure system coverage, frequency of use, the rate and reasons for **overrides**, as well as **user satisfaction**. These indicators reflect the system's acceptance and its integration into clinical practice.
- **Quality and clinical performance:** Monitor operational and clinical metrics, including **model calibration**, with disaggregated analysis by subgroups. This ensures that the system remains reliable in a variety of contexts.

- **Equity:** Assess differences in outcomes and use by **sex, age, center, comorbidities** or other relevant subgroups. Identifying and addressing inequalities is essential to complying with ethical and regulatory principles.
- **Efficiency:** Measure processing times, **avoided additional work**, and improvements in **productivity**, key data for justifying the investment and planning for scalability.

Expected deliverables: An updated scorecard with key indicators; periodic reports (e.g., monthly); and an **action plan derived from metrics**, which allows for correcting deviations and improving system performance.

Overall, the use of indicators and scorecards enhances **transparency, continuous improvement**, and **trust** in AI systems in healthcare, ensuring that they provide tangible and equitable value to the healthcare system.

Cyber resilience scorecard

The project will measure and monitor, at a minimum, the following indicators: **MTTD** (mean time to detection), **MTTR** (mean time to recovery), effective **RTO/RPO**, **% of successful restorations**, **number of drills/year**, **number of reported incidents**, and **% of segmented legacy endpoints**.

Operational definitions:

- **MTTD:** Mean time from the occurrence of the incident to its detection (source: SOC/SIEM).
- **MTTR:** Mean time from detection to full service restoration (source: incident management system/OTRS/Jira).
- **RTO/RPO:** Recovery time and recovery point objectives actually achieved during tests and incidents (source: runbooks and recovery logs).
- **Percentage of successful restorations:** Verified restorations/total restorations tested during the period.
- **Number of drills per year:** Documented cyber incident response exercises.
- **Number of reported incidents:** Incidents reported to the CSIRT/competent authority in accordance with established procedures.
- **% of segmented legacy endpoints:** Endpoints with no support or limited support located in isolated segments/zones, as a percentage of all legacy endpoints.

KPI governance:

- **Frequency:** At least monthly (quarterly for the executive review).
- **Data sources:** SOC/SIEM, incident management, backup platform, CMDB/inventory.
- **Data controller:** Project security manager (liaison with the CISO).
- **Threshold and trend:** Define objectives, alert thresholds, and corrective actions for improvement when exceeded.

With this framework of indicators and governance, the project ensures **objective evidence, traceability, and responsiveness** to uphold the clinical value, safety, and continuous improvement of the AI system throughout its entire lifecycle.

10.8. OPERATIONAL SUSTAINABILITY AND CONTINUITY

An AI system should not be considered successfully deployed until its **stable and secure operation over time** is ensured. Sustainability involves having the resources, processes, and tools in place to ensure **service continuity** even in the case of incidents, technological changes, or provider outages.

Minimum requirements:

- **Support and maintenance:** Definition of **Service Level Agreements (SLAs)** and **Service Level Objectives (SLOs)**, as well as **on-call and escalation** mechanisms to resolve critical incidents within predefined timeframes. These agreements are essential for maintaining user trust and patient safety.
- **Business continuity:** Implementation of **regular backups**, definition of **Recovery Point Objectives (RPOs)** and **Recovery Time Objectives (RTOs)**, and conducting **regular restoration tests**. There must be a specific plan for **supplier outage scenarios** that includes technical alternatives and contingency procedures.
- **MLOps and monitoring:** Integration of **CI/CD** pipelines, **observability** systems (metrics, logs, traces), and **automatic alerts** that enable early detection of anomalies and ensure operational resilience.
- **Knowledge management:** Maintaining an **up-to-date repository** that includes **standard operating procedures (SOPs)**, operating manuals, and a record of **lessons learned**, accessible to all roles involved in the operation and maintenance of the system.

Expected deliverables: An approved business continuity plan, disaster recovery test results, **an operations log** documenting incidents and corrective actions, and an up-to-date repository containing technical and procedural documentation.

Overall, **operational sustainability and continuity** are essential prerequisites for ensuring that AI systems in healthcare maintain their **clinical value, security, and reliability** over time.

10.9. PATIENT ENGAGEMENT AND COMMUNICATION

Patient engagement should not be limited to receiving information; rather, it should become an **active component of the lifecycle** of the AI system. Involving patients from the early stages improves **usability**, builds **trust**, and lends ethical legitimacy to the project.

Patient involvement in AI and big data projects in healthcare must go beyond mere consultation and move toward true **co-design**. To this end, it is recommended to incorporate structured participatory methodologies (e.g., design thinking, collaborative workshops, world café) in the initial phases of defining objectives, ensuring that the solutions developed address real and socially accepted needs.

It is also recommended to use **standardized tools for assessing perceived impact**, such as patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs), adapted for use with AI technologies. These instruments make it possible to assess key aspects such as trust in the system, the clarity of the results, or the perception of equity and non-discrimination.

Finally, it is recommended that **inclusive governance mechanisms** be established, such as patient advisory committees integrated into projects, with functions of reviewing and providing recommendations. This structured engagement strengthens the ethical and social legitimacy of these initiatives and helps anticipate and mitigate risks related to public acceptance and their actual impact on people's quality of life.

Minimum requirements:

- **Co-design and early involvement:** Including patient representatives in **design phases, pilot studies, and monitoring committees**, promoting a co-design approach that integrates their perspective into decision-making and facilitates the early identification of barriers.
- **Enhanced transparency:** Development of **clear, accessible, and understandable informational materials** that explain the purpose, benefits, and limitations of the system, the **data it uses**, the **potential risks**, and the **safeguards implemented**. These materials must be consistent with the principles of **explainability set forth in the AI Act**.
- **Accessibility and equity:** Adapting materials to different levels of **digital and linguistic literacy**, in inclusive formats (easy-to-read, audio, Braille, translations), ensuring equity and preventing discrimination, in line with the **EHDS** and international recommendations.
- **Ethics and informed consent:** When the use of AI may influence clinical decisions, sufficient information must be provided and the patient's consent must be documented, including the **possibility of revocation**. Even when it is not required, informing patients about the use of AI helps foster their autonomy and trust.
- **Two-way feedback and traceability:** Implement feedback mechanisms that go beyond one-off surveys, such as **PROMs, PREMs** and suggestion channels. There must be a documented process for **analyzing, prioritizing, and responding to** these inputs, with traceability of the resulting actions to demonstrate specific improvements.

Expected deliverables: Accessible informational materials; records accrediting patient participation in committees or pilot studies; results of surveys and other feedback mechanisms; and a **record of actions for improvement** implemented based on their input.

Overall, active engagement and transparent communication with patients strengthen the **ethical dimension, inclusion, and public trust**, and ensure that the implementation of AI in healthcare is aligned with **international recommendations** and **European regulatory frameworks**.

10.10. CLOSURE, TRANSFER, AND DECOMMISSIONING

The **end of the lifecycle** of an AI system in healthcare should not be treated as a mere technical formality, but rather as a critical phase for ensuring **safety, traceability**, and the **preservation of the value generated**. A disorderly decommissioning could jeopardize the clinical continuity, data protection, and the reuse of deliverables.

Minimum requirements:

- **Decommissioning criteria:** Definition of objective criteria such as a decline in clinical performance, the emergence of risks to patient safety, technological obsolescence, or strategic organizational decisions. These criteria must be documented and approved by the system's governance committee.
- **Exit plan:** Development of a structured plan that provides for the **migration or secure archiving** of data, models, and associated artifacts, ensuring **full traceability**. The plan must include the preservation of technical documentation, model versions, inference logs, and the **secure elimination of environments and credentials** to prevent unauthorized access.

- **Final assessment:** Analysis of the **clinical and economic outcomes** achieved, comparing them with the initial objectives, and compilation of **lessons learned** that can be shared in scientific and technical forums. This assessment promotes transparency, continuous improvement, and sustainability within the AI ecosystem in healthcare.
- **Regulatory aspects:** In regulated studies (ICPS), the closure must include the **final review by the CEIm** and the **submission of the closure report**, in accordance with **RD 192/2023** and the **MDR**. This process confirms compliance with the protocol and the review of incidents. In unregulated projects, it is not mandatory, but it is recommended as a best practice to enhance transparency and traceability.
- **Communication:** Notify all stakeholders involved (healthcare professionals, patients, regulatory bodies) of the closure, explaining the reasons, the impact, and the measures taken to ensure **safety and clinical continuity**.

Expected deliverables: Approved decommissioning plan; record of closure signed by the responsible committee; migration or archiving documentation; secure disposal record; and **post-implementation assessment report** with results, lessons learned, and recommendations for future projects.

Expected deliverables for section 10: Approved implementation plan, pilot protocol and progress criteria, training materials, **RACI** matrix, indicator dashboard, continuity and security plan, and management of change and decommissioning procedures. In addition, **patient engagement and communication plan**, including co-design deliverables, accessible materials, and **PREM/PROM** reports.

11. SUSTAINABILITY, SCALABILITY, AND ECONOMIC MODEL

Ensure the financial and operational sustainability of the **AI** system over time by planning costs, resources, contracts, and metrics that enable its maintenance, multicenter scaling, and the creation of clinical and organizational value.

11.1. ECONOMIC MODEL AND FUNDING

The sustainability of an AI system in healthcare depends not only on its technical performance, but also on its **economic viability**. A model without a **solid business case** runs the risk of becoming inoperable after the pilot phase, even if it provides clinical value. Therefore, it is essential to establish from the outset how it will be funded, what return is expected, and what risks could jeopardize its continued operation.

Minimum requirements:

- **Business case:** Description of the **clinical and organizational problem** being addressed, the **expected benefits**, the **existing alternatives**, and the **potential risks** that may affect adoption.
- **Scope and perspective:** Definition of the **analysis period** and the perspective adopted (hospital, health service, or SNS), taking into account various **scenarios of gradual adoption**.
- **TCO and ROI/ICER:** Calculation of the **Total Cost of Ownership (TCO)** to estimate the total lifecycle cost, the **Return on Investment (ROI)** to measure the expected return and, where applicable, the **Incremental Cost-Effectiveness Ratio (ICER)** along with a budget impact analysis.
- **Sensitivity analysis:** Development of **best-case, base-case, and worst-case** scenarios, varying critical parameters such as usage volume, infrastructure costs, licensing, or human resources, in order to

anticipate risks and identify areas for flexibility.

- **Cybersecurity:** The project will include a **specific, traceable budget item** for cybersecurity. The percentage will be justified based on the **risk analysis** and the **clinical exposure** (clinical use, criticality of processes and data, interconnections). It will be broken down into **CAPEX/OPEX**, and **expenditure traceability** will be ensured through milestones, supporting documentation, and the economic manager. Reports from **IBM** estimate the **average cost per data breach in the healthcare sector** at around **\$9.8–10.9 million** per incident, so **budgeting for mitigation and response is critical**.
- **Funding and procurement:** Identification of **funding sources** (internal budget, public calls for proposals, public procurement of innovation, co-funding) and **payment methods** (license, subscription, pay-per-use, pay-per-result). This plan must be aligned with a **timeline** that links technical and financial milestones.

Expected deliverables: Business case document; spreadsheet with assumptions and sensitivity analysis; detailed financing plan; and a timeline linking technical phases and financial needs.

Overall, the economic and funding model must ensure the **viability, sustainability, and scalability** of the AI system, enabling its stable integration into clinical practice and the SNS's strategy.

11.2. COSTS AND RESOURCES (CAPEX/OPEX)

An AI system in healthcare is not a one-off expense, but rather a long-term investment that combines initial costs (**CAPEX**) and recurring costs (**OPEX**). Identifying and breaking down these costs is essential to ensuring sustainability, scalability, and operational continuity, while avoiding disruptions caused by a lack of resources.

Minimum requirements:

- **CAPEX (capital expenditures):** These include technical integration, the necessary infrastructure (servers, GPUs, storage), data labeling and curation, system development or configuration, and testing and certification. Although they are concentrated in the early stages, they determine the potential for future scaling.

Cybersecurity (CAPEX):

- Pre-production technical audits and penetration tests, with verified remediation;
 - Initial hardening and secure configuration of on-prem/cloud environments (IAM, encryption, microsegmentation, secret management);
 - Launch of SOC/SIEM (licenses/activation) and observability (metrics, logs, traces);
 - Establishment of the CI/CD pipeline with security checks (SAST/DAST), SBOM, and dependency analysis (SCA);
 - Definition and initial testing of RTO/RPO and the recovery plan.
- **OPEX (operating expenses):** These include licenses, cloud services, support and maintenance, MLOps practices and monitoring, cybersecurity, ongoing training and skills development, insurance, and periodic audits. These are recurring issues and must be taken into account throughout the system's entire lifecycle.

Cybersecurity (OPEX):

- SOC/SIEM operations and orchestrated incident response.
- Continuous monitoring and vulnerability management (patching, SBOM tracking, SCA).
- Backups, regular verification of restorations, and review of RTO/RPO.
- Periodic audits and regular penetration tests with findings closure.
- Mandatory training and refresher courses with a record of completion.
- Incident response services (expert analysis, preservation of deliverables, notification, and communication).
- **Data costs:** These comprise data extraction, standardization, terminology mappings, anonymization/pseudonymization, and data governance. These processes are critical to ensuring quality, reproducibility, and regulatory compliance.
- **Human Resources:** Workforce planning for clinical, data science, IT, security, quality/regulatory, and management of change profiles. The availability of qualified personnel is a critical factor for sustained operations and continuous improvement.

Expected deliverables: Detailed CAPEX/OPEX budget (including a specific item for cybersecurity), a matrix of assigned managers, and a provisioning plan that links resources to the phases of the lifecycle.

Overall, proper cost and resource planning ensures that investment in AI translates into real clinical impact, operational continuity, and long-term financial sustainability.

11.3. SCALABILITY AND MULTICENTER DEPLOYMENT

For an AI system to have a **real impact on the National Health System**, it must be able to **be rolled out to other services and centers with as little additional effort as possible**. This objective requires planning for **technical portability**, managing **data heterogeneity**, and establishing **robust governance** across institutions.

Minimum requirements:

- **Technical portability:** The model and associated services must be delivered in **standard formats** (containers, ONNX where applicable), accompanied by scripts and documentation that facilitate deployment in different environments. The system must support **local parameterization** to adapt terminology, clinical thresholds, and clinical workflows without the need for retraining. In addition, detailed documentation of the **FHIR and DICOM profiles** used is required to ensure interoperability.
- **Data heterogeneity:** Each hospital may exhibit variations in **coding, processes, and data quality**. It is necessary to establish an **adaptation strategy** through mapping and transfer validations to ensure that the model maintains its **performance and calibration** in diverse environments. These tests must include subgroup analysis and local validation prior to operational deployment.
- **Governance and agreements:** The multicenter operation must be based on **formal agreements** that define responsibilities, **service levels (SLA/SLO)**, support mechanisms, and a **multicenter technical committee**. These agreements must provide for data protection through **DTA** and, where applicable, **joint controller or data processor agreements**, as well as business continuity plans.

- **Federated learning:** When used, the architecture and governance must allow for **training and validating models without moving raw data**, while preserving privacy and complying with the GDPR. This requires defining nodes, update protocols, security measures, and standardized metrics to evaluate overall performance and performance by center.

Expected deliverables: A multicenter implementation guide; a standard contract with clauses on governance and data protection; a record of participating centers with their profiles and mappings; and the results of local and consolidated validation.

Overall, **scalability and multicenter deployment** are necessary conditions for AI systems in healthcare to achieve a **sustainable and equitable impact** on the SNS, avoiding duplication and ensuring interoperability among institutions.

11.4. OPERATIONAL SUSTAINABILITY AND CONTINUITY

An AI system should not be considered successfully deployed until its **stable, secure, and traceable operation over time** is ensured. Sustainability involves having **resources, processes, and tools** in place to ensure **service continuity**, even in the case of incidents, technological changes, or provider outages.

Minimum requirements:

- **Service Plan:** Definition of **Service Level Agreements (SLAs)** and **Service Level Objectives (SLOs)**, as well as **maintenance windows**, **support** procedures, and **incident escalation** mechanisms. These agreements are essential for maintaining user trust and patient safety.
- **Business continuity:** Support through **regular backups**, definition of clear **Recovery Point Objectives (RPOs)** and **Recovery Time Objectives (RTOs)**, and conducting **regular restoration tests**. A **specific plan for supplier outage scenarios**, along with technical alternatives and contingency procedures, must be included.
- **Controlled evolution:** Establishment of a **versioning policy**, objective criteria for identifying **significant changes**, procedures for **version approval**, and mechanisms for **secure rollback** in the event of a failure. Each update must be tested in a **controlled environment** before being deployed in production.
- **Knowledge management:** Maintaining an **up-to-date document repository** that includes **standard operating procedures (SOPs)**, operating manuals, change logs, and **lessons learned**, accessible to all roles involved in the operation and maintenance of the system. This ensures continuity even in the event of staff turnover or changes in critical roles.

Expected deliverables: Approved business continuity plan; recovery test results; documented **change log**; and repository updated with manuals, SOPs, and technical and procedural documentation.

Overall, long-term operational sustainability is essential for AI systems in healthcare to deliver **real clinical and organizational value** and maintain the **trust of users and patients** over time.

11.5. ECONOMIC EVALUATION AND HEALTH OUTCOMES

The adoption of an AI system in healthcare must be justified not only by its **technical feasibility**, but also by the **clinical and economic value** it provides. Rigorously evaluating these aspects is key to informing decisions regarding **funding, scaling, and sustainability**.

Minimum requirements:

- **Clinical and usage metrics:** Inclusion of **relevant clinical outcomes** (e.g., reduction in adverse events, diagnostic improvement), **patient safety** indicators, resource utilization, and processing times. The **actual adoption of the system**, the **override rate**, and the experiences of healthcare professionals and patients must also be monitored through **PROMs** and **PREMs**.
- **Economic evaluation:** **Cost-effectiveness** or **cost-utility** analysis (e.g., **ICER**) and, where applicable, **budgetary impact** for large-scale adoption. The analysis should take into account **direct costs** (infrastructure, licenses, maintenance) and **indirect costs** (clinical time, training, management of the change), in comparison with the expected benefits in terms of health outcomes and operational efficiency. It is recommended to perform **sensitivity analyses** using best-case, base-case, and worst-case scenarios.
- **Equity:** Evaluation of the distribution of benefits and outcomes among **relevant subgroups** (gender, age, center, comorbidities), identifying potential inequalities in access or outcomes. This analysis is guided by both ethical principles and emerging requirements in regulatory and health technology evaluation frameworks.
- **Benchmarking and transparency:** Whenever possible, compare results with **clinical standards** or with other systems, and publish findings to promote **transparency** and the **reuse of deliverables**.

Expected deliverables: An approved evaluation protocol; periodic reports on clinical, economic, and adoption outcomes; a documented sensitivity analysis; user and patient experience metrics; and appendices detailing assumptions, calculations, and results by subgroup.

Overall, the **economic and health outcomes evaluation** is essential to demonstrating that an AI system not only works technically, but also **delivers real, equitable, and sustainable value** to the healthcare system.

11.6. CONTRACTS, INTELLECTUAL PROPERTY, AND LICENSING

When a project enters the **operational or scaling up** phase, it is essential to formalize contracts with technology providers (software, cloud, maintenance). The goal is to ensure **service continuity**, **data protection**, and **regulatory compliance** (GDPR/LOPDGDD, MDR/IVDR, AI Act), avoiding risks such as vendor lock-in or a lack of traceability.

A **clear contractual framework** is essential for mitigating legal risks, ensuring sustainability, and protecting the rights of all parties. The lack of clarity regarding aspects such as **data ownership**, **access to deliverables**, or **exit conditions** can compromise the operation and patient safety.

Minimum requirements:

- **Rights and ownership:** The contract must clearly define the ownership and terms of use of the **data**, **models**, **code**, **documentation**, and **resulting improvements**. It must include provisions that ensure **access to logs and traces** for regulatory and security audits.
- **Licenses and use:** Specify the **terms of use** (number of users, instances, territories), the **usage limits**, and the **associated obligations**. **Service Level Agreements (SLAs/SLOs)** and penalties for non-compliance must be included to ensure quality, availability, and continuity.
- **Portability and exit:** Ensure the **right to continued use** in the event of termination, the **handover of devices and resulting data**, and a **transition plan** with technical support. It is recommended to include mechanisms such as **code escrow and models** for scenarios involving the provider's bankruptcy or cessation of operations.

- **Compliance:** Reflect the obligations arising from **GDPR/LOPDGDD** (data protection, security, incident reporting), and, where applicable, **alignment with MDR/IVDR and the AI Act** for high-risk systems. The contract must also consider **subcontracting and international transfers**, requiring prior authorization and adequate safeguards.
- **Compatibility and improvements:** Define intellectual property regarding **improvements and derivatives**, and include an obligation to maintain **compatibility with open standards** that facilitate technical portability and reduce the risk of technological lock-in.
- **Conflicts of interest with suppliers:** When the supplier has previously participated in research, co-creation, or proof-of-concept activities related to the AI system, **specific procedures must be established for the identification and management** of potential conflicts of interest (formal disclosure of ties, traceability of prior interactions, and independent evaluation of bids), so that the transition from scientific collaboration to contracting is documented and functionally separated.

Expected deliverables: Standard contract and annexes; **contractual risk matrix; checklist for regulatory compliance;** and, where applicable, a copy of the **escrow agreement**.

Overall, a well-designed contractual framework ensures that AI systems in healthcare operate under **clear, secure, and sustainable conditions**, protecting both providers and healthcare institutions, and, ultimately, patients.

11.7. STRATEGIC RISKS AND MITIGATION

The sustainability of an AI system in healthcare depends not only on its technical design, but also on the ability to **anticipate and manage strategic risks** that could compromise its value and continuity. These risks are not always apparent in the initial stage, but their impact can be critical if preventive measures and monitoring mechanisms are not put in place.

Minimum requirements:

- **Vendor lock-in:** Require the use of **open formats, documented APIs** and, where applicable, establish **escrow mechanisms for code and models** that ensure continuity in the event of contract termination or vendor bankruptcy.
- **Technological obsolescence and regulatory changes:** Define a **technology roadmap** that includes planned updates and **annual regulatory compliance reviews**, particularly in relation to **MDR/IVDR, AI Act, and GDPR/LOPDGDD**.
- **Drift and performance degradation:** Establish **plans for recalibration, retraining, and clinical reevaluation**, with objective criteria to determine when action is needed to prevent clinical risks arising from a loss of model precision or validity.
- **Demand variability and cloud costs:** Implement **usage limits, early warning** systems, and resource optimization strategies (reserves, savings plans) to prevent budget overruns and ensure financial sustainability.

Expected deliverables: A risk log that includes impact and likelihood; documented mitigation plans; and deliverables of **regular monitoring** of identified risks and the effectiveness of the measures taken.

Overall, proactive strategic risk management ensures that AI systems in healthcare can remain **secure, viable, and sustainable over time**, even in the event of technological, regulatory, or market uncertainties.

11.8. KEY SUSTAINABILITY INDICATORS (KPIS)

The sustainability of an AI system in healthcare cannot be guaranteed by an initial plan alone: it requires **continuous monitoring** to anticipate risks, correct deviations, and demonstrate clinical, economic, and organizational value. **Key indicators (KPIs)** make it possible to assess the system's financial, operational, and clinical viability, as well as its capacity for **multicenter scaling**.

Minimum indicators:

- **Financial:** Monitoring of the annual **TCO (Total Cost of Ownership)**, the **cumulative ROI**, the **cost per episode/use**, and the **budget overrun** compared to the plan. This data is essential for justifying continued funding and prioritizing investments.
- **Operations:** Monitoring of **service availability**, **latency**, **error rate**, **incidents classified by severity**, **mean time to resolution**, and **rollback rate**. These indicators reflect stability, resilience, and service quality.
- **Clinics and equity:** Evaluation of **performance and safety metrics by subgroup** (gender, age, center, comorbidity), along with the **override rate** by professionals and **user and patient satisfaction**. These indicators ensure that the system remains reliable and prevents inequalities.
- **Scaling:** Number of **active centers or units**, **mean deployment time** and **parameterization effort** required. These indicators are key to planning a multicenter trial and optimizing resources.
- **Environmental sustainability:** Monitoring of **energy consumption** and the **carbon footprint** associated with operations and, where applicable, model training, as well as the efficiency of the algorithms and infrastructure used. These indicators make it possible to align the deployment of the AI system with institutional **sustainability** policies and facilitate accountability in terms of **environmental impact**.
- **Cyber resilience:** See the **cyber resilience scorecard** in section 10.7 for the definition, measurement method, and associated deliverables (**MTTD**, **MTTR**, **RTO/RPO**, **% of successful restorations**, **no. of drills/year**, **no. of reported incidents**, **% of segmented legacy endpoints**).

Expected deliverables: An updated scorecard with targets and thresholds; periodic reports (e.g., monthly); and an **action plan derived from metrics**, which allows for correcting deviations and improving system performance.

Taken together, sustainability KPIs serve as the **central tool for management and continuous improvement**, ensuring that the AI system delivers **tangible, equitable, and sustainable** value over time.

Expected output of section 11:

- Complete **business case**, including **TCO**, **ROI/ICER** and sensitivity analysis (best-case, base-case, and worst-case scenarios).
- **Detailed CAPEX/OPEX budget** with a matrix of responsible parties and a provisioning plan.
- **Financing plan and procurement methods**, with a timeline linked to technical and financial milestones.

- **Multicenter deployment guide** with profiles/mappings, governance agreements, and deliverables of local validation.
- **Continuity and operational sustainability plan**, including SLA/SLO, RPO/RTO, recovery testing, and a knowledge repository.
- **Contracts and compliance annexes** (DTA, SLA/SLO, portability clauses, escrow where applicable) and checklist of regulatory obligations (GDPR, MDR/IVDR, AI Act).
- **Strategic risk log**, including impact/probability, mitigation measures, and deliverables of follow-up.
- **Sustainability KPI scorecard**, including targets, thresholds, and a corresponding action plan.

ANNEX I. MEMBERS OF THE IIS ALLIANCE YEAR 2025 WORKING GROUPS.

WG1. MEMBERS WORKING GROUP. INCORPORATING CITIZEN ENGAGEMENT INTO HEALTH RESEARCH INSTITUTES

INSTITUTOS COORDINADORES

- IBS Granada:
 - Dirección Científica María José Sánchez Pérez
 - Dirección de Gestión: Sarah Biel Gleeson
 - Personal técnico Delegado: Francisco J Salcedo Avilés
 - (Responsable Secretaría Técnica, Calidad, Evaluación y Gestión del Conocimiento)
- IRYCIS:
 - Dirección Científica: María Laura García Bermejo
 - Dirección de Gestión: Laura Barreales Tolosa
 - Personal técnico Delegado: Eduardo Barrio Ferrero (Gestor I+D+i)

INSTITUTOS PARTICIPANTES

- IBSAL:
 - Dirección Científica: Luis García Ortiz
 - Dirección de Gestión: Raquel Carnicero Izquierdo
 - Personal técnico Delegado: Laura González Guerra – Olaya Tamayo Morales
 - (Gestión Científica IBSAL)
- IdiSBA:
 - Dirección Científica: Antonia Barceló Bennasar
 - Dirección de Gestión: Miguel Fiol Sala
 - Personal técnico Delegado: Maria Antonia Llopis Grimalt
 - Maria del Mar Ferrá Cañellas
 - (Gestión Científica)

- IIS-FJD:
 - Dirección Científica: Carmen Ayuso Garay
 - Dirección de Gestión: Alberto Montero Manso
 - Personal técnico Delegado: Ana Rubio Araiz
 - (Responsable Secretaría Técnica)
 - IdISSC: Dirección Científica: Elena Urcelay García
 - Dirección de Gestión: Joana Modolell Aguilar
 - Personal técnico Delegado: Laura Espino Paisán
 - (Responsable Secretaría Técnica)

- ISABIAL:
 - Dirección Científica: Cristia Alenda
 - Dirección de Gestión: Elena Bertomeu
 - Personal técnico Delegado: Enrique de Madaira (Subdirector técnico)
 - Andreu Campos (Director técnico)

- IdiPAZ:
 - Dirección Científica: Javier de Castro
 - Dirección de Gestión: Ana Coloma

- INIBIC:
 - Dirección Científica: Maria del Mar Castellanos Rodrigo
 - Dirección de Gestión: Patricia Rey Pérez
 - Personal técnico Delegado: Juan A. Pérez Longueira
 - (Responsable UCC+i)

- IRBLleida:
 - Dirección Científica: Diego Arango del Corro
 - Dirección de Gestión: Joan Sayós Ortega
 - Personal técnico Delegado: Meritxell Soria Yenez
 - Anna Belén Castilló Pérez
 - (Responsable de Comunicación Técnica de la Unidad de Innovación. Participantes en la Comisión de pacientes)

WG2. MEMBERS WORKING GROUP. NEW PROFESSIONAL ROLES IN ACCREDITED HEALTH RESEARCH INSTITUTES (IISS)

IIS Coordinadores:

- INSTITUTO DE INVESTIGACIÓN SANITARIA DEL PRINCIPADO DE ASTURIAS (ISPA).
- INSTITUTO DE INVESTIGACIÓN SANITARIA HOSPITAL LA PAZ (IdiPAZ).

IIS participantes:

- INSTITUTO HOSPITAL DEL MAR RESEARCH INSTITUTE BARCELONA (HMRIB).
- INSTITUTO DE INVESTIGACIÓN MARQUÉS DE VALDECILLA (IDIVAL).
- INSTITUT D'INVESTIGACIÓ EN CIÈNCIES DE LA SALUT GERMANS TRIAS I PUJOL (IGTP).
- IIS INSTITUTO DE INVESTIGACIÓN SANITARIA PUERTA DE HIERRO – SEGOVIA DE ARANA (IDIPHISA).
- INSTITUTO DE INVESTIGACIÓN SANITARIA FUNDACIÓN PARA LA INVESTIGACIÓN DEL HOSPITAL CLÍNICO DE VALENCIA (INCLIVA).
- INSTITUTO DE INVESTIGACIÓN SANITARIA ARAGÓN (IIS ARAGON).
- INSTITUTO DE INVESTIGACIÓN SANITARIA HOSPITAL UNIVERSITARIO DE LA PRINCESA (IIS LA PRINCESA)

WG3. MEMBERS WORKING GROUP. IMPACT MEASUREMENT: HEALTH RESEARCH INSTITUTES (IISS)

Coordinación Técnica:

Instituto de Investigación Biomédica de Bellvitge - IDIBELL (Gabriel Capellá, Beatriz Pinilla)

Instituto de Investigación Sanitaria Biogipuzkoa (Olatz Arrizabalaga, Maider San Torcuato)

Participantes:

- Instituto de Investigación Hospital 12 de Octubre (i+12).
- Instituto de Investigación Sanitaria del Hospital de La Princesa (IIS La Princesa).
- Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau (IR Sant Pau).
- Instituto de Investigación Sanitaria Biobizkaia (IIS Biobizkaia).
- Instituto Maimónides de Investigación Biomédica de Córdoba (IMIBIC).
- Institut d'Investigació i Innovació Parc Taulí (I3PT).
- Instituto de Investigación Sanitaria y Biomédica de Alicante (ISABIAL).
- Instituto de Investigación Sanitaria Gregorio Marañón (IiSGM).

WG4. MEMBERS WORKING GROUP. CAPABILITIES MAP OF ACCREDITED HEALTH RESEARCH INSTITUTES (IISS)

Centros coordinadores:

- Instituto de Investigación Sanitaria de Santiago de Compostela (IDIS)- María Luz Couce Pico, Isabel Lista García, equipo de Coordinación Científico-Técnica.
- Instituto de Investigación Sanitaria de Navarra (IDISNA) – Nicolás Martínez Velilla, Natalia Cal Purriños.

Centros participantes:

- Instituto de Investigación e Innovación Parc Taulí (I3PT) - Loli Prados Cazorla, Anna Ullastres.
- Instituto de Investigación Sanitaria Hospital La Paz (IdIPAZ) – Paloma Gómez Campelo.
- Instituto de Investigación Sanitaria Galicia Sur (IIS GS) - Eva Póveda, Beatriz Gil De Araújo.
- Instituto de Investigación Biomédica de Málaga y Plataforma en Nanomedicina (IBIMA Plataforma BIONAND) - Francisco J. Tinahones, José Miguel Guzmán.
- Instituto de Investigación Sanitaria (IIS La Fe) - Guillermo Sanz Santillana, Adriana Sandoval Duarte, Daniel Lurbe.
- Instituto Maimónides de Investigación Biomédica de Córdoba (IMIB) - María Fuensanta, Pablo Ramírez.
- Instituto de Investigación Hospital Universitari Vall d’Hebron (IR-HUVH) – Meritxel Álvaro Costa.
- Instituto de Biomedicina de Sevilla (IBIS) – José Cañón Campos.

WG5. MEMBERS WORKING GROUP. ARTIFICIAL INTELLIGENT

- Instituto de Investigación Hospital Universitari Vall d’Hebron (Barcelona) – Directora Científica Dra. Begoña Benito
- Instituto de Investigación Biomédica de Salamanca – Director Científico Dr. Luis García Ortiz
- Instituto de Investigación Sanitaria de la Fundación Jiménez Díaz (Madrid)
- Instituto de Investigación Biosanitaria de Granada (Granada)
- Instituto de Investigación Sanitaria Gregorio Marañón (Madrid)
- El Instituto de Investigación Sanitaria Hospital Clínico San Carlos de Madrid (Madrid) – Director Científico Dr. Julio Mayol
- Instituto de Investigación Biomédica de A Coruña (A Coruña)
- Instituto Sanitario Galicia Sur (Galicia Sur)
- Instituto de Investigación Sanitaria BioBizkaia (Bizkaia)
- Instituto Maemónides de Investigación Biomédica de Córdoba (Córdoba)
- Instituto de Investigación Sanitaria La Fe (Valencia)

ANNEX II. SURVEY TEMPLATE OR FORM(S).

ANNEX. WG3. IMPACT MEASUREMENT: HEALTH RESEARCH INSTITUTES (IISS)

ANEXOS GdT 3. METRICAS DE IMPACTO

- ANEXO 1: Presentación CREA “Incorporar el impacto en una institución de investigación”.



AGENDA

Research
Impact

Institutional
Context
for impact

Fostering
Impact at
CREAM

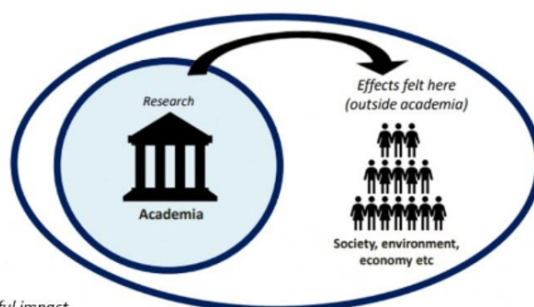
Impact
assessment





Research Impact is....

Provable **effects** (**benefits**) of **research** in the '**real world**'.



J. Bayley. *Creating meaningful impact.*



Research Impact is....





Impact domains

Impact has different categories which attempt to reflect the rich variety of contributions of science to society.

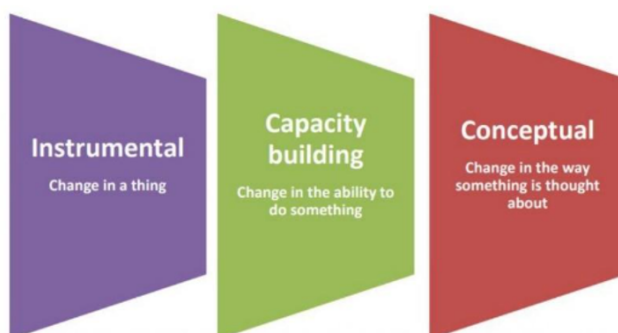


UCD Impact Toolkit



Impact types

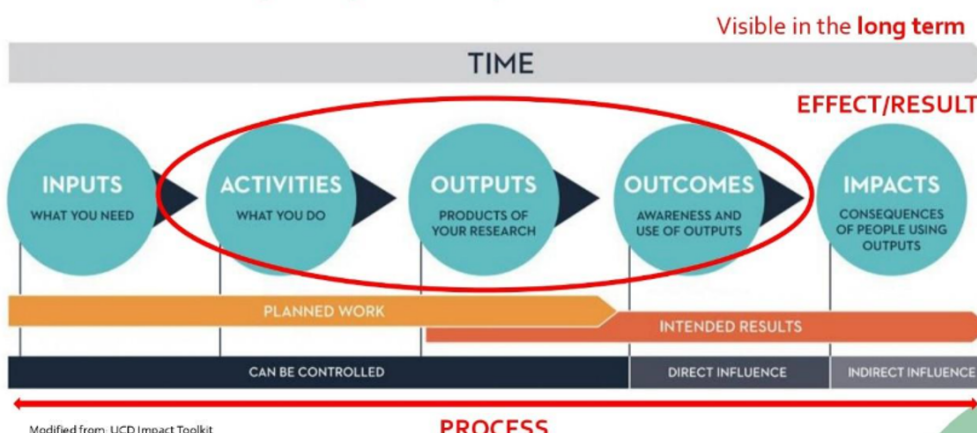
Depending on the nature of the element that changes.



See: <https://esrc.ukri.org/research/impact-toolkit/what-is-impact/>



Impact pathways



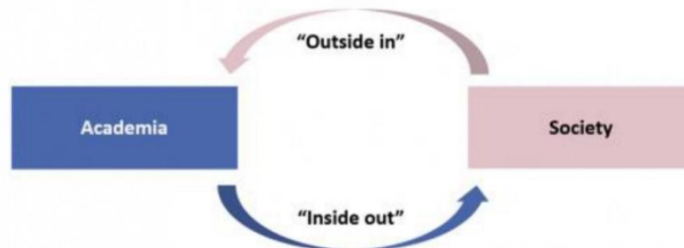
Modified from: UCD Impact Toolkit

Impact needs engagement and interaction



Impacts: valuable contributions

Academic and societal impact are interlinked and are not mutually exclusive.



Scientifically strong research can contribute to the societal impact of research.
Societally impactful research can also offer new scientific perspectives on research.



Research
Impact

Institutional
Context
for impact

Fostering
Impact at
CREAF

Impact
assessment



Internal motivations (Mission)





Opening Science to Society

Collaboration, participation and inclusion:



UNESCO Recommendations for Open Science, 2021



Reforming research assessment



- Focus on the **quality** rather than on the quantity.
- **Reduce bias** in evaluation through responsible research assessment.
- Evaluate a **broader range of contributions** to science and society.
- Help promote **diversity** in science and career paths and a more **inclusive** research culture.
- Focus on the **impact of research** rather than only the outputs.



National Assessments and Networks



UK



New Zealand



Canada



Netherlands



Hong Kong



Australian Government
Australian Research Council

Australia



USA



Chile

Sub-National

Catalonia



Research Impact Assessment 2024

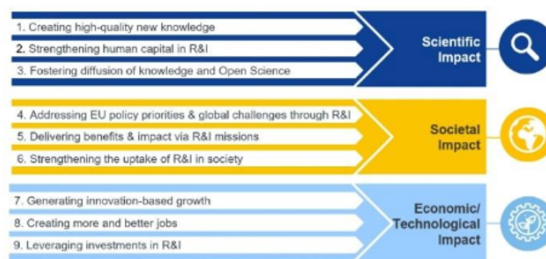


Researchers competencies

ResearchComp: the European Competence Framework for Researchers



Challenge based research funding



Article 50 & Annex V 'Time-bound indicators to report on an annual basis on progress of the Programme towards the achievement of the objectives referred to in Article 3 and set in Annex V along impact pathways'



Changing national research legislation

Spanish context



...they include Impact

'Use of criteria that **value the diversity of contributions** and the **impact of research outcomes on society**'.



Reforming research assessment

Spanish
context



Reform criteria and diversity
of contributions



CERCA Research Impact Assessment

Catalan
context



Research impact may be defined as a **change or benefit** to the economy, society, culture, public policy or services, health, the environment or quality of life, that goes **beyond the academic world**.

I-CERCA

- 1-2 Impact Narratives per institution every 4 years
- Institutional Impact strategies

RIA 2024



CERCA and Impact

- Initial formative assessment in 2019.
- International impact Advisory Council.
- Training for impact agents of all CERCA centers.
- Formative assessment 2024.
- Promoting impact strategies in CERCA centers.
- Impact Working Group.
- Incorporating impact (to some extent) in general assessments of the CERCA centers.



Catalan
context



Research
Impact

Institutional
Context
for impact

Fostering
Impact at
CREAF

Impact
assessment



A public consortium

CREAF is a **public research consortium** created in **1988**, dedicated to **terrestrial ecology** and **territorial analysis**. We produce **knowledge** and **methodologies** for **conservation, management** and **adaptation** of the natural environment to **global change**.

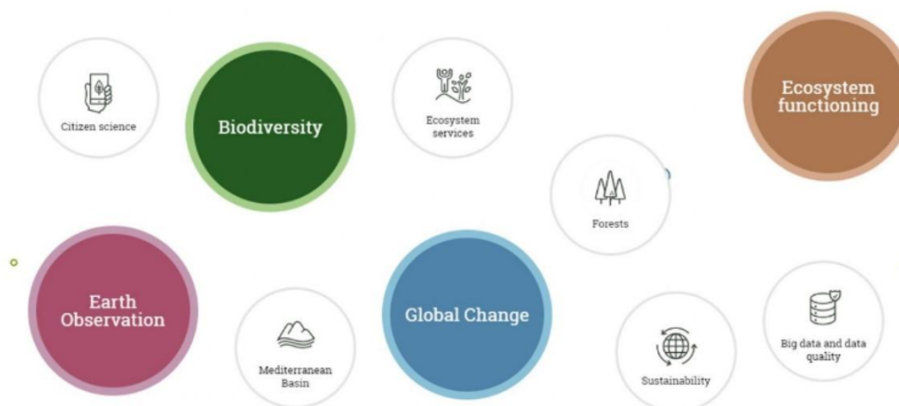


CREAF people





Research areas & crosscutting issues



Research Impact Officer at CREAM

Position included in Severo Ochoa project 2019-2023. Now, permanent position.

Strategy and Policy
Recognition and Reward
Networking
Interaction with stakeholders
Environmental education
Citizen Science



Training and capacity building
Research proposals
Project implementation
Planning and monitoring
Visibility



CREAF's 1st Impact strategy (2021-2025)

PROJECTS & RESEARCH

To **embed impact** from the initial stages of research inception and **analyse** information on **impact** achieved by previous research.

ASSESSMENT & VISIBILITY

To **value, assess** and give **visibility** to the benefits CREAM's research brings to society beyond academia.



CREAF INSTITUTION

To foster the mobilisation and **impact** of research into the non-academic world as an **institutional commitment and mission**.

CAPACITY

To build and nurture **staff impact literacy** and competencies.

STAKEHOLDERS & SOCIETY

To establish **direct and meaningful interaction** with public administration, key stakeholders and citizens.

Annual Impact Implementation Plans



Implementation Plan 2025

Impact Visibility

- Run impact comms plan, highlight impact externally.

Impact Tracking & Evaluation

- Revise survey instrument, set up initial impact monitoring database.

Impact Literacy & Capacity Building

- Deliver trainings, launch intranet section & acceleration programme.

Support to Research Teams

- Offer impact support, review proposals, meet teams, guide planning & monitoring.

Stakeholder Engagement

- Support engagement activities, boost stakeholder interactions.

Institutional Networks & Representation

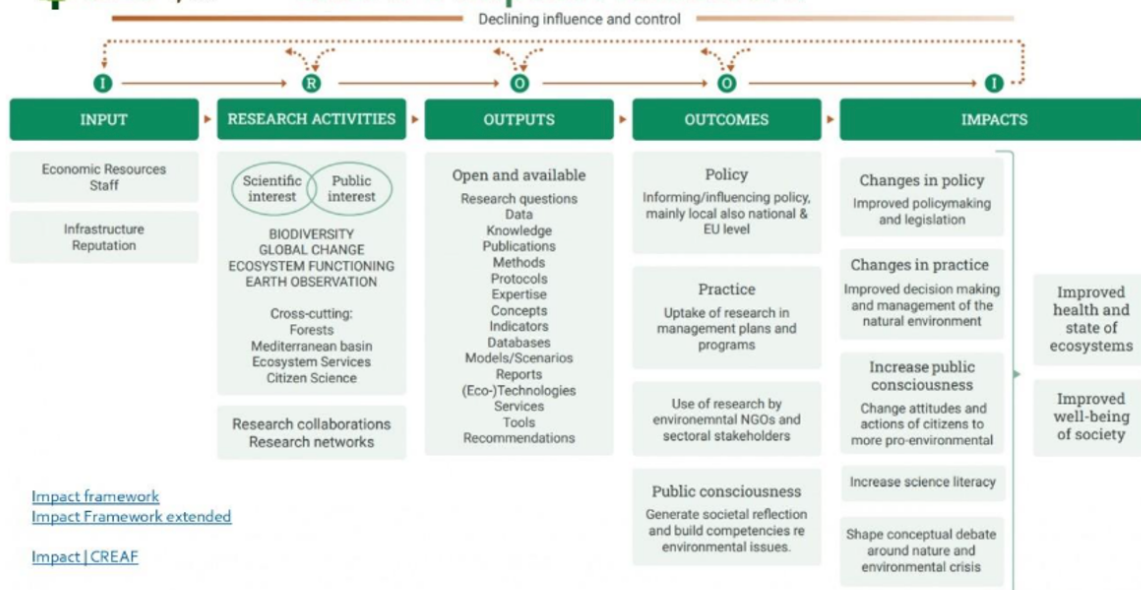
- Join conferences & working groups, maintain & expand networks.

Institutional Initiatives

- Co-lead CoARA plan, coordinate with other departments.



CREAF's Impact Framework



ANEXO 2: FIRST SURVEY. WG3. IMPACT.

Enlace Limesurvey: [GRUPO 3 DE LA ALIANZA IIS – MÉTRICAS DE IMPACTO](#)

GRUPO 3 DE LA ALIANZA IIS – MÉTRICAS DE IMPACTO

Encuesta acerca de la **Guía Técnica de Evaluación de Acreditación de Institutos de Investigación Biomédica o Sanitaria (IIS)** y su relación con el **IMPACTO**. Cada IIS podrá valorar la idoneidad de cada uno de los indicadores recogidos en la Guía y en cada caso, proponer sugerencias adicionales que maximicen su alcance.

Para ello, el cuestionario se divide en dos de las tres dimensiones en las que se estructura la propia Guía: “Estrategia, Capacidades y Rendimiento Científico” e “Impacto en la Sociedad”. La dimensión de “Gobernanza” se excluye por ser considerada de índole más teórica acerca de la estructura de los IIS.

Es un tipo de cuestionario que puede responderse por partes, sin necesidad de hacerlo de una vez. Para ello, podéis seleccionar los 3 puntos que aparecen en la parte superior derecha de la pantalla a “Continuar después”.

Fecha límite: 15 de mayo de 2025.

IMPORTANTE: una única respuesta por Instituto.

Muchas gracias por vuestra colaboración

IDIBELL y BIOGIPUZKOA

GRUPO 3 DE LA ALIANZA IIS – MÉTRICAS DE IMPACTO

Siguiente

- ANEXO 3: Informe de resultados de la primera encuesta.

RESULT FIRST SURVEY. WG3. IMPACT MEASUREMENT: HEALTH RESEARCH INSTITUTES (IISS)

Número de respuestas completas	Siete
Entidades que han completado la encuesta	<ol style="list-style-type: none"> 1. IIS Biobizkaia* 2. IIS Biogipuzkoa 3. IIS Princesa 4. IDIBELL 5. ISABIAL 6. IR SANTPAU* 7. I3PT
Entidades que no han completado la encuesta	<ol style="list-style-type: none"> 1. IIS i+12 2. IMIBIC 3. IISGM
Resumen general de las respuestas	<p>Por indicadores:</p> <ul style="list-style-type: none"> - Todas las entidades creen que 15 de los indicadores son válidos para la medición del impacto. - alguna o varias de las entidades creen que habría que adaptar 30 de los indicadores propuestos para que sean útiles para la medición del impacto. - No hay ningún indicador en la que todas las entidades indiquen que no sea útil para la medición del impacto. <p>Porcentaje de votos que indican que habría que adaptar los indicadores para que fuesen útiles para la medición del impacto de la investigación en salud. Por secciones:</p> <ul style="list-style-type: none"> - 2.2 Recursos y Procesos: 18%. - 2.3 Actividad Científica: 21%. - 3.1 Traslación e impacto en el SNS y la sociedad: 15%. - 3.2 Comunicación científica y participación: solo un 3%.
Resumen de sugerencias aportadas por los IIS	<ul style="list-style-type: none"> - Adaptar el indicador al tamaño o contexto del IIS. No definir un umbral mínimo que puede ser difícil de alcanzar por algunos IIS. - Algunos indicadores miden la capacidad de los IIS, no el impacto directo, habría que adaptarlas. - Varias instituciones destacan la importancia de la formación en comunicación y co-creación como habilitadora del impacto. <p>*Estos IIS han aportado datos de sus indicadores, no sugerencias.</p>

ANÁLISIS POR INDICADORES

2. Estrategia, Capacidades y Rendimiento Científico	Útil para la medición del impacto	No útil para la medición del impacto
2.2 Recursos y Procesos	13/70 votos indican no ser útiles para la medida del impacto (18%).	
2.2.1.5 Índice de Participación en redes o consorcios de investigación cooperativa	7	0
2.2.1.6 Infraestructuras o redes de investigación internacionales	7	0
2.2.3.1 Proyectos competitivos	5	2
2.2.3.2 Tasa de éxito en convocatorias públicas competitivas de ámbito estatal	6	1
2.2.3.3 Fondos públicos	6	1
2.2.3.4 Financiación media conseguida por IP	6	1
2.2.3.5 Ratio de Nº de proyectos internacionales financiados por IP	4	3
2.2.3.6 Financiación media conseguida por IP - fondos europeos	4	3
2.2.4.1 Índice de Efectividad del Plan de Formación	6	1
2.2.4.2 Índice de Apoyo a Grupos Emergentes de Investigación	6	1
2.3 Actividad Científica	24/112 votos indican no ser útiles para la medida del impacto (21%).	
2.3.1.1 Especificaciones del PCC del IIS	7	0
2.3.1.2 Cumplimiento del Ciclo de Monitorización y Evaluación del PCC	6	1
2.3.2.1 Impacto normalizado	6	1
2.3.2.2 Colaboración internacional	6	1
2.3.2.3 Colaboración interna	5	2
2.3.2.4 Impacto global	4	3
2.3.2.5 Liderazgo	6	1
2.3.2.6 Excelencia con liderazgo	4	3
2.3.2.7 Visibilidad	4	3
2.3.3.1 Implementación GBPC	6	1
2.3.3.2 Integridad y Buenas Prácticas Científicas del IIS	5	2
2.3.3.3 Cumplimiento de la normativa de Protección de Datos del IIS	6	1
2.3.4.1 Política de Acceso Abierto del IIS	6	1
2.3.4.2 Publicaciones en Open Access	5	2
2.3.4.3 Publicación de datos en abierto	5	2
2.3.4.4 Apoyo en la creación de PGD de investigación y opciones de Publicación	7	0

3. Impacto en la Sociedad	Útil para la medición del impacto	No útil para la medición del impacto
3.1 Traslación e impacto en el SNS y la sociedad	12/77 votos indican no ser útiles para la medida del impacto (15%).	
3.1.1.1 Plan de Traslación, Innovación y Transferencia del IIS	7	0
3.1.1.2 Acciones promoción innovación y transferencia	7	0
3.1.2.1 N° de GPC y documentos institucionales aportados por el IIS	5	2
3.1.2.2 Recogida de GPC publicadas y el nivel de implantación.	5	2
3.1.2.3 Traslación de resultados a la práctica asistencial	7	0
3.1.2.4 Difusión de resultados a práctica clínica	7	0
3.1.3.1 Difusión de resultados a empresas	7	0
3.1.3.2 Inversión en protección de resultados	6	1
3.1.3.3 N° de registros de la propiedad industrial	4	3
3.1.3.4 Licencias de resultados	5	2
3.1.3.5 Ingresos anuales por acuerdos de explotación	6	1
3.2 Comunicación científica y participación	2/56 votos indican no ser útiles para la medida del impacto (3%).	
3.2.1.1 Formación en comunicación y traslación	7	0
3.2.1.2 Formación en participación y co-creación	7	0
3.2.2.1 Comunicación Externa y Sinergias del IIS	7	0
3.2.2.2 Comunicación institucional externa	7	0
3.2.2.3 Acciones comunicación interna	7	0
3.2.3.1 Actores clave no científicos en el diseño del PE	6	1
3.2.3.2 Participación de Actores No Científicos en los órganos de gobierno	6	1
3.2.3.3 Actores clave no científicos en el diseño de proyectos de investigación	7	0

- **ANEXO 4:** Segunda encuesta dirigida a la Alianza.

SECONT SURVEY. WG3. IMPACT MEASUREMENT: HEALTH RESEARCH INSTITUTES (IISS)



GdT Métricas de Impacto - Alianza IIS 2025

El objetivo de esta encuesta es recoger la opinión de los Institutos de Investigación Sanitaria (IIS) sobre distintos aspectos relacionados con la medición del impacto de la investigación, incluyendo indicadores, co-creación, traslación a la práctica clínica, participación de actores no científicos y capacidades institucionales. Las respuestas permitirán orientar futuras acciones y propuestas en el marco del Grupo de Trabajo de Métricas de Impacto.

Agradecemos de antemano su colaboración, y es por ello que le solicitamos si pudiese dedicar 15 minutos a contestar este cuestionario

* Obligatoria

Datos sobre la Institución

1. Nombre completo de la institución *

2. Nombre y apellidos de la persona que responde el cuestionario *

3. Cargo que ocupa *

4. Correo electrónico de contacto *

INDICADORES BIBLIOMÉTRICOS

Explorar la percepción sobre la utilidad de los indicadores bibliométricos y posibles formas de complementarlos para reflejar mejor el impacto en salud.

5. ¿Consideras que los indicadores bibliométricos actuales de la Guía Técnica de Evaluación reflejan adecuadamente el impacto en salud? *

- ☐ 1-Nada
- ☐ 2-Poco
- ☐ 3-Regular
- ☐ 4-Bastante
- ☐ 5-Mucho

6. ¿Estás de acuerdo con complementar las métricas de los indicadores bibliométricos con indicadores de aplicabilidad o transferencia de resultados liderados? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

7. ¿Qué tan importante te parece adaptar los indicadores bibliométricos a las directrices de COARA (Coalition for Advancing Research Assessment)? *

- ☐ 1-Nada importante
- ☐ 2-Poco importante
- ☐ 3-Medianamente importante
- ☐ 4-Importante
- ☐ 5-Muy importante

8. En el caso que tu institución sea firmante de COARA, ¿cómo valoras el grado de dificultad de la adaptación a esas directrices?

- ☐ 1-Destacable grado de dificultad
- ☐ 2-Relativa dificultad
- ☐ 3-Poca dificultad

9. ¿Consideras que deberían excluirse de las métricas las publicaciones en acceso restringido? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

10. Comentarios a la sección

GUÍAS DE PRÁCTICA CLÍNICA (GPC)

Analizar aspectos relacionados con la autoría, implementación y uso de las GPC como indicadores del impacto de la investigación.

11. ¿Crees que se debería considerar entre los criterios para evaluación de las GPC la participación de los investigadores del instituto en su redacción? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

12. ¿Crees que deberían establecerse criterios claros de autoría de los profesionales de los IIS en la elaboración de las GPC? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

13. ¿Qué tan importante te parece medir el nivel de implantación de las GPC desarrolladas a partir de la actividad investigadora del IIS como indicador de impacto? *

- ☐ 1-Nada importante
- ☐ 2-Poco importante
- ☐ 3-Medianamente importante
- ☐ 4-Importante
- ☐ 5-Muy importante

14. ¿Consideras que es viable para un IIS medir el nivel de implantación de las GPC como indicador de impacto? *

- ☐ 1-Nada viable
- ☐ 2-Poco viable
- ☐ 3-Medianamente viable
- ☐ 4-Viable
- ☐ 5-Muy viable

15. ¿Cuáles consideras que son las principales dificultades para medir ese nivel de implantación?

16. Comentarios a la sección

TRASLACIÓN DE RESULTADOS A LA PRÁCTICA ASISTENCIAL

Evaluar la relevancia y viabilidad de medir cómo se aplican los resultados de investigación en la práctica clínica real, más allá de las guías de práctica clínica.

17. ¿Estás de acuerdo en que este es un ámbito relevante para medir el impacto? *

- ☐ 1-Nada relevante
- ☐ 2-Poco relevante
- ☐ 3-Medianamente relevante
- ☐ 4-Relevante
- ☐ 5-Muy relevante

18. ¿Consideras interesante que el IIS recoja esta información como valor añadido de su actividad? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

19. En caso afirmativo, ¿tu institución cuenta con mecanismos para recoger esta información? *

- ☐ Sí
- ☐ No
- ☐ Parcialmente
- ☐ NS/NC

20. ¿Consideras que esta información debe recogerla otra instancia ajena al IIS? *

- ☐ Sí
- ☐ No

21. En caso afirmativo, ¿quién debería recogerla? *

22. Comentarios a la sección

CO-CREACIÓN

Indagar sobre la importancia de incluir la participación activa de pacientes y ciudadanía en los proyectos como indicador de impacto.

23. ¿Debería incluirse como indicador de impacto el número de proyectos con co-participación de pacientes, ciudadanía u otros actores? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

24. ¿Considerarías como indicador de impacto la participación de la ciudadanía en la co-creación de objetivos estratégicos y/o líneas de investigación? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

25. ¿Qué nivel de relevancia le otorgas a la co-creación como indicador de impacto? *

- ☐ 1-Nada relevante
- ☐ 2-Poco relevante
- ☐ 3-Medianamente relevante
- ☐ 4-Relevante
- ☐ 5-Muy relevante

26. Comentarios a la sección

COMUNICACIÓN E INSTITUCIONALIZACIÓN DEL IMPACTO

Revisar la existencia y utilidad de planes institucionales para orientar las acciones de comunicación y evaluación del impacto. Un Plan de Impacto institucional es una estrategia organizada que define como una entidad busca generar, medir y comunicar el impacto de su investigación más allá del ámbito académico.

27. ¿Tu institución dispone de una estrategia organizada que define actuaciones orientadas a generar, medir y comunicar el impacto de su investigación más allá del ámbito académico? *

- ☐ Sí
- ☐ No
- ☐ En desarrollo
- ☐ NS/NC

28. ¿Consideras importante que las instituciones cuenten con un Plan de Impacto para orientar sus acciones de comunicación? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

29. Comentarios a la sección

PARTICIPACIÓN DE ACTORES NO CIENTÍFICOS

Considerar el valor de integrar a actores no científicos en la planificación, gobernanza, ejecución de la investigación y comunicación de resultados

30. ¿Consideras que la participación de actores no científicos en el Plan Estratégico Institucional es relevante para orientar la investigación hacia necesidades reales y maximizar su impacto? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

31. ¿Crees que incorporar a los actores no científicos en los órganos de gobierno, que responde al principio de abrir la sociedad a la I+D+i, es un indicador clave de orientación al impacto? *

- ☐ Sí
- ☐ No
- ☐ NS/NC

32. ¿Consideras que la participación de estos actores contribuye a la consecución de impacto? *

- ☐ 1-En desacuerdo
- ☐ 2-Un poco de acuerdo
- ☐ 3-Medianamente de acuerdo

- ☐ 4-Bastante de acuerdo
- ☐ 5-Muy de acuerdo

33. Comentarios a la sección

SISTEMAS DE INFORMACIÓN

Analizar la capacidad de los sistemas de información para recopilar, integrar y explotar datos relacionados con el impacto, así como su adecuación a las necesidades de evaluación actuales.

34. ¿Consideras que los sistemas de información de tu institución permiten capturar la información suficiente como para medir el impacto? *

- ☐ 1-En desacuerdo
- ☐ 2-Un poco de acuerdo
- ☐ 3-Medianamente de acuerdo
- ☐ 4-Bastante de acuerdo
- ☐ 5-Muy de acuerdo

35. Comentarios a la sección

CONSIDERACIONES GENERALES

Recoger consideraciones y valoraciones sobre la complejidad de medir el impacto y los recursos necesarios para hacerlo adecuadamente

36. ¿Cuáles consideras que son las principales barreras en tu institución para desarrollar la orientación del impacto? *

- ☐ Sensibilización
- ☐ Formación
- ☐ Apoyo tecnológico
- ☐ Sistemas de información adaptados
- ☐ Recursos humanos
- ☐ Apoyo de las instancias directivas
- ☐ Liderazgo desde la institución
- ☐ Otras

37. ¿Qué prioridad consideras que debería darse a la medición del impacto dentro de tu institución? *

- ☐ 1-Muy baja
- ☐ 2-Baja
- ☐ 3-Media
- ☐ 4-Alta
- ☐ 5-Muy alta

¿Qué grado de viabilidad percibes para que tu institución asuma los costes asociados a medir el impacto (recursos, herramientas, formación, etc.)? *

- ☐ 1-Muy baja
- ☐ 2-Baja
- ☐ 3-Media
- ☐ 4-Alta
- ☐ 5-Muy alta

- **ANEXO 5:** Informe de resultados de la segunda encuesta.

RESULTS SECONT SURVAY. WG3. IMPACT MEASUREMENT: HEALTH RESEARCH INSTITUTES (IISS)

GOBIERNO DE ESPAÑA

MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES

GdT Métricas de Impacto - Alianza IIS 2025

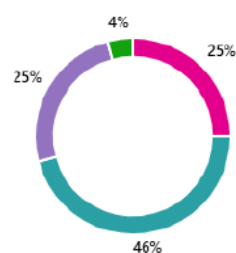
El objetivo de esta encuesta es recoger la opinión de los Institutos de Investigación Sanitaria (IIS) sobre distintos aspectos relacionados con la medición del impacto de la investigación, incluyendo indicadores, co-creación, traslación a la práctica clínica, participación de actores no científicos y capacidades institucionales. Las respuestas permitirán orientar futuras acciones y propuestas en el marco del Grupo de Trabajo de Métricas de Impacto.

Agradecemos de antemano su colaboración, y es por ello que le solicitamos si pudiese dedicar 15 minutos a contestar este cuestionario

Indicadores bibliométricos

5. ¿Consideras que los indicadores bibliométricos actuales de la Guía Técnica de Evaluación reflejan adecuadamente el impacto en salud?

1-Nada	0
2-Poco	6
3-Regular	11
4-Bastante	6
5-Mucho	1



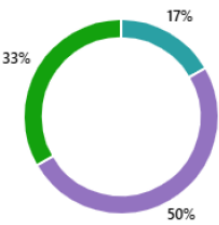
6. ¿Estás de acuerdo con complementar las métricas de los indicadores bibliométricos con indicadores de aplicabilidad o transferencia de resultados liderados?

Sí	23
No	1
NS/NC	0



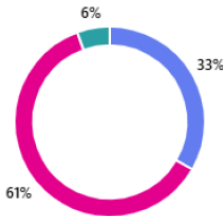
7. ¿Qué tan importante te parece adaptar los indicadores bibliométricos a las directrices de COARA (Coalition for Advancing Research Assessment)?

1-Nada importante	0
2-Poco importante	0
3-Medianamente importante	4
4-Importante	12
5-Muy importante	8



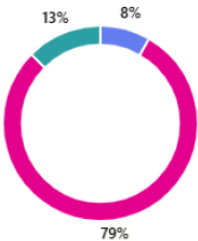
8. En el caso que tu institución sea firmante de COARA, ¿cómo valoras el grado de dificultad de la adaptación a esas directrices?

1-Destacable grado de dificultad	6
2-Relativa dificultad	11
3-Poca dificultad	1



9. ¿Consideras que deberían excluirse de las métricas las publicaciones en acceso restringido?

Sí	2
No	19
NS/NC	3



Guías de Práctica Clínica (GPC)

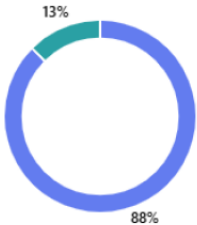
11. ¿Crees que se debería considerar entre los criterios para evaluación de las GPC la participación de los investigadores del instituto en su redacción?

● Sí	23
● No	1
● NS/NC	0



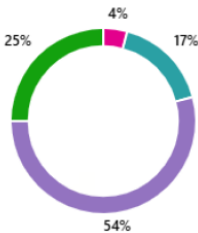
12. ¿Crees que deberían establecerse criterios claros de autoría de los profesionales de los IIS en la elaboración de las GPC?

● Sí	21
● No	0
● NS/NC	3



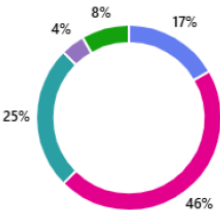
13. ¿Qué tan importante te parece medir el nivel de implantación de las GPC desarrolladas a partir de la actividad investigadora del IIS como indicador de impacto?

● 1-Nada importante	0
● 2-Poco importante	1
● 3-Medianamente importante	4
● 4-Importante	13
● 5-Muy importante	6



14. ¿Consideras que es viable para un IIS medir el nivel de implantación de las GPC como indicador de impacto?

● 1-Nada viable	4
● 2-Poco viable	11
● 3-Medianamente viable	6
● 4-Viable	1
● 5-Muy viable	2



Traslación de resultados a la práctica asistencial

17. ¿Estás de acuerdo en que este es un ámbito relevante para medir el impacto?



18. ¿Consideras interesante que el IIS recoja esta información como valor añadido de su actividad?



19. En caso afirmativo, ¿tu institución cuenta con mecanismos para recoger esta información?



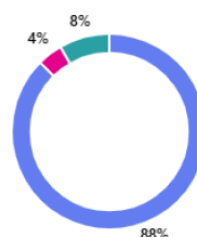
20. ¿Consideras que esta información debe recogerla otra instancia ajena al IIS?



Co-creación

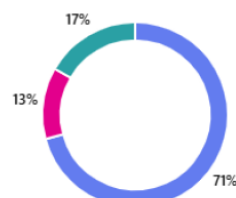
23. ¿Debería incluirse como indicador de impacto el número de proyectos con co-participación de pacientes, ciudadanía u otros actores?

● Sí	21
● No	1
● NS/NC	2



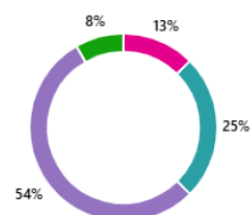
24. ¿Considerarías como indicador de impacto la participación de la ciudadanía en la co-creación de objetivos estratégicos y/o líneas de investigación?

● Sí	17
● No	3
● NS/NC	4



25. ¿Qué nivel de relevancia le otorgas a la co-creación como indicador de impacto?

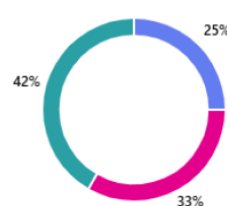
● 1-Nada relevante	0
● 2-Poco relevante	3
● 3-Medianamente relevante	6
● 4-Relevante	13
● 5-Muy relevante	2



Comunicación e institucionalización del impacto

27. ¿Tu institución dispone de una estrategia organizada que define actuaciones orientadas a generar, medir y comunicar el impacto de su investigación más allá del ámbito académico?

● Sí	6
● No	8
● En desarrollo	10
● NS/NC	0



28. ¿Consideras importante que las instituciones cuenten con un Plan de Impacto para orientar sus acciones de comunicación?

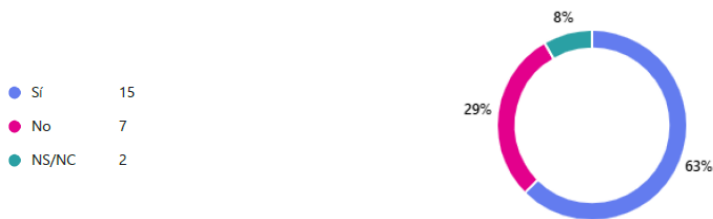


Participación de actores no científicos

30. ¿Consideras que la participación de actores no científicos en el Plan Estratégico Institucional es relevante para orientar la investigación hacia necesidades reales y maximizar su impacto?



31. ¿Crees que incorporar a los actores no científicos en los órganos de gobierno, que responde al principio de abrir la sociedad a la I+D+i, es un indicador clave de orientación al impacto?



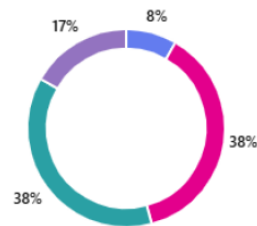
32. ¿Consideras que la participación de estos actores contribuye a la consecución de impacto?



Sistemas de información

34. ¿Consideras que los sistemas de información de tu institución permiten capturar la información suficiente como para medir el impacto?

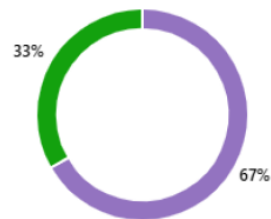
1-En desacuerdo	2
2-Un poco de acuerdo	9
3-Medianamente de acuerdo	9
4-Bastante de acuerdo	4
5-Muy de acuerdo	0



Consideraciones generales

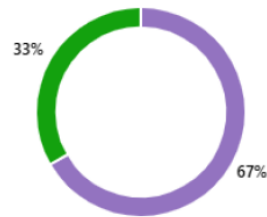
37. ¿Qué prioridad consideras que debería darse a la medición del impacto dentro de tu institución?

1-Muy baja	0
2-Baja	0
3-Media	0
4-Alta	16
5-Muy alta	8



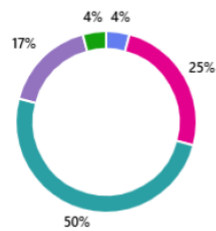
37. ¿Qué prioridad consideras que debería darse a la medición del impacto dentro de tu institución?

1-Muy baja	0
2-Baja	0
3-Media	0
4-Alta	16
5-Muy alta	8



38. ¿Qué grado de viabilidad percibes para que tu institución asuma los costes asociados a medir el impacto (recursos, herramientas, formación, etc.)?

1-Muy baja	1
2-Baja	6
3-Media	12
4-Alta	4
5-Muy alta	1



ANEXO II. SURVEY. WG4. MAP OF ACCREDITED HEALTH RESEARCH INSTITUTES

Mapa Capacidades de los IIS

Se pretende crear un Mapa de Capacidades de los grupos de investigación sanitaria acreditados, en el que se identifiquen tanto las capacidades como el potencial de I+D+i de los grupos de investigación y plataformas de apoyo a la investigación, del ecosistema de salud nacional.

Este Mapa se convierte en una base de datos que permite conocer con mayor detalle y profundidad las capacidades de los grupos de investigación y promover con mayor eficacia la participación de todo el ecosistema de salud en programas de I+D+i optimizando el uso de los recursos disponibles, de acuerdo las fortalezas e intereses de los institutos de investigación sanitarios.

1. IIS al que hace referencia

EJE 1. Capacidades científicas

Capital humano y áreas de liderazgo. Preguntas de respuesta múltiple.

En el siguiente apartado, cada centro debe mostrar las potencialidades y sus principales áreas de liderazgo, dentro de las líneas de investigación estratégicas descritas en el Plan Estatal de Ciencia y Tecnología e Innovación 2021-2027, de forma que se pueda componer un mapa con las principales fortalezas de cada centro.

2. Línea estratégica 1. Medicina de precisión

Selecciona todos los que correspondan.

- ☐ Medicina personalizada, más allá de técnicas ómicas
 - ☐ Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc. Nutrición y dieta personalizadas
 - ☐ Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
 - ☐ Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada
 - ☐ Otro:
-
-

3. Línea estratégica 2. Enfermedades infecciosas

Selecciona todos los que correspondan.

- ☐ Respuesta inmunitaria
 - ☐ Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
 - ☐ Zoonosis
 - ☐ Vacunas
 - ☐ Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
 - ☐ Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
 - ☐ Nuevos métodos de profilaxis, detección y tratamiento
 - ☐ Vigilancia de la salud y epidemiología
 - ☐ Otro:
-
-

4. Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

Selecciona todos los que correspondan.

- ☐ Ingeniería biomédica
 - ☐ Nuevas técnicas diagnósticas basadas en imagen Farmacología, farmacogenómica, nuevos fármacos y terapias Terapia génica
 - ☐ Medicina regenerativa
 - ☐ Nuevos materiales biomédicos Inteligencia Artificial
 - ☐ Nanotecnología aplicada a la biomedicina Implantes y órganos artificiales
 - ☐ Nuevas técnicas quirúrgicas Salud digital
 - ☐ Car-T
 - ☐ Otro:
-
-

5. Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

Selecciona todos los que correspondan.

- ☐ Perfiles moleculares del envejecimiento saludable
- ☐ Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)

- ☐ Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
 - ☐ Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina
 - ☐ Fragilidad y prevención de la discapacidad
 - ☐ Otro:
-
-

6. Observaciones (inserte cualquier aclaración que considere en relación a los apartados anteriores)

EJE 2. Capacidades tecnológicas / servicios

El objetivo es mostrar las infraestructuras, equipos, plataformas o servicios **generales** de cada IIS e **identificar las infraestructuras singulares**. Preferiblemente añadir un enlace de los equipos para incluir en el mapa.

*Según el Ministerio de Ciencia e Innovación, se definen **infraestructuras singulares** como aquellas que son únicas en su especie, pudiendo ser:*

-Grandes equipamientos que permitan observar, analizar e interpretar fenómenos de interés.

-Infraestructuras complejas de experimentación destinadas a crear, reproducir y estudiar fenómenos físicos, químicos, o biológicos de interés.

-Grandes infraestructuras de experimentación para la ingeniería y para el desarrollo de nuevas tecnologías de aplicación en diversos campos.

-Infraestructuras necesarias para facilitar el acceso de los científicos a entornos naturales que ofrecen y presentan características únicas para la investigación.

Fuente: Mapa de Infraestructuras Científicas y Técnicas Singulares (ICTS) 2021-2024 del Ministerio de Ciencia e Innovación.

Equipos generales se refiere a equipos de utilidad y disponibles para compartir con otros centros.

7. 1a. Tecnologías ómicas. Equipos generales

8. 1b. Tecnologías ómicas. Equipos singulares

9. 2a. Tecnologías de imagen. Equipos generales

10. 2b. Tecnologías de imagen. Equipos singulares

11. 3a. Unidades de experimentación animal. Infraestructuras o equipos generales

12. 3b. Unidades de experimentación animal. Infraestructuras, equipamiento o características singulares

13. 4a. Unidades de Biología Celular. Infraestructuras o equipos generales (p.ej. sala blanca)

14. 4b. Unidades de Biología Celular. Infraestructuras o equipos singulares

15. 5a. Investigación clínica. Servicios e infraestructuras generales (p. ej.: biobanco)

16. 5b. Servicios e infraestructuras singulares de interés en investigación clínica, p. ej. fabricación de radiofármacos y acelerador de protones (protonterapia)

17. 6a. Servicios generales de apoyo metodológico, bioinformática, estadística, IA, etc.

18. 6b. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA, etc.

19. 7. Otros equipos, unidades o infraestructuras que no encajan en las descripciones anteriores

20. 8. ¿Dispone el IIS de infraestructuras, unidades o plataformas acreditadas por alguna norma (ISO, GMP, etc.). Indicar cuáles y la norma correspondiente

EJE 3. Capacidades de traslación a la sociedad / paciente

En el siguiente apartado se trata de identificar las unidades existentes en cada centro de cara a la gestión de la transferencia e innovación, la gestión de ensayos clínicos, los canales de comunicación con asociaciones de pacientes, la gestión del dato, ...

21. A. Unidades de transferencia e innovación

Marca solo un óvalo.

	0	1	2	3	4	5	6	7	8	9	10	
No hay Personas a tiempo completo activas en 2024	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Personas a tiempo completo

22. B. Unidades de estudios clínicos

Marca solo un óvalo.

	0	1	2	3	4	5	6	7	8	9	10	
No hay Personas a tiempo completo activas en 2024	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Personas a tiempo completo

23. C. Canales de participación de asociaciones de pacientes y otros actores no científicos (web, comisiones, jornadas, etc.)

Marca solo un óvalo.

	0	1	2	3	4	5	6	7	8	9	10	
Hay unidad	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No hay

24. Observaciones. Describir los canales del apartado anterior

25. D1. Gestión de dato. El IIS dispone de un sistema de gestión y/o almacenamiento de datos de investigación institucional

Marca solo un óvalo.

Sí ☐

No ☐

26. Observaciones.

En caso de existir alguna en el apartado anterior, indicar cuál/es.

27. D2. Repositorio documental en abierto. El IIS dispone de un repositorio institucional

Marca solo un óvalo.

Sí ☐

No ☐

28. E. Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual

Selecciona todos los que correspondan.

- ☐ Técnicas de diagnóstico
- ☐ Terapia
- ☐ Dispositivos
- ☐ Prevención
- ☐ Cardiovascular
- ☐ Oncología
- ☐ Reumatología
- ☐ Nutrición o metabolismo

- ☐ Genética
- ☐ Enfermedades infecciosas
- ☐ Cirugía
- ☐ Epidemiología
- ☐ Otro:

EJE 4. Capacidades de colaboración

En el siguiente apartado se trata de identificar las principales redes de colaboración existentes.

29. 1.1 Colaboraciones temáticas. Participación en consorcios CIBER

Selecciona los que correspondan

- ☐ CIBERSAM
- ☐ CIBEROBN
- ☐ CIBERDEM
- ☐ CIBERBBN
- ☐ CIBERESP
- ☐ CIBEREHD
- ☐ CIBERER
- ☐ CIBERES
- ☐ CIBERCV
- ☐ CIBERINC
- ☐ CIBERNED
- ☐ CIBERINFEC

30. 1.2. Colaboraciones temáticas. Participación en RICORS

Selecciona todos los que correspondan.

- ☐ RIAPAd
- ☐ RICAPPS
- ☐ RICORS REI
- ☐ RICORS2040 (KIDNEY DISEASE)
- ☐ RICORS-ICTUS
- ☐ RICORS TERA V
- ☐ RICORS-SAMID

31. 1.3. Participación en plataformas del ISCIII

Selecciona todos los que correspondan.

- ☐ Ítemas
- ☐ Biobancos y biomodelos
- ☐ Sren

32. 1.2. Colaboraciones temáticas. Participación en RICORS

Selecciona todos los que correspondan.

- ☐ RIAPAd
- ☐ RICAPPS
- ☐ RICORS REI
- ☐ RICORS2040 (KIDNEY DISEASE)
- ☐ RICORS-ICTUS
- ☐ RICORS TERA V
- ☐ RICORS-SAMID

33. 1.3. Participación en plataformas del ISCIII

Selecciona todos los que correspondan.

- ☐ Ítemas
- ☐ Biobancos y biomodelos
- ☐ Sren

34. 1.4. Participación en clústers

- ☐ Clúster de salud
- ☐ Clúster tecnológico
- ☐ Otros

35. 2.1. Colaboraciones internacionales. Partenariados de proyectos europeos. Número de partenariados en los que participa el IIS (indicar web en su caso)

36. 2.2. Colaboraciones internacionales. Redes internacionales.

37. 3. Colaboración con empresas de base tecnológica. Empresas que colaboran en proyectos con el IIS

SURVEY
WG5. ARTIFICIAL INTELLIGENT.
SUBPROJECT 2: NATIONAL SURVEY: MAP OF THE STATE OF BIG DATA AND AI RESEARCH AT ISS

Versión: 1.2 · **Fecha:** 03/12/2025
Grupo de trabajo: GdT5
Coordinadores: VHIR · FJD · IISGM

Control de versiones

VERSIÓN	FECHA	CAMBIOS PRINCIPALES
1.0	15/09/2025	Publicación versión inicial
1.1	30/09/2025	Revisión GdT5-IA
1.2	02/12/2025	Revisión GT-IA ISCIII

Objetivo: Encuesta dirigida a conocer el estado actual de la capacitación para realizar investigación con Big Data e IA en los IISA, identificar obstáculos y áreas de mejora, y analizar la evolución temporal de dichas capacitaciones en nuestro país.

A quién va dirigida: Institutos de Investigación Sanitaria Acreditados de España.

Qué aporta:

1. Un **mapa de capacidades actuales para la investigación con Big Data e IA** en los IISA de España, con oportunidad para identificar barreras y obstáculos comunes y modelos de éxito exportables a otros centros.
2. Un **seguimiento de la evolución** de capacitaciones a lo largo del tiempo.

Estado del documento: en revisión final, versión semidefinitiva

Fecha de aprobación: [Pendiente]

Próxima revisión programada: [12 meses desde aprobación]

SUBPROYECTO 2: ENCUESTA NACIONAL: MAPA SOBRE LA SITUACIÓN DE LA INVESTIGACIÓN CON BIG DATA E IA EN LOS IISA

CONTACTO

CORREO ELECTRÓNICO PARA DUDAS Y ACLARACIONES (OPCIONAL)

(texto libre, formato: xxxx@xxx.xxx)

_____@_____._____

1. INFORMACIÓN GENERAL DEL CENTRO

2. NOMBRE DEL IISA:

(texto libre)

3. COMUNIDAD AUTÓNOMA:

(seleccionar una)

- ☐ Andalucía
- ☐ Aragón
- ☐ Asturias
- ☐ Balears
- ☐ Canarias
- ☐ Cantabria
- ☐ Castilla y León
- ☐ Castilla-La Mancha
- ☐ Cataluña
- ☐ Comunidad Valenciana
- ☐ Extremadura
- ☐ Galicia
- ☐ La Rioja
- ☐ Madrid
- ☐ Murcia
- ☐ Navarra
- ☐ País Vasco
- ☐ Ceuta
- ☐ Melilla

4. CENTROS VINCULADOS AL IISA:

(opción múltiple, en caso de selección centro, indicar nombre en formato texto libre)

- ☐ Hospital/-es: _____
- ☐ Centro/-s de investigación: _____
- ☐ Universidad/-es: _____
- ☐ Otros: _____

4.1. Nº aproximado de investigadores vinculados:

(respuesta única)

- ☐ < 100
- ☐ 100-249
- ☐ 250-499
- ☐ 500-999
- ☐ ≥ 1000 (especificar) _____

4.2. Nº personal de gestión y administración (soporte a la investigación, incluyendo servicios científico-técnicos):

(respuesta única)

- ☐ < 20
- ☐ 20-49
- ☐ 50-99
- ☐ 100-199
- ☐ ≥ 200 (especificar) _____

5. RECURSOS HUMANOS Y CAPACITACIÓN

5.1. ¿Dispone su centro de las siguientes unidades o servicios?

(respuesta múltiple, si selecciona otros, especificar en formato texto libre)

- ☐ Bioestadística
- ☐ Bioinformática / Big data
- ☐ Oficina de gestión de datos clínicos (data office) sin servicio de análisis de datos
- ☐ Oficina de IA aplicada a la investigación
- ☐ Otros (especificar) _____

5.2. ¿Dispone su centro de profesionales con estos perfiles? ¿De cuántos profesionales dispone en cada caso?

(respuesta múltiple, indicar cuántos. Considerar solo el personal perteneciente a estructura, no los pertenecientes a grupos de investigación). En otros: especificar perfil y cantidad

- ☐ Bioestadística; _____
- ☐ Bioinformática; _____
- ☐ Ingeniería de ciencia de datos; _____
- ☐ Ingeniería Inteligencia Artificial; _____
- ☐ Expertos en protección de datos de carácter personal; _____
- ☐ Expertos en regulatoria de IA; _____
- ☐ Otros (especificar); _____

¿Dispone su centro de programas de formación interna en IA/Big Data?

(respuesta única)

- ☐ Sí, estructurada y regular (especificar) _____
- ☐ Sí, ocasional (especificar) _____
- ☐ En desarrollo
- ☐ No

6. INFRAESTRUCTURA TECNOLÓGICA

6.1. Infraestructura de almacenamiento de datos

6.1.1. ¿Cómo almacena el IIS los datos?

(selección múltiple)

- ☐ Infraestructura física on premise-centralizada en el propio IIS
- ☐ Infraestructura física on premise-centralizada en el centro hospitalario
- ☐ Infraestructura física on premise-no centralizada, en los grupos de investigación.
- ☐ Infraestructura en la nube
- ☐ Otros (especificar) _____

En caso de respuesta múltiple, describa el reparto:

6.1.2. ¿Dispone el IIS de una estrategia para repercutir los costes del uso del almacenamiento al grupo de investigación usuario?

(respuesta única)

- ☐ Sí, definida
- ☐ Sí, en desarrollo
- ☐ No
- ☐ No aplica / no lo sabe

6.1.3. En el caso de la infraestructura de almacenamiento en la nube, seleccionar el modelo de nube utilizado:

(respuesta múltiple)

- ☐ Nube pública (Azure, AWS, Google, etc.)
- ☐ Nube gestionada por una institución externa con uso privado
- ☐ Nube privada gestionada por el propio IIS / centro hospitalario
- ☐ Otros (especificar)

Nube gestionada por institución externa: infraestructura de terceros (p.ej., BSC, CSUC, RedIRIS). Servicio compartido (multi-tenant), acceso por proyectos/cuotas/convocatorias, escalado según oferta. Coste por uso/acuerdos marco/subvención. Cumplimiento/seguridad: políticas del proveedor; el IIS encaja su DPIA, ENS/ISO en esos marcos.

Nube privada gestionada por IIS/hospital: infraestructura propia (on-premise), control total (HW, red, contenedores, colas, políticas). Modelo single-tenant o multi-tenant interno, prioridades/cuotas propias. Con Costes CAPEX+OPEX. Cumplimiento/seguridad: controles propios alineados a ENS/ISO, integración directa con redes clínicas, identidades corporativas y residencia del dato local.

6.1.4. Modelo de contratación de los datos en la nube:

(respuesta múltiple)

- ☐ Pago por uso
- ☐ Financiación institucional / subvencionado
- ☐ Otro (especificar) _____

6.1.5. Capacidades técnicas de almacenamiento (en caso de más de una, especificar en cada lugar):

6.1.5. 1. Almacenamiento alta velocidad centralizada en el IIS:

(respuesta única)

- ☐ < 50 TB
- ☐ 50–200 TB
- ☐ 200–500 TB
- ☐ 500 TB – 1PB
- ☐ > 1PB (especificar) _____
- ☐ No aplica

6.1.5. 2. Almacenamiento alta velocidad centralizada en el centro hospitalario:

(respuesta única)

- ☐ < 50 TB
- ☐ 50–200 TB
- ☐ 200–500 TB

- ☐ 500 TB – 1PB
- ☐ > 1PB (especificar) _____
- ☐ No aplica

6.1.5. 3. Almacenamiento total alta velocidad no-centralizada en los grupos de investigación:

(respuesta única)

- ☐ < 50 TB
- ☐ 50–200 TB
- ☐ 200–500 TB
- ☐ 500 TB – 1PB
- ☐ 1PB (especificar) _____
- ☐ No aplica

6.1.5. 4. Almacenamiento alta velocidad en la nube:

(respuesta única)

- ☐ < 50 TB
- ☐ 50–200 TB
- ☐ 200–500 TB
- ☐ 500 TB – 1PB
- ☐ > 1PB (especificar) _____
- ☐ No aplica

6.1.5. 5. Sistema almacenamiento-centralizado, con redundancia y seguridad:

(respuesta única)

- ☐ No
- ☐ Si, RAID (especificar Nivel RAID 1 a 6): _____
- ☐ Si, sin RAID (especificar sistema de redundancia empleado) _____

6.1.5. 6. Sistema centralizado de copias de seguridad en cinta:

(respuesta única)

- ☐ Si, Cinta (LTO-Linear Tape-Open u otras)
- ☐ No
- ☐ Otro sistema de backup (especificar: disco, nube, etc): _____

6.1.5. 7. Periodo de retención (p.ej. 30 días, 3 meses, 5 años):

(texto libre)

6.1.6. Administración de almacenamiento (quién administra -instala, configura, gestiona, gobierna, realiza copias de seguridad- los sistemas de almacenamiento):

(respuesta única)

- ☐ Se administra centralizadamente por el departamento de IT o similares
- ☐ Cada grupo de investigación administra sus sistemas de almacenamiento
- ☐ Mixto (especificar) _____

6.2. Infraestructura de computación y supercomputación

6.2.1. ¿Dónde se encuentra la infraestructura de computación?

(respuesta múltiple)

- ☐ Infraestructura física on premise en el IIS
- ☐ Infraestructura física on premise-local en grupos de investigación
- ☐ Infraestructura externa (en la nube)
- ☐ No dispone de infraestructura propia

En caso de respuesta múltiple, detallar _____

6.2.2. En el caso de la infraestructura on premise, ¿ dónde se encuentran los servidores de computación y supercomputacion?

(respuesta múltiple)

- ☐ En el Centro de Procesamiento Datos centralizado y ubicado en el IIS
- ☐ En el CPD del hospital
- ☐ Cada grupo de investigación tiene / gestiona sus servidores

En caso de selección múltiple, detallar _____

6.2.3. ¿Dispone el IIS de una estrategia para repercutir los costes del uso de los servicios de computación al grupo de investigación usuario?

(respuesta única)

- ☐ Sí, definida
- ☐ Sí, en desarrollo
- ☐ No
- ☐ No aplica

6.2.4. En el caso de la infraestructura de computación en la nube, seleccionar el modelo de nube utilizado:

(respuesta múltiple)

- ☐ Nube pública (Azure, AWS, Google, etc.)
- ☐ Nube gestionada por una institución externa (BSC, CSUC, REDIRIS...)
- ☐ Nube privada gestionada por el propio IIS / hospital
- ☐ Otros (especificar) _____

Nube gestionada por institución externa: infraestructura de terceros (p.ej., BSC, CSUC, RedIRIS). Servicio compartido (multi-tenant), acceso por proyectos/cuotas/convocatorias, escalado según oferta. Coste por uso/acuerdos marco/subvención. Cumplimiento/seguridad: políticas del proveedor; el IIS encaja su DPIA, ENS/ISO en esos marcos.

Nube privada gestionada por IIS/hospital: infraestructura propia (on-prem/housing), control total (HW, red, contenedores, colas, políticas). Modelo single-tenant o multi-tenant interno, prioridades/cuotas propias. Costes CAPEX+OPEX. Cumplimiento/seguridad: controles propios alineados a ENS/ISO, integración con redes clínicas e identidades corporativas.

6.2.5. Modelo de contratación de los servicios de computación en la nube:

(respuesta múltiple)

- ☐ Pago por uso
- ☐ Financiación institucional / subvencionado
- ☐ Contrato marco con proveedor público (ej. RedIRIS, CSUC)
- ☐ Otro (especificar) _____

6.2.6. Capacidades técnicas de computación centrada en CPD IIS:

(respuesta única)

- ☐ Básica (< 200 cores/nucleos)
- ☐ Media (200–1000 cores/nucleos)
- ☐ Alta (> 1000 cores) (especificar/nucleos) _____
- ☐ No aplica

6.2.7. Capacidad de supercomputación (GPU) centrada en CPD IIS:

(respuesta única)

- ☐ Nula
- ☐ Baja (1–10 GPUs)
- ☐ Media (11–50 GPUs)
- ☐ Alta (> 50 GPUs) (especificar número GPUs) _____
- ☐ No aplica

6.2.8. Capacidades técnicas de computación centrada en CPD Hospital:

(respuesta única)

- ☐ Básica (< 200 cores/nucleos)
- ☐ Media (200–1000 cores/nucleos)
- ☐ Alta (> 1000 cores) (especificar/nucleos) _____
- ☐ No aplica

6.2.9. Capacidad de supercomputación (GPU) centrada en CPD Hospital:

(respuesta única)

- ☐ Nula
- ☐ Baja (1–10 GPUs)
- ☐ Media (11–50 GPUs)
- ☐ Alta (> 50 GPUs) (especificar número GPUs) _____
- ☐ No aplica

6.2.10. Capacidades técnicas de computación no centralizada, en servidores locales gestionadas por cada grupo:

(respuesta única)

- ☐ Básica (< 200 cores/nucleos)
- ☐ Media (200–1000 cores/nucleos)
- ☐ Alta (> 1000 cores) (especificar/nucleos) _____
- ☐ No aplica

6.2.11. Capacidad de supercomputación (GPU) no centralizada, en servidores locales gestionados por cada grupo:

(respuesta única)

- ☐ Nula
- ☐ Baja (1–10 GPUs)
- ☐ Media (11–50 GPUs)
- ☐ Alta (> 50 GPUs) (especificar número GPUs) _____
- ☐ No aplica

6.2.12. Capacidades técnicas de computación externalizada (CSUC,BSC,...) :

(respuesta única)

- ☐ Básica (< 200 cores/nucleos)
- ☐ Media (200–1000 cores/nucleos)
- ☐ Alta (> 1000 cores) (especificar/nucleos) _____
- ☐ No aplica

6.2.13. Capacidad de supercomputación (GPU) externalizada (CSUC,BSC,RedIris,...):

(respuesta única)

- ☐ Nula
- ☐ Baja (1–10 GPUs)
- ☐ Media (11–50 GPUs)
- ☐ Alta (> 50 GPUs) (especificar número GPUs) _____
- ☐ No aplica

6.2.14. ¿Quién administra (instala, configura, gestiona, gobierna, realiza copias de seguridad,...) la infraestructura local de los grupos?

(respuesta única)

- ☐ Departamento de IT
- ☐ El propio grupo de investigación
- ☐ Otros (especificar) _____

6.2.15. ¿Quien administra los sistemas de computación y almacenaje centralizados?

(respuesta única)

- ☐ Departamento de IT
- ☐ Otros (especificar) _____

6.3. Estrategia y gestión de la ciberseguridad en el IIS

6.3.1. ¿Dispone el IIS de una política institucional de ciberseguridad que incluya procedimientos, recursos y formación específica para la protección de datos en investigación biomédica?

(respuesta única)

- ☐ Sí, existe una estrategia formal y consolidada
- ☐ Si, está en desarrollo
- ☐ No
- ☐ No existe estrategia formal, pero se aplican medidas puntuales (especificar) _____

6.3.2. En caso afirmativo, ¿qué ámbitos están cubiertos en la estrategia de ciberseguridad?

(respuesta múltiple)

- ☐ Planes de respuesta ante incidentes de seguridad
- ☐ Protocolos de continuidad de negocio y recuperación ante desastres
- ☐ Formación periódica al personal investigador y técnico
- ☐ Auditorías internas/externas de seguridad
- ☐ Certificaciones (ISO 27001, ENS u otras)
- ☐ Otros (especificar) _____

7. GOBERNANZA Y MODELO DE GESTIÓN

7.1. ¿Dispone el IIS de una política de gobernanza de datos clínicos definida?

(respuesta única)

- ☐ Sí, aprobada y publicada
- ☐ Sí, existente pero no publicada
- ☐ Sí, en desarrollo
- ☐ No

7.2. En caso afirmativo, ¿está esta política consensuada con el hospital de referencia?

(respuesta única)

- ☐ Sí, aprobada conjuntamente
- ☐ En proceso de consenso
- ☐ No

7.3. Tecnologías empleadas para gestión de datos:

(respuesta múltiple)

- ☐ RedCAP
- ☐ Omibio
- ☐ OpenClinica
- ☐ Castor EDC
- ☐ Medidata Rave
- ☐ OpenEDC
- ☐ Plataforma propia interna
- ☐ Otros (especificar) _____

7.4. Tecnologías de orquestación / contenedores:

(respuesta múltiple)

- ☐ Kubernetes
- ☐ Docker
- ☐ Singularity / Apptainer
- ☐ Otros (especificar)

7.5. ¿Cómo accede el IIS a los datos clínicos del hospital?

(respuesta única)

- ☐ No accede
- ☐ Acceso in situ únicamente dentro del recinto del hospital
- ☐ Acceso remoto mediante VDI (Virtual Desktop Infrastructure), VPN (Virtual Private Network), VLAN (Virtual Local Area Network)/ escritorio seguro
- ☐ Otros (especificar) _____

7.6. Modelo de compartición de datos entre el hospital y el IIS:

(respuesta única)

- ☐ Pseudoanonimizados
- ☐ Anonimizados
- ☐ En crudo (sin anonimizar)
- ☐ No se comparten

7.7. Formas de compartición de datos clínicos con otros centros de investigación

(respuesta múltiple)

- ☐ Anonimización
- ☐ Pseudoanonimización
- ☐ Plataformas federadas (los datos no salen del centro)
- ☐ Generación y compartición de datos sintéticos
- ☐ Acuerdos de transferencia de datos (DTA)
- ☐ Plataformas europeas (EGA, EHDS, etc.)
- ☐ Otros (especificar) _____

8. ÉTICA Y REGULATORIA

8.1. ¿Se ha previsto alguna política/planificación relativa a la futura aplicación del Reglamento europeo sobre IA?

(respuesta múltiple)

- ☐ Sí
- ☐ No
- ☐ En proceso

8.2. ¿Dispone su IIS de certificación ENS (Esquema Nacional de Seguridad)?

(respuesta única)

- ☐ Sí
- ☐ En proceso
- ☐ No

8.2.1. En caso de disponer de certificación ENS, nivel de seguridad de la certificación ENS:

(respuesta única)

- ☐ Bajo
- ☐ Medio
- ☐ Alto

8.2.2. En caso de disponer de certificación ENS, tipología de datos bajo la certificación ENS:

(respuesta múltiple)

- ☐ Datos de carácter general / administrativos (Ejemplo: información de contacto, datos de proyectos, facturación, inventario de equipos...)
- ☐ Datos personales no sensibles (Ejemplo: nombre y apellidos de investigadores, curricular, datos profesionales.)
- ☐ Datos personales sensibles (categorías especiales del RGPD) (Ejemplo: datos de salud de pacientes, historia clínica, datos genómicos, biomarcadores.)
- ☐ Datos de investigación biomédica agregados / anonimizados (no reversible) (Ejemplo: cohortes estadísticas anonimizadas, big data pseudonimizado para IA.)
- ☐ Datos de investigación biomédica agregados pseudoanonimizados (reversible=) (Ejemplo: cohortes estadísticas anonimizadas, big data pseudonimizado para IA.)
- ☐ Datos críticos para continuidad del servicio (Ejemplo: sistemas de supercomputación, CPDs, infraestructuras que soportan ensayos clínicos o proyectos europeos.)
- ☐ Otros _____

8.3. ¿Dispone su IIS de certificación ISO 27001?

(respuesta única)

- ☐ Sí
- ☐ En proceso
- ☐ No

8.4. ¿Dispone su centro de un Comité de Ética de Datos?

(respuesta única)

- ☐ Sí
- ☐ En proceso
- ☐ No

8.5. En caso afirmativo, el Comité de Ética de Datos es:

(respuesta única)

- ☐ Propio (dentro del CEIm)
- ☐ Independiente
- ☐ Compartido

8.6. ¿Se ha desarrollado una estrategia interna para integrar los principios éticos en los Proyectos de IA?:

(respuesta única)

- ☐ Sí
- ☐ En proceso
- ☐ No

8.7. Adherencia a la normativa ética y regulación aplicable:

(respuesta múltiple)

- ☐ Declaración de Helsinki
- ☐ RGPD
- ☐ EU Artificial Intelligence Act
- ☐ Reglamento europeo sobre Productos Sanitarios
- ☐ Beneficencia / no maleficencia
- ☐ Equidad / ausencia de sesgos
- ☐ Transparencia / explicabilidad
- ☐ Privacidad / protección de datos
- ☐ Supervisión humana
- ☐ Ninguno formalizado

8.8. ¿Cuenta su CEIm con expertise específico para evaluación de proyectos sobre IA?

(respuesta única)

- ☐ Sí
- ☐ No

8.9. Las bases de datos utilizadas para el desarrollo de IA (entrenamiento, validación, prueba), ¿cumplen con la normativa de protección de datos y su utilización?

(respuesta única)

- ☐ Sí
- ☐ No

8.10. En el desarrollo de sistemas de IA que tienen un fin médico, ¿se prevén desde fases tempranas (idea/diseño) los recursos necesarios para la certificación del sistema de IA como producto sanitario?

(respuesta única)

- ☐ Sí, en todos los casos
- ☐ Sí, en algunos casos
- ☐ No

8.11. En el caso de los sistemas de IA ya desarrollados, ¿se ha procedido a la certificación como Productos Sanitarios con IA de acuerdo con su finalidad de uso antes de su implementación clínica?

(respuesta única)

- ☐ Sí, en todos los casos
- ☐ Sí, en algunos casos
- ☐ No

8.12. ¿Se aplican en su centro guías de referencia para garantizar las Buenas Prácticas en Investigación con IA?

(respuesta única)

- ☐ Sí, en todos los casos
- ☐ Sí, en algunos casos
- ☐ No

8.13. ¿Qué guías de referencia se utilizan?

(respuesta múltiple)

- ☐ SPIRIT-AI
- ☐ CONSORT-AI
- ☐ TRIPOD-AI
- ☐ STARD-AI
- ☐ Otros _____
- ☐ No aplica

8.14. ¿Participa su instituto en proyectos relacionados con el Espacio Europeo de Datos de Salud (EHDS)?

(respuesta única)

- ☐ Sí, con proyectos en marcha
- ☐ No, en proceso de incorporación
- ☐ No

8.15. ¿Dispone el IIS de una estrategia institucional para acompañar a los investigadores a desarrollar evaluaciones de impacto de protección de datos de carácter personal?

(respuesta única)

- ☐ Sí, con proyectos en marcha
- ☐ No, en proceso de incorporación
- ☐ No

8.16. ¿Dispone el IIS de una estrategia institucional para acompañar a los investigadores a desarrollar evaluaciones de impacto derivadas del Reglamento Europeo de Inteligencia Artificial?

(respuesta única)

- ☐ Sí, con proyectos en marcha
- ☐ No, en proceso de incorporación
- ☐ No

8.17. ¿Dispone el IIS de una estrategia institucional de gobernanza que permita detectar si se cumplen las obligaciones que se derivan del Reglamento Europeo de Inteligencia Artificial?

(respuesta única)

- ☐ Sí, con proyectos en marcha
- ☐ No, en proceso de incorporación
- ☐ No

9. PROYECTOS CON USO DE BIG DATA E IA EN INVESTIGACIÓN BIOMÉDICA:

9.1. ¿Existe en su centro un circuito definido para la preparación, planificación y aprobación de proyectos con uso de Big Data e IA?

(respuesta única)

- ☐ Sí
- ☐ En proceso de definición
- ☐ No
- ☐ Otros: (especificar) _____

9.2. ¿Con qué tipología de datos se trabaja en los proyectos de investigación del centro?

(respuesta múltiple)

- ☐ Historia Clínica Electrónica:
 - Datos Clínicos
 - Datos de Laboratorio
 - Imagen médica
 - Otros
- ☐ Wearables / dispositivos médicos
- ☐ Genómicos / ómicos
- ☐ Biobanco
- ☐ Administrativos / gestión
- ☐ Socioeconómicos
- ☐ Ambientales
- ☐ Registros nacionales/autonómicos
- ☐ Otros (especificar) _____

9.3. Respecto a los datos clínicos, ¿existe en su centro u hospital asociado la posibilidad de obtener volcado masivo para uso secundario en investigación?

(respuesta única)

- ☐ Sí
- ☐ En proceso de construcción
- ☐ No
- ☐ Otros: (especificar) _____

9.4. Respecto a los datos clínicos, ¿con qué nivel de estandarización están disponibles?

(respuesta única)

- ☐ Datos clínicos no estandarizados.
- ☐ Datos parcialmente estandarizados (OMOP, i2b2, CDISC, FHIR, SNOMED, LOINC, OMOP, etc.)
- ☐ Datos completamente estandarizados (OMOP, i2b2, CDISC, FHIR, SNOMED, LOINC, OMOP, etc)

9.5. ¿Qué nivel de integración tienen los datos clínicos entre centros?

(respuesta múltiple)

- ☐ Local (entre centros pertenecientes al IIS)
- ☐ Provincial (entre centros de la región o provincia)
- ☐ Autonómico (entre centros de la Comunidad Autónoma)
- ☐ Ninguna de las anteriores

9.6. Número de proyectos activos con Big Data / IA en el año previo:

(respuesta única)

- ☐ 0
- ☐ 1-9
- ☐ 10-24
- ☐ 25-49
- ☐ ≥ 50 (especificar): _____
- ☐ NS/NC

9.7. Número de proyectos activos con Big Data / IA en el año actual

(respuesta única)

- ☐ 0
- ☐ 1-9
- ☐ 10-24
- ☐ 25-49
- ☐ ≥ 50 (especificar): _____
- ☐ NS/NC

9.8. Número de proyectos con Big Data / IA finalizados en el año previo

(respuesta única)

- ☐ 0
- ☐ 1-9
- ☐ 10-24
- ☐ 25-49
- ☐ ≥ 50 (especificar): _____
- ☐ NS/NC

9.9. N° de investigadores implicados en proyectos con Big Data/IA:

(respuesta única)

- ☐ 0
- ☐ 1-9
- ☐ 10-24
- ☐ 25-49
- ☐ ≥ 50 (especificar): _____
- ☐ NS/NC

9.10. Estos proyectos son estudios:

(indicar % en cada categoría, suma debe ser 100%)

- ☐ (%) prospectivos
- ☐ (%) retrospectivos
- ☐ (%) Mixtos

9.11. ¿En qué estado de madurez se encuentran estos proyectos?

(indicar % en cada categoría, suma debe ser 100%)

- ☐ (%) Fase de idea
- ☐ (%) Fase de diseño
- ☐ (%) Fase de desarrollo
- ☐ (%) Fase de validación
- ☐ (%) Fase de marcado CE
- ☐ (%) Fase de implementación en la práctica clínica

9.12. ¿Están sus proyectos protegidos intelectualmente?

(respuesta única)

- ☐ Sí, en su totalidad
- ☐ Sí, parcialmente
- ☐ No

9.13. ¿En qué áreas se aplican los proyectos de investigación con IA? Indique el % aproximado

(respuesta múltiple, suma debe ser 100%)

- ☐ (%) Investigación clínica
- ☐ (%) Epidemiología / salud poblacional
- ☐ (%) Imagen médica (radiología, anatomía patológica, oftalmología, etc.)
- ☐ (%) Genómica / multi-ómica
- ☐ (%) Gestión hospitalaria / eficiencia
- ☐ (%) Otras (especificar) _____

9.14. Fuentes de financiación de los proyectos de investigación con Big Data e IA:

(respuesta múltiple, suma de % debe ser 100%)

- ☐ Fondos europeos (Horizon Europe, Digital Europe, etc.) ____%
- ☐ Fondos nacionales (ISCIII / Agencia Estatal de Investigación) ____%
- ☐ Fondos autonómicos ____%
- ☐ Fondos privados (industria farmacéutica, tecnológica) ____%
- ☐ Fondos propios del IIS ____%
- ☐ Otros (donaciones, ... especificar) _____ %

9.15. ¿Participa el IIS en colaboraciones público-privadas para el desarrollo de proyectos de investigación con Big Data e IA?

(respuesta única)

- ☐ Sí
- ☐ No

9.16. ¿Cuenta su IIS con participación ciudadana y de pacientes en proyectos de IA?

(respuesta única)

- ☐ Sí, estructurada (comités, grupos de trabajo)
- ☐ Sí, puntual
- ☐ No

9.17. ¿Participa su centro en consorcios multicéntricos en proyectos de IA?

(respuesta múltiple)

- ☐ Sí, a nivel local/regional
- ☐ Sí, a nivel nacional
- ☐ Sí, a nivel internacional
- ☐ Sin participación en estudios multicéntricos

9.18. ¿Dispone de proyectos en marcha con aprendizaje federado?

(respuesta única)

- ☐ Sí, en operación
- ☐ Planificados
- ☐ No

9.19. En caso afirmativo, indique qué plataformas utiliza: (respuesta múltiple)

- ☐ OTwin
- ☐ Flower

- ☐ FATE
- ☐ Google FL
- ☐ Otras (especificar) _____

9.20. ¿Se utiliza IA Generativa en los proyectos de investigación del IIS?

(respuesta única)

- ☐ Sí, en varios proyectos
- ☐ Sí, en piloto
- ☐ No
- ☐ NS/NC

9.21. ¿Se utilizan datos sintéticos en los proyectos de investigación del IIS?

(respuesta única)

- ☐ Sí
- ☐ En exploración
- ☐ No

10. OBSTÁCULOS Y RETOS:

10.1. ¿Cuáles son las principales barreras para llevar a cabo los proyectos con Big Data e IA en su instituto?

(respuesta múltiple)

- ☐ Demasiadas obligaciones regulatorias
- ☐ Falta de conocimiento de las obligaciones regulatorias
- ☐ Técnicas (interoperabilidad, estandarización)
- ☐ Financiación insuficiente
- ☐ Infraestructura insuficiente
- ☐ Escasez de personal cualificado
- ☐ Dificultades de colaboración entre centros
- ☐ Dificultad de obtención del dato para investigación
- ☐ Otros (especificar) _____

10.2. Tiempo medio de aprobación de proyectos Big Data/IA en CEIm:

(respuesta única)

- ☐ < 3 meses
- ☐ 3–6 meses
- ☐ > 6 meses

10.3. Una vez aprobado el proyecto, tiempo medio de espera para recepción de los datos clínicos para su desarrollo:

(respuesta única)

- ☐ < 3 meses
- ☐ 3–6 meses
- ☐ > 6 meses

10.4. ¿Cuáles son las dificultades de la transferencia de activos de IA generados en investigación?

(respuesta múltiple)

- ☐ Financieros
- ☐ Aprobaciones por organismos reguladores.
- ☐ Falta de conocimiento del proceso de transferencia.
- ☐ Alta competencia internacional
- ☐ Política de implementación en el sistema nacional de salud.
- ☐ Otros (especificar) _____

11. PERSPECTIVAS Y NECESIDADES

11.1. Principales necesidades inmediatas:

(respuesta múltiple)

- ☐ Infraestructura tecnológica
- ☐ Personal especializado
- ☐ Formación
- ☐ Marco normativo
- ☐ Gobernanza
- ☐ Financiación
- ☐ Colaboración con otros centros
- ☐ Otras (especificar) _____

11.2. Que ayudaría más al IIS para poder desarrollar Proyectos de IA (ordenar de 1 a 5 del más importante al menos importante):

(respuesta múltiple)

- ☐ (___) Financiación específica
- ☐ (___) Formación
- ☐ (___) Infraestructuras
- ☐ (___) Adaptación de la normativa europea a nivel español
- ☐ (___) Otros (especificar) _____

11.3. Expectativas de evolución en 3–5 años:

(especificar) _____

12. OBSERVACIONES ADICIONALES:

12.1. ¿Considera útil repetir la encuesta periódicamente?

- ☐ Sí, cada año
- ☐ Sí, cada 2 años
- ☐ No

12.2. Otras observaciones finales

ANNEX III. BIBLIOGRAPHY AND REGULATIONS.

WG 2. NEW PROFESSIONAL ROLES IN ACCREDITED HEALTH RESEARCH INSTITUTES (IISS)

ANEXO B. NORMATIVA Y ESTÁNDARES DE REFERENCIA (SELECCIÓN)

- RGPD y LOPDGDD (protección de datos).
- ICH-GCP E6(R2) y RD 1090/2015 (ensayos clínicos).
- Reglamento (UE) 2017/745 (MDR) y 2017/746 (IVDR) para dispositivos y diagnósticos in vitro.
- ISO 9001, ISO 15189, ISO 17025 (sistemas de gestión y laboratorios).
- ISO 20387 (biobancos) y guías de biobancos nacionales.
- Estándares HL7-FHIR y DICOM (interoperabilidad y imagen).

WG 4. CAPABILITIES MAP OF ACCREDITED HEALTH RESEARCH INSTITUTES

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- Estrategia Española de Ciencia, Tecnología e Innovación (2021-27).
- Plan Estatal de Investigación Científica, Técnica y de Innovación (2024-27).
- Guía técnica de evaluación de acreditación de los IIS.
- Mapa de Infraestructuras Científicas y Técnicas Singulares (ICTS) 2021-2024 del Ministerio de Ciencia e Innovación.

WG5. ARTIFICIAL INTELLIGENT. SUBPROJECT 1: POSITION PAPER: ARTIFICIAL INTELLIGENCE IN HEALTHCARE RESEARCH

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NORMATIVA CONSULTADA

- Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos (Reglamento General de Protección de Datos).
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- **MDCG 2020-1 (2020): clinical evaluation/performance evaluation of medical device software.** Comisión Europea.
 - Enlace: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_1_guidance_clinic_eva_md_software_en_0.pdf
- **MDCG – índice de documentos y otras guías.** Comisión Europea.
 - Enlace: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

- **AEMPS – legislación y guías sobre productos sanitarios (incluye RD 192/2023).**
 - Enlace: <https://www.aemps.gob.es/la-aemps/legislacion/legislacion-sobre-productos-sanitarios/>

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- **ICH E6(R3) Guideline for Good Clinical Practice (GCP).** ICH, Step 4/Final (06.01.2025).
 - Enlace: <https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline#ich-e6r3-principles-and-annex-1-current-version-effective-from-23-july-2025-8264>
- **ISO 14155:2020 – investigación clínica de productos sanitarios en sujetos humanos (GCP).** Organización Internacional de Normalización.
 - Enlace (ficha oficial): <https://www.iso.org/standard/71690.html>

NORMAS TÉCNICAS (CALIDAD, SOFTWARE Y RIESGO)

- **IEC 62304 – procesos del ciclo de vida del software de producto sanitario.** ISO/IEC Webstore.
 - Enlace: <https://www.iso.org/standard/38421.html>
- **ISO 14971:2019 – gestión de riesgos para productos sanitarios.** ISO.
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CIBERSEGURIDAD Y RESILIENCIA

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 - Enlace: <https://www.boe.es/buscar/doc.php?id=DOUE-L-2025-80049>
- **Ley de Ciberresiliencia (CRA, *Cyber Resilience Act*):** en vigor **10/12/2024**; obligaciones principales desde **11/12/2027**.
 - Enlace: <https://digital-strategy.ec.europa.eu/en/library/cyber-resilience-act>
- **Directiva (UE) 2022/2555** del Parlamento Europeo y del Consejo de 14 de diciembre de 2022 relativa a las medidas destinadas a garantizar un elevado nivel común de ciberseguridad en toda la Unión. Conocida como **NIS2**.
 - Enlace: <https://www.boe.es/buscar/doc.php?id=DOUE-L-2022-81963>
- **Real Decreto 311/2022, de 3 de mayo, por el que se regula el Esquema Nacional de Seguridad. (ENS):**
 - Enlace: <https://www.boe.es/buscar/act.php?id=BOE-A-2022-7191>
- **CSIRT de referencia:** **INCIBE-CERT** (privado) y **CCN-CERT** (sector público/AGE); coordinación y notificación definidas en **RD-ley 12/2018** y **RD 43/2021**.
- **Dictamen del Comité Europeo de las Regiones Ciberseguridad de los hospitales y los prestadores de asistencia sanitaria.**
 - Enlace: https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=OJ:C_202504415

- **ISO/IEC 27001** es un estándar para la seguridad de la información (*Information security, cybersecurity and privacy protection - Information security management systems - Requirements*)
 - Enlace: <https://www.iso.org/es/norma/27001>
- **ISO/IEC 27002** es una norma internacional que brinda orientación a las organizaciones que desean **establecer, implantar y mejorar un sistema de gestión de seguridad de la información** (SGSI) centrado en la **ciberseguridad**.
 - Enlace: <https://www.iso.org/es/contents/data/standard/07/56/75652.html>
- **ISO/IEC 27701** es una norma internacional que especifica los requisitos y aporta orientación para **establecer, implementar, mantener y mejorar continuamente un sistema de gestión de información de privacidad** (PIMS).
 - Enlace: <https://www.iso.org/es/contents/data/standard/08/58/85819.html>
- **IEC 81001-5-1:2022** establece los requisitos de seguridad para el software sanitario y los **HITS**.
 - Enlace: <https://www.iso.org/standard/76097.html>
- **ISO/IEC 30111** es una norma internacional que describe el manejo adecuado de la información de posibles vulnerabilidades en productos.
 - Enlace: <https://www.iso.org/standard/69725.html>
- **ISO/IEC 29147** es una norma internacional que proporciona directrices para los procesos de divulgación de vulnerabilidades..
 - Enlace: <https://www.iso.org/es/contents/data/standard/07/23/72311.html>

DATOS, ÉTICA Y GOBERNANZA DE LA IA EN SALUD

- **Ethics guidelines for trustworthy AI**. High-Level Expert Group on AI, Comisión Europea (08.04.2019).
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INTEROPERABILIDAD Y TERMINOLOGÍAS

- **HL7 FHIR – overview y especificación**. HL7.
 - Enlace: <https://hl7.org/fhir/overview.html>
- **DICOM – estándar y edición vigente**. NEMA/MITA.
 - Enlaces: <https://dicomstandard.org> y <https://dicom.nema.org/medical/dicom/current>
- **openEHR – especificaciones**.

Enlace: <https://specifications.openehr.org/>

- **OMOP Common Data Model – documentación**. OHDSI.
 - Enlace: <https://ohdsi.github.io/CommonDataModel/>

ANNEX IV. ADDITIONAL DOCUMENTATION
GDT 1: PARTICIPACION CIUDADANA. CUADRO DE MANDO

DIMENSIÓN	OBJETIVOS ESPECÍFICOS	ACCIONES CLAVE	INDICADORES PROPUESTOS	MEDICIÓN	OBSERVACIONES
1. Gobernanza y estrategia institucional	Consolidar un marco organizativo que integre a la ciudadanía en la misión, planificación y definición de estrategias, organización y gestión del IIS	Inclusión de la ciudadanía en órganos de gobierno	Presencia de representantes de ciudadanía en órganos de gobernanza (1)	Si/No + N°	
		Aprobación de la política de participación ciudadana	Política de participación ciudadana aprobada por el IIS y en vigor	Si/No + Fecha	
		Creación del Grupo de Trabajo de Participación Ciudadana (GTPC) (2)	N° total de reuniones del Grupo de trabajo/comisión de participación ciudadana realizadas por año (3)	N°	
			Participación de la Ciudadanía en el CCI	Si/No + N°	Incluido en nueva GTE
			Existencia de un Plan Estratégico institucional que incluya la participación ciudadana y/o de la sociedad (si/no) (4)	Si/No	Incluido en nueva GTE
2. Diseño y ejecución de proyectos de investigación / innovación	Incluir activamente a la ciudadanía en todas las fases del proceso de investigación y en la definición de las líneas estratégicas de los IIS		Existe un plan de traslación e innovación y transferencia de resultados científicos del IIS a la práctica clínica y al sector productivo, en el propio entorno y a nivel global. Esta estrategia incluye acciones para la participación de actores clave no científicos	Si/No	Incluido en nueva GTE
		Participación en el diseño y ejecución, de proyectos	Número de proyectos de investigación con participación ciudadana documentada en el diseño (cocreación) y la ejecución	N°	

DIMENSIÓN	OBJETIVOS ESPECÍFICOS	ACCIONES CLAVE	INDICADORES PROPUESTOS	MEDICIÓN	OBSERVACIONES
3. Formación y capacitación ciudadana	Desarrollar capacidades en la ciudadanía para una participación efectiva	Formación en investigación para ciudadanía	Nº de actividades de formación dirigidas a ciudadanía y otros actores clave no científicos realizadas anualmente	Nº	Al menos 1 al año. Incluido en nueva GTE
		Elaboración de materiales formativos	Nº total de personas que completaron actividades formativas con registro de asistencia.	Nº	
			% de satisfacción de los participantes ciudadanos formados	%	Medida a través de encuestas
			Nº de actividades de formación sobre participación y co-creación en investigación científica u otras formas de abrir la participación en la investigación a la ciudadanía	Nº	Al menos una vez en los últimos 2 años en GTE
4. Comunicación y diseminación de resultados	Asegurar una comunicación clara, accesible y bidireccional con la ciudadanía	Elaboración de materiales accesibles	Nº de materiales divulgativos/informes de resultados de investigación en lenguaje claro y accesible	Nº	
		Difusión comprensible de los resultados	Nº de encuentros ciudadanos, foros o jornadas realizados anualmente	Nº asistentes	
		Establecimiento de canales de comunicación	Existencia de una sección específica en el portal web para mecanismos de participación ciudadana	Si/No	Incluido en nueva GTE
5. Evaluación del impacto de la participación y mejora continua	Medir el valor añadido de la participación ciudadana en la investigación	Aplicación de métodos de evaluación cualitativa	Inclusión de indicadores de participación ciudadana en la memoria científica anual (5)	Si/No	
		Seguimiento del impacto	Nº de artículos científicos firmados como coautores o con mención (material y métodos, agradecimientos...) de ciudadanía en el año.	Nº	
		Realización de encuestas de satisfacción	% de satisfacción de los participantes involucrados en el proceso de participación	%	Satisfacción global

DIMENSIÓN	OBJETIVOS ESPECÍFICOS	ACCIONES CLAVE	INDICADORES PROPUESTOS	MEDICIÓN	OBSERVACIONES
6. Recursos y sostenibilidad	Asegurar recursos estables que permitan una participación ciudadana duradera	Asignación de un presupuesto específico	Financiación anual dedicada en el IIS para promover actividades de participación ciudadana	%	% sobre total del presupuesto e incluir financiación interna y externa
		Asignación de personal técnico específico	Nº de personas asignadas como personal técnico de apoyo a la participación ciudadana (6)	Nº	
			Nº de convocatorias del Plan Propio con criterios específicos de participación ciudadana	Nº	
7. Representación, inclusión y diversidad	Garantizar la diversidad y representatividad de los participantes	Seguimiento sociodemográfico	Diversidad sociodemográfica de las personas participantes	Índice de diversidad	En función de sexo, edad, nivel educativo, origen, etc
		Aplicación de estrategias inclusivas	Nº de acciones específicas para incluir colectivos vulnerables o infrarrepresentados.	Nº	
			Nº de colectivos vulnerables representados en las actividades.	Nº	
		Establecimiento de convenios con asociaciones	Nº de convenios/acuerdos firmados con asociaciones de base ciudadana.	Nº	

Observaciones:

(1) Tener en cuenta la tipología de representación a la hora de seleccionar la representación ciudadana (representante de asociaciones, comunidad educativa, paciente tipo, estratificación edades ciudadanía, balance de género, etc.).

(2) Considerar la creación de un reglamento de funcionamiento interno del grupo de trabajo que establezca como mínimo: perfiles de los integrantes, funciones, régimen de funcionamiento.

(3) Documentar las reuniones mediante actas.

(4) Incluir acciones concretas dentro del Plan Estratégico. Valorar la creación de un subplan específico sobre participación ciudadana.

(5) Establecimiento de, como mínimo, un indicador común para todos los IIS (se tendría que establecer a través del ISCIII)

(6) Nº personal con dedicación exclusiva o parcial.

Cada indicador deberá acompañarse de su fuente de verificación (actas, memorias, informes, publicaciones o registros internos del IIS) para garantizar la trazabilidad y la calidad de los datos reportados.

Salvo que se indique lo contrario, la periodicidad de medición de los indicadores será anual.

La revisión sistemática de este cuadro de mando permitirá identificar áreas de mejora, promover buenas prácticas y reforzar la cultura de evaluación, aprendizaje y participación en los IIS.

El Instituto de Salud Carlos III, en coordinación con los IIS acreditados, podrá definir un conjunto de indicadores comunes para facilitar la evaluación agregada y la comparación entre instituciones.

GDT4. MAPA DE CAPACIDADES

Respuestas recibidas del formulario por parte de los IIS acreditados ordenados por Comunidad Autónoma.

ANDALUCÍA

IBIMA Plataforma BIONAND - Instituto de Investigación Biomédica de Málaga y Plataforma en Nanomedicina

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. MEDICINA PERSONALIZADA, MÁS ALLÁ DE TÉCNICAS ÓMICAS
2. INTEGRACIÓN DE TECNOLOGÍAS DE PROTEÓMICA, GENÓMICA, EPIGENÓMICA, METABOLÓMICA, ETC.
3. NUTRICIÓN Y DIETA PERSONALIZADAS
4. MEDICINA PERSONALIZADA EN CÁNCER, ENFERMEDADES RARAS, SALUD MENTAL Y OTRAS PATOLOGÍAS
5. ASPECTOS SOCIOLÓGICOS, PSICOLÓGICOS, ECONÓMICOS, ÉTICOS, INTELIGENCIA ARTIFICIAL, SALUD DIGITAL EN LA MEDICINA PERSONALIZADA

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Vacunas
3. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Inteligencia Artificial
5. Nanotecnología aplicada a la biomedicina
6. Salud digital

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
4. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina
5. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías de imagen. Equipos singulares

<https://ibima.eu/es/nanoimagen/>

2.2. Unidades de Biología Celular. Infraestructuras o equipos singulares

<https://ibima.eu/es/produccion-celular-y-salas-gmp/>

2.3. Otros equipos, unidades o infraestructuras

<https://ibima.eu/es/histologia/>

2.4 Infraestructuras, unidades o plataformas acreditadas

- Nanoimagen y Biobanco certificadas por ISO9001:2015.
- Sala GMP certificada para la fabricación de Medicamentos en Investigación de Uso Humano, AEMPS.
- Unidad de Gestión de la Investigación certificada por UNE166.002:2021.
- Unidad de Fase I de ensayos clínicos en proceso de certificación.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Web, comisiones (Comité Científico Interno - AECC), jornadas, Claustros, reuniones, visitas al instituto

3.2. Gestión de dato.

FUNDANET, INVESTIGA+, Portal iSALUD

3.3. Repositorio documental en abierto.

3.4 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

Técnicas de diagnóstico; Terapia; Dispositivos; Prevención; Cardiovascular; Oncología; Reumatología; Nutrición o metabolismo; Genética

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberOBN/CiberDEM/CiberEHD/CiberER/CiberCV/CiberONC/CiberNED

4.2 Colaboraciones temáticas. Participación en RICORS

RIAPAd/RICAPPS/RICORS2040 (KIDNEY DISEASE)/RICORS-ICTUS/RICORS TERAV/RICORS-SAMID

4.3. Participación en plataformas del ISCIII

Items; Biobancos y biomodelos; Sren

4.4. Participación en clúster

Clúster de salud/Otros

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

15 Partenariados de proyectos europeos: CONECT4CHILDREN, iGAME, TRANSBIOLINE, AC19/00082 DrNanoDALL, 3TR, AFFIRMO, halt-RONIN, ProCure, PROVIDE, INTERACT-EUROPE 100, ORTHOALLOUNION, LIVERaTION, ERA4Health, STOP IATRO, ECRAID-Base

4.6 Colaboraciones internacionales. Redes internacionales.

Colaboración de varios grupos del Instituto en 38 redes europeas.

4.6. Colaboración con empresas de base tecnológica

Se colabora con empresas de base tecnológica para el desarrollo de proyectos de investigación. Por ejemplo, en el último año se han firmado 23 acuerdos con este objetivo.

IBiS – Instituto de Biomedicina de Sevilla

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
3. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Terapia génica
5. Medicina regenerativa
6. Nuevos materiales biomédicos
7. Inteligencia artificial
8. Nanotecnología aplicada a la biomedicina
9. Implantes y órganos artificiales
10. Nuevas técnicas quirúrgicas
11. Salud digital
12. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
4. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina
5. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías ómicas. Equipos singulares

GeneChip de ThermoFisher Scientific; SECUENCIDOR AB3500; SISTEMA DE ANÁLISIS DE LA EXPRESIÓN GÉNICA ; Miseq; Cromatógrafo líquido de alta presión (HPLC); Espectrómetro de masas híbrido cuadrupolo Orbitrap (LC-MS Quadrupole-Orbitrap); nano-HPLC Easy-nLC 1000

2.2 Unidades de experimentación animal. Equipos singulares

Resonancia magnética.

2.3 Infraestructuras, unidades o plataformas acreditadas

Instalaciones de animalario (EQUIPAMIENTO SALA DE LIMPIEZA Y ESTERILIZACIÓN*:1. CENTRAL DE ASPIRACION DE VIRUTAS CON CICLON DE DESCARGA AUTOMATICA (SE RENOVÓ EL ANTIGUO).; 2. SISTEMA AUTOMÁTICO DE LLENADO DE BATEAS; 3. AUTOCLAVE ESTERILIZADORA VAPOR 20l.; 4. SISTEMA DE PREPARACIÓN DE MATERIAL5. CARROS DE AUTOCLAVE Y TRANSPORTE; 6 EQUIPO DE LIMPIEZA ULTRASONIDOS7. SISTEMAS DE DESCONTAMINACIÓN POR NEBULIZACIÓN EQUIPAMIENTO ESTABULACIÓN*:1. RACKS VENTILADOS SEAL SAFE PARA RATA RATÓN (25 UNIDADES) + UNIDADES DE VENTILACIÓN (10 UNIDADES); 2. CABINAS DE FLUJO LAMINAR DE CAMBIO (5 UNIDADES)3. CABINAS DE SEGURIDAD BIOLÓGICA (2 UNIDADES); 4. UNIDAD DE RECUPERACIÓN EL EQUIPAMIENTO DE ESTABULACIÓN DE ADQUIRIÓ AL INICIO Y SE HA IDO RENOVANDO EN PARTE GRACIAS A AYUDAS DE INFRAESTRUCTURAS.

Quirófano Experimental

2.4. Unidades de Biología Celular.

CITÓMETRO ANALIZADOR ; MICROSCOPIO FLUORESCENTE CON ESTEREOLOGÍA; MICROSCOPIO FLUORESCENTE CON ESTEREOLOGÍA; Cámaras de Hipoxia; CITÓMETRO ANALIZADOR; Microscopio confocal espectral de barrido LEICA TCS-SP2 AOBS; Microscopio confocal espectral de barrido LEICA TCS-SP2; Microscopía confocal de barrido de alta velocidad y alta resolución Nikon A1R+, con el sistema de super-resolución STORM y con el sistema TIRF; Microdisector láser MMI-SLML sobre microscopio de fluorescencia invertido; SEPARADOR CELULAR; CITÓMETRO ANALIZADOR; CITÓMETRO ANALIZADOR ESPECTRAL

2.5 Infraestructuras, unidades o plataformas acreditadas

Fabricación Car T

2.6 Infraestructuras, unidades o plataformas acreditadas

La sala blanca se ha acreditado por las normas de correcta fabricación (NCF, GMP en inglés) de la AEMPS. Que a su vez se rigen/cumplen las farmacopea europea, de la EMA.- Certificación sistema de gestión de la I+D+i conforme con la Norma UNE 166002:2021 para las actividades de “Investigación, Desarrollo e Innovación en Ciencias Clínicas, Cirugía, Tecnología de los ordenadores, Tecnología Médica y Estadística” que se realizan en el HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO - INSTITUTO DE BIOMEDICINA DE SEVILLA.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Web (Sociedad y divulgación); Semana de la ciencia; Noche de l@s investigador@s; IBiSiviliza (Jornada de puertas abiertas); Visita centros educativos; Comisión de Divulgación y Sociedad

3.2. Gestión de dato.

Investiga+/Portal I+D+i

3.3. Repositorio documental en abierto.

El IIS no dispone, pero sí cada una de las entidades consorciadas (CSIC, Universidad, BVSSPA)

3.4 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Prevención
- Cardiovascular
- Oncología
- Genética
- Enfermedades infecciosas
- Cirugía
- Epidemiología
- Otro: salud digital

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

- CiberSAM

- CiberESP
- CiberEHD
- CiberER
- CiberES
- CiberONC
- CiberNED
- CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

- RICORS REI
- RICORS2040 (KIDNEY DISEASE)
- RICORS-ICTUS
- RICORS TERA V

4.3. Participación en plataformas del ISCIII

- Items
- Biobancos y biomodelos
- Sren

4.4. Colaboraciones internacionales. Partenariados de proyectos europeos.

tipo ERANETs: 6 activos en 2025

EITHealth: 24 activos en 2025

4.5 Colaboraciones internacionales. Redes internacionales.

REDES INTERNACIONALES CON FINANCIACIÓN GESTIONADA POR FISEVI - 8 ACTIVOS
EN 2025 ACCIONES COST: 5 (4 de partner y 1 de coordinador)

4.6. Colaboración con empresas de base tecnológica

En 2024, se afianzaron 9 alianzas con la industria para la realización de proyectos en colaboración entre empresas y algunos de nuestros grupos de investigación.

IIS ibs.GRANADA - Instituto de Investigación Biosanitaria de Granada

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
2. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
3. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
4. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen
2. Farmacología, farmacogenómica, nuevos fármacos y terapias
3. Terapia génica
4. Medicina regenerativa
5. Nuevos materiales biomédicos
6. Implantes y órganos artificiales
7. Car-T
8. Otro: Bioimpresión 3D

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías ómicas. Equipos singulares

BIACORE T200; ION S5 (NGS).

2.2 Unidades de experimentación animal. Equipos singulares

Microscopio quirúrgico de experimentación.

2.3 Infraestructuras, unidades o plataformas acreditadas

Sala Blanca con certificado de cumplimiento de NFC.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Comisiones, web, jornadas, eventos.

3.2. Gestión de dato.

Fund@net

3.3. Repositorio documental en abierto.

RISalud, Digibug.

3.4 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Prevención
- Oncología
- Nutrición o metabolismo
- Genética
- Enfermedades infecciosas
- Cirugía
- Epidemiología
- Otro: tecnologías de la información y comunicación

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

- CiberOBN
- CiberESP
- CiberEHD
- CiberER
- CiberFES
- CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

- RICORS2040 (KIDNEY DISEASE)
- RICORS TERA V
- RICORS-SAMID

4.3. Participación en plataformas del ISCIII

- Itemas
- Biobancos y biomodelos
- Sren

4.4. Colaboraciones internacionales. Partenariados de proyectos europeos.

ERA4Health (<https://era4health.eu/>); Innovative Health Initiative (<https://www.ih.europa.eu/>); ERAPerMed (<https://erapermed.isciii.es/>)

4.5 Colaboraciones internacionales. Redes internacionales.

Colaboraciones activas en 2023: EATRIS, ECRIN, CA19132 (ENABLE ADHERENCE), CA18127 (NUCLEOME), CA21113 (GenE-Humdi), CA21108 (NETSKINMODELS), CA21116 (TRANSPAN), CA18138 (Riseup-PPD), CA22114 (TREASURE).

4.6. Colaboración con empresas de base tecnológica

INNITIUS, PHARMAMEL, NARANJO INTELLIGENT SOLUTIONS.

IMIBIC - Instituto Maimónides de Investigación Biomédica de Córdoba

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Nutrición y dieta personalizadas
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Zoonosis
4. Vacunas
5. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
6. Nuevos métodos de profilaxis, detección y tratamiento
7. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen
1. Terapia génica
2. Inteligencia Artificial
3. Nuevas técnicas quirúrgicas
4. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías ómicas

Plataforma de Espectrometría de masas e imagen molecular del IMIBIC (<https://www.imibic.org/core-facilities%2Fproteomica>): Equipamiento para Proteómica y Metabolómica

2.2. Tecnologías de imagen

Plataforma de Espectrometría de masas e imagen molecular del IMIBIC (<https://www.imibic.org/core-facilities%2Fproteomica>): Imagen Molecular (MSImaging (Proteómica/Lipidómica))

Plataforma de Imagen Preclínica: MicroCT, PET-RMN (<https://www.imibic.org/core-facilities%2Fimagen-preclinica>) (ver respuesta 3b)

2.3 Unidades de experimentación animal.

Equipo de Imagen y Plataforma PET-RMN-MicroCT

2.4. Unidades de Biología Celular.

Sala P3

2.5 Infraestructuras, unidades o plataformas acreditadas

Unidades de: Genómica, Espectrometría de masas e imagen molecular, Citometría de flujo, microscopía Óptica Avanzada y Biobanco. Todas ellas por ISO9001

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Web del IIS, 4 comisiones del IMIBIC cuentan con actores no científicos (Formación, Investigación clínica, Innovación e Igualdad), el IMIBIC recibe visitas de asociaciones de pacientes y otros actores no científicos.

3.2. Gestión de dato

Fundanet, CTMS y una nueva intranet en desarrollo

3.3. Repositorio documental en abierto

Desde la Biblioteca Virtual del SSPA, se ha creado un repositorio a nivel regional (RISALUD), pero no lo tenemos a nivel institucional.

3.4 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia

- Dispositivos
- Cardiovascular
- Oncología
- Reumatología
- Nutrición o metabolismo
- Enfermedades infecciosas
- Cirugía

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberOBN / CiberEHD / CiberER / CiberFES / CiberCV / CiberONC / CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICORS REI /RICORS2040 (KIDNEY DISEASE)

4.3. Participación en plataformas del ISCIII

- Items
- Sren

4.4 Participación en clúster

- Clúster de salud

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

2 (ERA4Health y, aprobada pero aún no activa TRANSCAN 3)

4.6 Colaboraciones internacionales. Redes internacionales.

7 COSTs

4.7. Colaboración con empresas de base tecnológica

Bioincubadora (con más de 9 empresas)

ARAGÓN

IIS Aragón - Instituto de Investigación Sanitaria de Aragón

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas.
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.

3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías.
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune.
2. Enfermedades emergentes y reemergentes causadas por hongos, bacterias y virus.
3. Vacunas.
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes.
5. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica.
2. Nuevas técnicas diagnósticas basadas en imagen.
3. Medicina regenerativa.
4. Nuevos materiales biomédicos.
5. Inteligencia Artificial.
6. Nanotecnología aplicada a la biomedicina.
7. Implantes y órganos artificiales.
8. Nuevas técnicas quirúrgicas.
9. Car-T.

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer).
2. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable.

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Unidades de experimentación animal. Infraestructuras, equipamiento o características singulares

Servicio de cirugía experimental y animales inmunodeficientes

2.2. Otros equipos, unidades o infraestructuras

Unidad de investigación toxicológica mediante nanotecnología.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1 *Know How.* Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

1. Técnicas de diagnóstico.

2. Terapia.
3. Dispositivos.
4. Enfermedades infecciosas.
5. Cirugía.

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberOBN / CiberBBN / CiberESP / CiberEHD / CiberER / CiberCV / CiberONC / CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICAPPS

4.3. Participación en plataformas del ISCIII

Itemas, Biobancos y biomodelos, Sclera

4.4 Participación en clúster

Clúster de Salud

ASTURIAS

ISPA - Instituto de Investigación Sanitaria del Principado de Asturias

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas,
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.,
3. Nutrición y dieta personalizadas,
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías,

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune,
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus,
3. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes,
4. Nuevos métodos de profilaxis, detección y tratamiento,
5. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica,
2. Farmacología, farmacogenómica, nuevos fármacos y terapias,
3. Medicina regenerativa,
4. Inteligencia Artificial,
5. Nanotecnología aplicada a la biomedicina,
6. Implantes y órganos artificiales,
7. Nuevas técnicas quirúrgicas,
8. Salud digital,
9. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

En este anexo se incluyen las infraestructuras, equipos y/o servicios **singulares**, no los generales

2.1 Tecnologías ómicas

Proteómica en bruto y en célula aislada.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1 Canales de participación

Página web. Organización de eventos. Canal de comunicación y difusión.

3.2. Gestión de dato

Sistema de almacenamiento compartido.

3.3 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual:
Técnicas de diagnóstico, Terapia, Oncología, Cirugía

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberESP / CiberER/ CiberES/CiberONC

4.2 Colaboraciones temáticas. Participación en RICORS

RICORS2040 (KIDNEY DISEASE); RICORS-ICTUS

4.3. Participación en plataformas del ISCIII

ITEMAS; Biobancos y biomodelos;

4.4 Participación en clúster

Clúster salud

4.5 Colaboraciones internacionales. Participación en partenariados europeos

JPND (<https://neurodegenerationresearch.eu>) Transcan (<https://transcan.eu>)

4.6 Colaboraciones internacionales. Redes internacionales.

EATRIS

4.6. Colaboración con empresas de base tecnológica

Platelet biotechnologies

BALEARES

IDISBa -Instituto de Investigación Sanitaria Illes Balears

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Nutrición y dieta personalizadas
2. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune,
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus,
3. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes,
4. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Medicina regenerativa,
2. Nuevos materiales biomédicos,
3. Inteligencia Artificial,
4. Nanotecnología aplicada a la biomedicina,
5. Nuevas técnicas quirúrgicas,
6. Salud digital,
7. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

Perfiles moleculares del envejecimiento saludable,

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías ómicas

Plataforma de Análisis multiómicos en imagen molecular basada en espectrometría de masas de ultra-alta resolución (en proceso de compra)

2.2. Unidades o plataformas acreditadas

Plataforma Biobanco y Biomodelos: ISO9001:2015

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1 Canales de participación

3 canales

3.2 Gestión del dato

PRISIB: plataforma de investigación en salud Illes Balears

3.3 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual: **Técnicas de diagnóstico; Dispositivos; Nutrición o metabolismo; Genética; Enfermedades infecciosas; Cirugía.**

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberOBN/ CiberESP/CiberER/CiberES/CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICAPPS/RICORS-ICTUS

4.3. Participación en plataformas del ISCIII

Itemas / Biobancos y biomodelos /Scren

4.4 Participación en clúster

Clúster tecnológico

4.5 Colaboraciones internacionales. Partenariados de proyectos europeos

Health 4Eukids; Relecar 2.0; Reverse; Healthy W8; Integrativ; Ambrosia; Tenet

4.6 Colaboraciones internacionales. Redes internacionales.

PISCIIIB, BBMRI, SCRn, ECRIN, EHDEN, OHDSI, EATRIS, EOSC

CANTABRIA

IDIVAL - Instituto de Investigación Marqués de Valdecilla

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada más allá de las técnicas ómicas
2. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías.

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune.
2. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes.
3. Nuevos métodos de profilaxis, detección y tratamiento.

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica.
2. Nuevas técnicas quirúrgicas.
3. Car-T.

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad.
2. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable.

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Otros equipos, unidades o infraestructuras

Biblioteca Marquesa de Pelayo

2.2. Infraestructuras, unidades o plataformas acreditadas

ISO 9001:2015 Biobanco Valdecilla

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Redes sociales, canal de Youtube, Jornadas conjuntas con asociaciones de pacientes, visitas escolares a IDIVAL, jornadas de divulgación conjuntas.

Con universidad (semana de la ciencia, noche de los investigadores, la mujer en ciencia, pint of science, etc.).

3.2 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual. Destaca el área de **Cirugía**

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberBBN/ CiberEHD / CiberONC/ CiberNED/CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICORS2040 (KIDNEY DISEASE)/ RICORS-SAMID

4.3. Participación en plataformas del ISCIII

ITEMAS; Biobancos y biomodelos; Sclero

4.4 Colaboraciones internacionales. Partenariados en Proyectos Europeos.

THCS (<https://www.thcspartnership.eu/>)

4.5. Colaboración con empresas de base tecnológica

ONCOMATRYX BIOPHARMA S.L.; AMBAR TELECOMUNICACIONES S.L.; BIOSYSTEMS, S.A.; BIOINTAXIS S.L.; IDP DISCOVERY PHARMA, S.L.; INHIBITEC ANTICUERPOS SL

CASTILLA Y LEÓN

IBSAL - Instituto de Investigación Biomédica de Salamanca

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Sepsis

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen
2. Farmacología, farmacogenómica, nuevos fármacos y terapias
3. Terapia génica
4. Medicina regenerativa
5. Inteligencia Artificial
6. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
2. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías ómicas. Equipos singulares

Plataforma de proteómica de altas prestaciones

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Comisión ciudadana del IBSAL

Participación en comisiones del instituto

Participación en jornadas del instituto

3.2. Gestión de dato.

Plataforma

3.3. Repositorio documental en abierto.

Zenodo. Se ha creado la comunidad IBSAL

3.4 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Prevención
- Cardiovascular
- Nutrición o metabolismo
- Otro: actividad física. Satisfacción de usuarios

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberFES / CiberCV / CiberONC / CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RIAPAd/RICAPPS/RICORS REI/RICORS2040 (KIDNEY DISEASE)/RICORS TERA V

4.3. Participación en plataformas del ISCIII

- Scleren

4.4 Participación en clúster

4.5 Colaboraciones internacionales. Redes internacionales.

ECRIN; COST

4.6. Colaboración con empresas de base tecnológica

PHILIPS. MEDTRONIC

CATALUÑA

I3PT -Institut d'Investigació i Innovació Parc Taulí

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Nutrición y dieta personalizadas
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
5. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada
6. Otro: Medicina de precisión y personalizada en el paciente crítico y en enfermedades autoinmunes sistémicas.

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
3. Vigilancia de la salud y epidemiología
4. Otro: Sepsis

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Terapia génica
5. Medicina regenerativa
6. Nuevos materiales biomédicos
7. Inteligencia Artificial
8. Nanotecnología aplicada a la biomedicina
9. Nuevas técnicas quirúrgicas
10. Salud digital

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Infraestructuras, unidades o plataformas acreditadas

Laboratorio de impresión 3D: licencia de fabricación de producto sanitario a medida

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Web Redes sociales Jornadas y conferencias dirigidas a la ciudadanía y/o pacientes Visitas al centro de investigación Visitas y talleres a institutos de secundaria Participación en comités: CEIm

3.2. Gestión de dato.

FUNDANET, REDCap

3.3. Repositorio documental en abierto.

DDD UAB, CORA RDR, Portal de investigación, Portal de Recerca de Catalunya

3.4 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

Técnicas de diagnóstico; Terapia; Dispositivos; Prevención; Oncología; Enfermedades infecciosas; Cirugía; Otro: Salud mental

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM/CiberDEM/CiberEHD/CiberES

4.2. Participación en plataformas del ISCIII

Ítemas

4.3. Colaboraciones internacionales. Partenariados de proyectos europeos.

INTELLILUNG: <https://intellilung-project.eu/consortium-members/>

EHDEN: <https://www.ehden.eu/datapartners/>

N-PATH: <https://npath.eu/#consortium>

ECOQUIP: <https://www.ecoquip.eu/A>

VASCOVID: <https://vascovid.eu/partners/#3---cspt>

TOUCH: Towards the next generatiOn of excellent yoUng doctoral researchers on mental health by developing an intersectoral & transdisciplinary approaCH European Commission (europa.eu)

FLIGHT: Fostering research careers in LIGHT sciences; CORDIS | European Commission (europa.eu)

GENESYS: en fase de negociación, todavía no ha empezado.

4.4 Colaboraciones internacionales. Redes internacionales.

EHPPA: A network providing a strategic position in the European market. I3PT shares innovative public procurement practices within this network.

EDHEN: A network focused on generating knowledge and evidence, enabling the execution of innovation projects with data.

EURIPHI: European network to promote a change in innovation procurement practices in European healthcare systems around the concept of value-based purchasing (Value Based Public Procurement).

4.5. Colaboración con empresas de base tecnológica

PULSO EDICIONES, S.L.; STIMULO DESIGN S.L.; TESAI CARE S.L.; ANAIS Medical S.L.; BetterCare S.L.; Tailor Surgery S.L.; HP S.L. Brawn S.L.; Eodyne S.L.; Tree logic S.L.; DEDALUS S.L.; Mediktor S.L.; T Systems S.L.; AsorCad S.L.; Loopdx S.L.; VecMedical S.L.; V Ventura S.L.; Brain Health Solutions S.L.; Eurecat Centre Tecnològic

IDIBELL - Instituto de Investigación Biomédica de Bellvitge

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Nutrición y dieta personalizadas
2. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Vacunas
2. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
3. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen
2. Farmacología, farmacogenómica, nuevos fármacos y terapias
3. Terapia génica
4. Medicina regenerativa
5. Implantes y órganos artificiales
6. Nuevas técnicas quirúrgicas
7. Salud digital
8. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Servicios e infraestructuras singulares de interés en investigación clínica

Síntesis de radiofármacos PET

2.2. Otros equipos, unidades o infraestructuras

Unidad de citometría de flujo: <https://idibell.cat/es/servicios/servicios-cientificotecnico/citometria-de-flujo/>

Unidad de Interacciones Moleculares: <https://idibell.cat/es/servicios/servicios-cientificotecnico/interacciones-moleculares/>

Laboratorio de Ratones: <https://idibell.cat/es/servicios/servicios-cientificotecnico/ratones-y-micromanipulacion-de-embriones/>

Estabulario de Pez Cebra: <https://idibell.cat/es/servicios/servicios-cientificotecnico/estabulario/>

Banco de Células Madre: <https://idibell.cat/es/servicios/servicios-cientificotecnico/banco-celulas-madre/>

Unidad de Investigación Clínica en Ensayos Clínicos: <https://idibell.cat/es/servicios/servicios-cientificotecnico/uicec/>

2.3 Infraestructuras, unidades o plataformas acreditadas

Biobanco (ISO 9001:2015)

UICEC (ISO 9001:2015)

Área de Innovación y desarrollo de negocio (UNE 166002:2021)

Estabulario (Acreditación AAALAC)

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

- Jornadas Investigación y salud, estamos cerca de ti: jornadas coorganizadas con asociaciones de pacientes del territorio (Barcelona, L'Hospitalet y Baix Llobregat)
- Procesos de priorización de proyectos de investigación: asociaciones, o empresas colaboradoras, que participan activamente en la definición de la investigación del IDIBELL priorizando, para su financiación, los proyectos que proponen los investigadores del instituto.
- Visitas a los laboratorios: ofrecemos sesiones de visitas a las instalaciones de investigación, que comprenden charlas y espacios para el diálogo. Se gestionan a través de la Fundació La Marató de 3Cat y también mediante vínculo directo con asociaciones de pacientes que donan recursos para la investigación.
- Proyectos de co-creación con la ciudadanía: como el proyecto de investigación +ACTIU, que se centra en la salud comunitaria y promueve la participación de la ciudadanía en el diseño y cocreación de ciudades más activas y saludables que faciliten la práctica de actividad física.

3.2. Gestión de dato

Idibell dispone como sistema de almacenamiento de datos de investigación las cabinas de discos NetApp, que proporcionan almacenamiento SAN con alta redundancia y diversas opciones de conectividad, y que

permiten ajustes y mantenimiento sin interrupciones. El sistema está integrado con el programario de copias de seguridad Commvault y con el Directorio Activo de Microsoft, asegurando la integridad y disponibilidad de los datos de investigación del centro.

3.3. Repositorio documental en abierto.

No hay repositorio documental abierto propio, pero tenemos acceso al repositorio de publicaciones de la Universidad de Barcelona (Dipòsit Digital UB) y el repositorio de datos CORA del Consorci de Serveis Universitaris de Catalunya (CSUC), donde contamos con colecciones propias.

3.4 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Prevención
- Cardiovascular
- Oncología
- Nutrición o metabolismo
- Genética
- Cirugía
- Epidemiología

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberOBN / CiberDEM / CiberBBN / CiberESP / CiberEHD / CiberER / CiberES / CiberCV / CiberONC / CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

Σ RICORS TERAV

4.3. Participación en plataformas del ISCIII

- Items
- Biobancos y biomodelos
- Sren

4.4 Participación en clúster

- Clúster de salud

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

Actualmente, IDIBELL participa en 7 partenariados como socio y en 1 como coordinador. De estos 8 partenariados, 1 está financiado por el ISCIII, 4 por ISCIII/AECC y 3 por el Departament de Salut Catalán.

4.5 Colaboraciones internacionales. Redes internacionales.

La Unidad de Investigación Clínica en Ensayos Clínicos del IDIBELL (UICEC) forma parte de la red europea ECRIN de infraestructuras de investigación clínica.

Centro Experto por EATRIS designado en 2023, para ofrecer servicios de apoyo a la innovación de alto valor añadido. Así el Área de Innovación y Desarrollo Empresarial del IDIBELL podrá ofrecer servicios en las áreas de Soporte Normativo, Gestión de la Innovación y Soporte a la Factibilidad Traslacional.

Además, en estos momentos 4 grupos de investigación del instituto participan en COST Actions, una de ellas desde la coordinación.

4.6. Colaboración con empresas de base tecnológica

Jorge S.L., MiMARK Diagnostics, Oryzon Genomics, Reveal Genomics, Werfen, Bicara Therapeutics, Vivan Therapeutics, Mogling Bio, Phillips, Canon Medical Systems, Biogen, Sanofi, Novartis, Aveo, Daiichi Sankyo, ALMA Medical, Papelmatic, Medtronic, Ommniscope, Alexion Pharma, Palex Medical, Cambrian Bio, Hoffmann-La Roche, Euroimmun, RoslinCT, AstraZeneca.

IGTP - Instituto de investigación Germans Trias i Pujol

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Vacunas
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
5. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
6. Nuevos métodos de profilaxis, detección y tratamiento
7. Vigilancia de la salud y epidemiología
8. Otro

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen
2. Terapia génica

3. Medicina regenerativa
4. Nuevos materiales biomédicos
5. Inteligencia Artificial
6. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
2. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
3. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías ómicas. Equipos singulares

Secuenciadores Illumina MiSeq y NextSeq, GeneTitan

2.2 Tecnologías de imagen. Equipos singulares

Microscopio confocal STEDICON y microscopio superresolución ABBERIOR

2.3 Unidades de experimentación animal. Equipos singulares

CMCiB Resonancia Magnética 3T (ensayos pre-clínicos y clínicos) y sala de radiodiagnóstico para animal grande

2.4. Unidades de Biología Celular. Infraestructuras o equipos singulares

Plataforma de Proteómica y Metabolómica, Plataforma de Citometría

2.5. Servicios e infraestructuras singulares de interés en investigación clínica

Resonancia Magnética de 3T

2.6. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

Centro de Procesamiento de Datos (CPD)

2.7. Otros equipos, unidades o infraestructuras

Plataforma de Criobiología

2.8 Infraestructuras, unidades o plataformas acreditadas

CMCiB tiene implementadas las BPL

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Gestión de dato.

Fundanet

3.2 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico

- Terapia
- Dispositivos
- Prevención
- Cardiovascular
- Oncología
- Reumatología
- Genética
- Enfermedades infecciosas
- Cirugía
- Otro: Neurología, gastroenterología

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

- CiberESP
- CiberEHD
- CiberES
- CiberCV
- CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

- RIAPAd
- RICORS REI
- RICORS2040 (KIDNEY DISEASE)
- RICORS-ICTUS
- RICORS TERA V

4.3. Participación en plataformas del ISCIII

- Itemas
- Sren

4.4. Colaboraciones internacionales. Partenariados de proyectos europeos.

55 Partenariados, entre ellos:

RELECOV 2.0. Proyecto Relecov2.0 – RELECOV NETWORK BT4ChildLC - <https://imagineformargo.org/en/bt4childlc-the-research-program-against-childhood-liver-cancer/>

MSCA4Ukraine:MSCA4UkraineSAREuropeGL-EECA2

<https://webs.uab.cat/gelea2lt/es/proyectos/>

ExTra: <https://extra-horizon.eu/>

THRIVE project – Tumor-host interactions in liver cancer of childhood and adults

HYPIEND <https://hypiend.eu/>

AFM Telethon GN <https://www.afm-telethon.fr/en>

PATH2XNAT ISIDORE project: services for infectious disease outbreak research TNA - ISID_8d02

ISIDORE project: services for infectious disease outbreak research

COBATEST DAH 2024 <https://cobatest.org/>

ESCALATOR The Awards - Women As One TETRA Action CA23125

COST NANOBICAR <https://cordis.europa.eu/project/id/101186252>

ESICM ARDS <https://www.esicm.org/?s=ARDS>

EuropeGL-EECA2 <https://webs.uab.cat/gelea2lt/es/proyectos/ExTrahttps://extra-horizon.eu/>

4.5 Colaboraciones internacionales. Redes internacionales.

4 colaboraciones internacionales: MSCA, EATRIS, ECRIN, COST ACTION

4.6. Colaboración con empresas de base tecnológica

IMIM - Instituto de investigaciones médicas Hospital del Mar

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas,
2. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías,
3. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune,
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus,

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen,
2. Farmacología, farmacogenómica, nuevos fármacos y terapias,
3. Medicina regenerativa,
4. Inteligencia Artificial,
5. Nanotecnología aplicada a la biomedicina,
6. Car-T
7. Otros: RNA-based therapies

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
2. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Servicios e infraestructuras singulares de interés en investigación clínica

Unidad de Investigación con voluntarios sanos. Se desarrollan actividades clínicas con medicamentos de forma voluntaria, estudios nutricionales y otras actividades de apoyo para el desarrollo de tratamientos en diferentes áreas terapéuticas. Se desarrolló una unidad de Fase I.

Servicios:

- Estudios farmacocinéticos i metabolismo (incluye los ensayos de bioequivalencia, tolerabilidad, primera administración en humanos dosis única o dosis múltiple)
- Efectos farmacodinámicos: efectos subjetivos, seguridad cardiovascular.
- Efectos en la conducta, evaluación del estrés.
- Ensayos clínicos fase I y fase II de eficacia y tolerabilidad.
- Ensayos clínicos fase I en poblaciones especiales (Pediatría, ancianos, síndrome de Down o del X-Frágil, consumidores de sustancias tóxicas o adictivas)
- Estudios de interacciones fármaco-fármaco
- Asesoramiento clínico de intervención nutricional.
- Beneficios de la nutrición para la salud en el rendimiento cognitivo
- Estudios de interacción fármaco-alimento
- Colaboraciones en ensayos clínicos de fase II-IV: visitas de selección, extracciones de muestras, biopsias, preguntas.
- Estudio de medición de la función renal.
- Estudios de excreción en el marco del control del dopaje
- Determinación e identificación de productos farmacéuticos y metabólicos, en sangre, orina, cabello, saliva y otras células biológicas. Estudios metabolómicos dirigidos.

2.2. Infraestructuras, unidades o plataformas acreditadas

- Instalaciones centrales y Biobanco: ISO9001 (Sistema de Gestión de Calidad).
- Unidad de Innovación: Norma UNE 166002 (Sistema de Gestión R+D+I).
- Laboratorio Antidopaje de Cataluña: ISO17025 (Requisitos generales para la competencia de los laboratorios de ensayo).
- Grupo de investigación: Farmacología Integrada y Neurociencia de Sistemas: ISO17025 (Requisitos generales para la competencia de los laboratorios de ensayo).
- Unidad de investigación clínica: Normas de Buenas Prácticas Clínicas.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

- Participación de miembro del foro de pacientes del Hospital del Mar en la comisión rectora del instituto
- Web
- Jornada de puertas abiertas
- Visitas de pacientes a través de la Marató
- Co-creación con asociaciones de Down

3.2. Gestión de dato

Aplicaciones Odoo

3.3. Repositorio documental en abierto

Se utiliza un repositorio de la Universidad Pompeu Fabra que forma parte del Instituto, el cual recoge la información y producción intelectual en formato digital que resulta de la actividad académica e investigadora de la UPF, revistas científicas y las publicaciones institucionales. Su finalidad es contribuir a aumentar el impacto de la investigación hecha en la UPF y preservar la memoria intelectual de la UPF.

3.4. *Know How.* Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual: **Prevención, Enfermedades infecciosas**

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberESP / CiberFES

4.2. Colaboraciones temáticas. Participación en RICORS

RICAPPS/ RICORS2040 (KIDNEY DISEASE)/ RICORS-ICTUS

4.3. Participación en plataformas del ISCIII

ITEMAS; Biobancos y biomodelos

4.4. Colaboraciones internacionales. Participación en partenariados europeos

- Biomarkers of ANTidepressant RESponse : early indicators and novel targets.
- EURO-FINGERS multimodal precision prevention toolbox for dementia in Alzheimer's disease.
- Cardiovascular stress impacts on neuronal function: intracellular pathways to cognitive impairment.
- Toward PrecisiOn Medicine for the Prediction of Treatment response in major depressive disorder through stratification of combined clinical and -omics signatures.
- Towards Personalized Clinical Management of Suicide Risk through Data-Driven Clinical Decision Support using Transnational Electronic Registry Data.
- Understanding the mechanisms of non-pharmacological interventions.

- Crosstalk between exercise and brain lipid metabolism in the protection against Alzheimer's Disease.
- How GATA2 Deficiency affects development and disease.
- Early and accurate diagnostic and prognostic markers for Alzheimer's disease.

4.5 Colaboraciones internacionales. Redes internacionales.

- Red/ Consorcio
- ACARE – Angioedema Centers of Reference and Excellence
- ADCARE – Atopic Dermatitis Centers of Reference and Excellence
- Cochrane Occupational Safety and Health Review Group (COSHRG)
- Dow Syndrome and Other Genetic Developmental Disorders Network
- EASO COM: European Association Study Obesity Collaborative Center for Obesity Management
- EBRA Trisomy 21 Cluster
- EECDRG European Environmental Contact Dermatitis Research Group
- European Infrastructure for Translational Medicine (EATRIS)
- European network for advancing Electromagnetic hyperthermic medical technologies (MyWAVE)
- European Prospective Investigation into Cancer and Nutrition (EPIC)
- European Research Network on Signal Transduction (ERNEST)
- ExAC (Exome Aggregation Consortium)
- GENomics of MusculoSkeletal traits Translational Network
- GENOMOS Consortium
- gnomAD (Genome Aggregation Database)
- Informal Scientific Network of the UNO Drugs and Crime and WHO
- International Network on Hepatitis in Substance Users (INSHU)
- International Society for Quality of Life Research (ISOQOL)
- Monitoring Occupational Diseases and tracing New and Emerging Risks in a NETWORK (MODERNET)
- NCD risk factor collaboration (NCD-RisC)
- NIH GWAS Data Repository
- PROMIS Health Organization (PHO)
- Training network to advance integrated computational simulations in translational medicine, applied to intervertebral disc degeneration
- UCARE - Urticaria Centers of Reference and Excellence

IR Sant Pau - Instituto de Investigación Sant Pau

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Nutrición y dieta personalizadas
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
5. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
3. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
4. Nuevos métodos de profilaxis, detección y tratamiento
5. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Terapia génica
5. Nuevos materiales biomédicos
6. Inteligencia Artificial
7. Nanotecnología aplicada a la biomedicina
8. Nuevas técnicas quirúrgicas
9. Salud digital
10. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
2. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Unidades de experimentación animal. Equipos singulares

Como equipos singulares en el servicio de experimentación animal disponemos de:

- Sistema imagen in vivo 2D y 3D: IVIS® Spectrum CT
- Sistema imagen in vivo: IVIS® Spectrum
- Ecógrafo pequeños animales Vevo F2
- Torres de laparoscopia Covidien
- Ecógrafo Philips Affinity con sonda transesofágica Arco de RX OEC Elite
- Carto® sistema de navegación 3D

2.2. Otros equipos, unidades o infraestructuras

La plataforma de citometría del IR Sant Pau dispone de los siguientes equipos:

- Citómetros MacsQuant10 Miltenyi Biotec. 2 unidades
- Citómetro MacsQuant VYB Miltenyi Biotec
- Citómetro MacsQuant16 Miltenyi Biotec
- Separador Celular AutomacsPro Miltenyi Biotec
- Disociador Gentlemacs Octo Dissociator Miltenyi Biotec
- Sorter Facs Aria de Becton Dickinson

Plataforma de multiplexación MAGPIX de Luminex

Infraestructuras y equipos comunes de laboratorio del IR Sant Pau:

- Salas para equipos de frío y de criopreservación y cámaras frías (4°C i -20°C)
- Purificación agua: obtención agua osmotizada, pura y ultrapura
- Equipos de limpieza y esterilización
- Armarios de seguridad
- Cabinas y vitrinas de uso general Balanzas de precisión
- Ultracentrífugas, centrífugas alta velocidad y sobremesa

2.3. Infraestructuras, unidades o plataformas acreditadas

Todas nuestras plataformas están acreditadas por la ISO 9001 y la Unidad de Terapias avanzadas está acreditada bajo las Normas de Correcta Fabricación.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Participación de un representante de la asociación de pacientes española en nuestro comité asesor externo.

Numerosas sesiones de divulgación científica en centros cívicos.

Numerosas visitas de escuelas.

Jornada de puertas abiertas a la ciudadanía.

3.2. Repositorio documental en abierto.

Se utiliza el repositorio de la Universidad Autónoma de Barcelona

3.3 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Dispositivos
- Prevención
- Cardiovascular
- Oncología
- Genética
- Cirugía

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

- CiberSAM
- CiberOBN
- CiberDEM
- CiberBBN
- CiberESP
- CiberEHD
- CiberER
- CiberES
- CiberCV
- CiberNED

4.2. Colaboraciones temáticas. Participación en RICORS

- RICORS-ICTUS
- RICORS TERA V
- RICORS-SAMID

4.3. Participación en plataformas del ISCIII

- Itemas
- Sren

4.4. Participación en clúster

- Otros

4.5. Colaboraciones internacionales. Redes internacionales.

EATROS, ASTP

4.6. Colaboración con empresas de base tecnológica

Algunas de ellas:

- AHEAD THERAPEUTICS
- QUBIOTECH
- Geisercare
- Cleerly Health
- Roche
- BIONANO GENOMICS, INC.
- NOVO NORDISK PHARMA, S.A.
- ADX neuroscience
- Cleerly Health
- EDENRED ESPAÑA, S.A.
- BLUECLINICAL
- Ephion Health SL
- Alnylam Pharmaceuticals, Inc
- INBRAIN
- LABORATOIRES THÉA S.A.S
- Fortrea Inc.
- ICN2
- Eurecat
- Leita

IRBLleida - Instituto de Investigación Biomédica de Lleida Fundación Dr. Pifarré

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Nutrición y dieta personalizadas
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
2. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
3. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

Farmacología, farmacogenómica, nuevos fármacos y terapias

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
2. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías ómicas

Plataforma lipidómica, consta de dos equipos HPLC (Cap Pump 1200 Series G1376A, Nano Pump 1200 Series G2226A, Agilent Technologies), dos equipos UPLC (Agilent 1290 Infinity Quaternary Pump), dos sistemas de detección de masas QTOF (QTOF LC/MS G6520A y 6545, Agilent Technologies), un sistema de detección de masas TQD (Triple Quad 6420 LC/MS Agilent Technologies), un sistema de ionización en nanoelectrospray mediante tecnología Chip Cube (HPLC Chip Cube G4240A, Agilent Technologies) y el software necesario para el análisis bioinformático de los datos metabólicos generados en dicha plataforma (MassHunter Data Acquisition, MassHunter Qualitative Analysis, MassHunter Quantitative Analysis, MassHunter Mass Profiler, Agilent Technologies).

2.2. Unidades de experimentación animal. Equipos singulares

El CREBA (Centro de Investigación Experimental Biomédica Aplicada) está dedicado a la investigación y formación en el ámbito de la Biomedicina utilizando el modelo porcino.

2.3. Infraestructuras, unidades o plataformas acreditadas

Biobanco (ISO 9001)

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Comisión de pacientes, Jornadas "Som Recerca"

3.2 Repositorio documental en abierto

Utilizamos el repositorio CORA del CSUC (<https://cora.csuc.cat/es/>)

3.3 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Terapia
- Dispositivos

- Oncología
- Nutrición o metabolismo

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberDEM / CiberES / CiberFES / CiberONC

4.2. Colaboraciones temáticas. Participación en RICORS

RICORS-ICTUS / RICORS-SAMID

4.5. Participación en plataformas del ISCIII

- Items
- Biobancos y biomodelos
- Sren

4.4. Colaboraciones internacionales. Partenariados de proyectos europeos.

DISTRIMUSE (<https://www.rulex.ai/project/distrimuse/>)

4.5 Colaboraciones internacionales. Redes internacionales.

EATRIS; EpiLipidNET; APORED; PARQ COST; VascAgeNet; INCOSACT; AtheroNET; IMPROVE-PD

4.6 Colaboración con empresas de base tecnológica

Indivumed therapeutics; Evotel informatica; Xenomatix; Trilitec; Televic; Smart robotics; Sentigrate; ACORDE Technologies; Bittium; eLive Ecosystem; Finapres Medical Systems; HI Iberia Ingeniería y Proyectos, S.L.; Infineon Technologies AG; Prodrive Technologies

Innovation Services B.V.; Alma medical

FRCB-IDIBAPS - Fundació de Recerca Clínic Barcelona-Institut d'Investigacions Biomèdiques August Pi i Sunyer

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
2. Nutrición y dieta personalizadas
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune

2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Vacunas

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Terapia génica
5. Medicina regenerativa
6. Nuevos materiales biomédicos
7. Inteligencia Artificial
8. Nanotecnología aplicada a la biomedicina
9. Nuevas técnicas quirúrgicas
10. Salud digital
11. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
2. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
3. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Equipos, unidades o infraestructuras

En la plataforma de citometría encontramos:

- Citómetros de flujo (citometría clásica de paso de banda): 4 citómetros de hasta 21 parámetros de fluorescencia y un LASER Infra Red
- Citómetros de flujo de espectro completo: 1 citómetro de 5 LASER
- FACS (separadores celulares): 1 separadores de 5 LASER y 18 parámetros de fluorescencia más un separador espectral con 5 LASER y 3 parámetros de imagen.

En la plataforma del Biobanco también existe infraestructura y capacidad técnica para servicios de inmunohistoquímica, servicios de histología, así como aislamiento de células PBMCs y granulocitos. Infraestructura para la congelación y criopreservación de muestras biológicas. Sistema informático Noraybanks para el control de trazabilidad de muestras y datos asociados de Biobanco.

2.2. Infraestructuras, unidades o plataformas acreditadas

Biobanco tiene la certificación ISO 9001:2015.

FUNDACIÓ DE RECERCA CLÍNICA BARCELONA-INSTITUT D'INVESTIGACIONS BIOMÈDIQUES está inscrita en el Registro de OTC con nº 12

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Visita para asociaciones de pacientes; Patient Advisory Board para el programa FORTALECE; Observatorio de la Experiencia del Paciente en el Hospital Clinic de Barcelona; participación de asociaciones de pacientes en múltiples proyectos nacionales e europeos; jornadas de puertas abiertas, etc.

3.2. Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Prevención
- Cardiovascular
- Oncología

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberOBN / CiberDEM / CiberESP / CiberEHD / CiberER / CiberES / CiberCV / CiberONC / CiberNED / CiberINFEC

4.2. Colaboraciones temáticas. Participación en RICORS

- RIAPAd
- RICORS REI
- RICORS2040 (KIDNEY DISEASE)
- RICORS-ICTUS
- RICORS TERA V
- RICORS-SAMID

4.3. Participación en plataformas del ISCIII

- Itemas
- Biobancos y biomodelos
- Scleren

4.4. Colaboraciones internacionales. Partenariados de proyectos europeos.

EDCTP: <https://www.edctp.org/>

Neuron-Eranet: <https://www.neuron-eranet.eu/>

Transcan: <https://transcan.eu/>

Flagera: <https://www.flagera.eu/>

Ejprd: <https://www.ejprarediseases.org/>

Erapermed: <https://erapermed.isciii.es/>

JPND: <https://neurodegenerationresearch.eu/>

Euronanomed: <https://euronanomed.net/>

4.5. Colaboraciones internacionales. Redes internacionales.

STEPUPIORS <https://www.stepupiors.eu/>

META-TOO: EU Funding & Tenders Portal (europa.eu)

PANERIS: Pan-European Network for Neuroscience Research Infrastructure and Strengthening of Support capacities | PANERIS | Project | Fact sheet | HORIZON | CORDIS | European Commission (europa.eu)

PPMI <https://www.ppmi-info.org/>

EBRAINS: <https://www.ebrains.eu/>

EIT Health: <https://eithealth.eu/>

INNODIA: <https://www.innodia.org/>

EATRIS: <https://eatris.eu/>

COGENT: <https://www.nature.com/articles/6605338>

ICGC: <https://dcc.icgc.org/>

IIBDGC: <https://www.ibdgenetics.org/>

IGC: <https://intgen.org/>

HCCGC: <https://labs.ica hn.mssm.edu/llovetlab/liver-cancer-consortium/>

Euro-Bioimaging: <https://www.eurobioimaging.eu/>

EARA: <https://www.eara.eu/>

4.6. Colaboración con empresas de base tecnológica

CORIFY (Proyecto SAVE COR), Health Circuit, MIWENDO

VHIR - Vall d'Hebron Instituto de Investigación

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas,
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.,

3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías,
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune,
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus,
3. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes,
4. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas,
5. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen,
2. Farmacología, farmacogenómica, nuevos fármacos y terapias,
3. Terapia génica,
4. Medicina regenerativa,
5. Nuevos materiales biomédicos,
6. Inteligencia Artificial,
7. Nanotecnología aplicada a la biomedicina,
8. Implantes y órganos artificiales,
9. Nuevas técnicas quirúrgicas,
10. Salud digital,
11. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Equipos, unidades o infraestructuras

Oncología molecular: La unidad aplica las tecnologías más avanzadas basadas en tejidos a la investigación básica, traslacional y clínica, con un claro enfoque hacia el desarrollo y la validación de nuevos biomarcadores tumorales para la medicina de precisión en oncología. Participa activamente en todos los proyectos que implican el uso de tejidos humanos recogidos de pacientes. Esto incluye los análisis de biomarcadores para la estratificación de pacientes y su inclusión en ensayos clínicos, la patología digital, los bancos de tejidos y el

desarrollo de modelos primarios de xenoinjertos derivados del paciente (PDX).

Infraestructuras, unidades o plataformas acreditadas

El IIS IR-HUVH cuenta con un Sistema de Gestión de la Calidad certificado según la norma ISO 9001:2015, que abarca: Servicios de la Unidad de Estadística y Bioinformática (UEB), Servicios del Biobanco (BB) para obtener, procesar, almacenar, gestionar y proporcionar muestras biológicas para la investigación biomédica; Servicios de la Academic Research Organization (ARO) para la gestión de ensayos clínicos y estudios de investigación clínica; Servicios de la Unidad de Alta Tecnología (UAT), que incluyen la gestión de equipos, desarrollo de métodos de metabolómica, la aplicación de técnicas y la docencia mediante la realización de actividades formativas; Servicios de la Unidad de Apoyo a la Investigación Clínica (USIC); Servicios de la Unidad de Cirugía Experimental (ESU), para la gestión en modelos animales grandes preclínicos con fines de apoyo a la investigación y la docencia en modelos de experimentación.

Laboratorios clínicos. Con la Norma ISO 15189 se encuentran acreditados:

- Servicios de Genómica en tejido fresco o parafinado ADN genómico (muestras tumorales) para la determinación de mutaciones en genes relacionados con procesos tumorales mediante amplicon-seq NGS (PCR-multiplex y posterior ultrasecuenciación), la determinación de mutaciones y variantes de número de copias (CNA) en genes relacionados con procesos tumorales mediante secuenciación dirigida basada en captura (enriquecimiento por captura en solución y posterior ultrasecuenciación) y determinación de la Carga Mutacional Tumoral (TMB).

- Servicios de Oncología Molecular en tejido fresco o parafinado (muestras tumorales) para la evaluación del porcentaje tumoral, tinción con hematoxilina y eosina, microscopía óptica, la visualización y detección de secuencias de ADN específicas mediante hibridación in situ (ISH) y la visualización y detección de antígenos celulares específicos mediante Inmunohistoquímica (IHQ).

Norma de Buenas Prácticas Clínicas (estándares GCP ICH E6): las Unidades ARO, USIC y UEB, el Sistema de Gestión de la Calidad integra y da cumplimiento tanto a requisitos ISO 9001 como a ICH E6.

- La Unidad de Fase I de Oncología está acreditada por la Generalitat de Cataluña de acuerdo con los requisitos técnicos para Unidades de fase I y de acuerdo a ICH E6.

- El Plan de Investigación de Calidad Clínica tiene como objetivo promover el cumplimiento de las Normas de Buenas Prácticas Clínicas (ICH E6).

- Existe en el VHIO un Plan de Auditorías tanto para los archivos generales de los ensayos como en una muestra aleatoria de ensayos.

- Acreditación de la Unidad de Investigación en Terapia Molecular del Cáncer (UITM) por parte de la Generalitat de Cataluña

- El Sistema de Gestión de la Calidad para la Unidad de Cirugía Experimental de modelo de animal grande (ESU) se encuentra certificado por la norma ISO 9001 y acreditado a su vez según la AAALAC (Asociación para la Evaluación y Acreditación del Cuidado de Animales de Laboratorio).

High Technology Unit.

Laboratory Animal Service and Experimental Surgery Unit.

Proteomics Group.

Statistics and Bioinformatics Unit.

Biobank.

Academic Research Organization.

Genomics Group.

Molecular Oncology Group.

Clinical Research Support Unit.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Unidad de Participación Ciudadana compuesta por:

- Oficina de Atención a las Asociaciones de Pacientes (cuenta con un radar de entidades de más de 370 registros).
- Comisiones Estables de Trabajo (CET). Existen: CET de Corazón, de Diagnóstico por la imagen-unidad de mama, de embarazo y puerperio, de especialidades pediátricas, de enfermedades digestivas, de oftalmología, de onco-hematología pediátrica, de oncología adultos, de trasplante de órgano sólido, de hematología, de innovación (transversal), de infecciosas y de endocrino.
- Se está trabajando en una nueva CET de investigación transversal para fomentar la participación de pacientes en IIS y el YPAG (Youth PAtient Advisory Group)
- Otros canales de participación:
- Participación en ensayos clínicos con campañas por las redes del VHIR y VHebron.
- Participación en jornadas específicas de los Grupos de Investigación .
- Proyectos competitivos específicos junto con entidades de pacientes.

3.2. Gestión de dato

En proceso un acuerdo con CSUC.

3.3. Repositorio documental en abierto

En proceso un acuerdo con CSUC.

3.4 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual: **Técnicas de diagnóstico, Terapia, Dispositivos, Prevención, Oncología, Nutrición, Genética y Otro (Imagen médica).**

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberDEM / CiberBBN / CiberESP / CiberEHD / CiberER/ CiberES / CiberCV /

CiberONC / CiberNED / CiberINFEC

4.2. Colaboraciones temáticas. Participación en RICORS

RICORS REI/ RICORS2040 (KIDNEY DISEASE)/ RICORS-ICTUS

4.3. Participación en plataformas del ISCIII

ITEMAS; Biobancos y biomodelos;

4.4. Colaboraciones internacionales. Participación en partenariados europeos.

Scren, ECRIN, EUHA, EURORDIS, EATRIS, EUPATI, EJP RD, EuroBloodNet, EUCCAT, ERDERA.

4.5. Colaboración con empresas de base tecnológica

Más de 25 colaboraciones con empresas privadas de base tecnológica (los datos de las mismas no pueden ser compartidos por cuestiones de confidencialidad).

COMUNIDAD VALENCIANA

IIS La Fe – Instituto de Investigación Sanitaria de La Fe

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas.
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Nutrición y dieta personalizadas.
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías.
5. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune.
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus.
3. Zoonosis.
4. Vacunas.
5. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes.
6. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas.
7. Nuevos métodos de profilaxis, detección y tratamiento.
8. Vigilancia de la salud y epidemiología.

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica.
2. Nuevas técnicas diagnósticas basadas en imagen.
3. Farmacología, farmacogenómica, nuevos fármacos y terapias.
4. Terapia génica.
5. Medicina regenerativa.
6. Nuevos materiales biomédicos.
7. Inteligencia Artificial.
8. Nanotecnología aplicada a la biomedicina.
9. Implantes y órganos artificiales.
10. Nuevas técnicas quirúrgicas.
11. Salud digital.
12. Car-T.

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable.
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer).
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable.
4. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina.
5. Fragilidad y prevención de la discapacidad.

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías de imagen.

Plataforma de Radiología Experimental y biomarcadores de imagen (PREBI): PET/MR (GEHC Signa): Dispositivo multimodal simultáneo con gantry de 60 cm para estudios de alta resolución espacial en investigación clínica con paciente.

2.2. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

Plataforma de Big Data, Inteligencia Artificial, Bioestadística y Bioinformática. Contiene información clínica, epidemiológica y biológica a nivel individual de su cohorte poblacional asignada (300.000 personas) y de los pacientes que acoge por su carácter de referencia, en un formato local e interoperable (OMOP CDM). Dicha información se actualiza a diario, semanal o mensualmente, dependiendo del datamart. A estas cohortes poblacionales se suma un histórico de $\pm 1,5$ millones de pacientes. El personal de esta plataforma está capacitado para prestar los siguientes servicios: 1. Asesoramiento metodológico. 2. Servicios de ciencia de datos. 3. Servicios de bioestadística. 4. Servicios de bioinformática. 5. Diseño y ejecución de proyectos de Real World Data. 6. Proyectos de medicina basada en el valor. 7. Innovación organizativa. 8. Redacción científica. 9. eHealth.

2.3. Otros equipos, unidades o infraestructuras

Plataforma de Apoyo al Desarrollo e Innovación de Medicamentos (PADIM): trabaja en el desarrollo de estrategias experimentales que permitan la identificación y caracterización de dianas farmacológicas, así como la búsqueda de nuevos principios terapéuticos.

FPLC AKTA, GE Healthcare. Calorímetro Microcal PEAQ-ITC, Malvern Panalytical. Biacore X100, GE Healthcare. Bruker AVANCE-TM 600 MHz, 5 mm BBI probe, 5mm, BBO probe. Robot muestreador SampleJet Bruker.

Servicio de Análisis de Vesículas Extracelulares (SAVE):

- Plataforma 'qEV AFC' (IZON Science LTD, Nueva Zelanda) para el aislamiento de vesículas extracelulares empleando cromatografía por exclusión de tamaño.
- Sistema 'Exoid' (IZON Science LTD, Nueva Zelanda) basado en Tunable Resistive Pulse Sensing (TRPS) para la determinación de tamaño, concentración y potencial zeta de nanopartículas.
- Plataforma 'ExoView R200+' (NanoView Biosciences, MA, USA) para el análisis de co-localización de proteínas en vesículas extracelulares.
- Plataforma de espectroscopia vibracional 'ATR-FTIR Alpha-II' (Bruker Optics, MA, USA) y 'ATR3110-532nm' (Optosky Photonics Inc., China) para la adquisición de espectros vibracionales de vesículas extracelulares.

2.4. Infraestructuras, unidades o plataformas acreditadas

Biobanco (ISO 9001).

Unidad de Terapias Avanzadas (GMP).

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación: Web corporativa. Web de captación de fondos. Comisión Ciudadana. Jornadas tu Hospital investiga. Redes sociales. Notas de prensa

3.2. Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico.
- Terapia.
- Dispositivos.
- Prevención.
- Cardiovascular.
- Oncología.
- Reumatología.
- Nutrición o metabolismo.
- Genética.

- Enfermedades infecciosas.
- Cirugía.
- Epidemiología.

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberBBN / CiberEHD / CiberER / CiberCV / CiberNED

4.2. Colaboraciones internacionales. Partenariados de proyectos europeos.

Más de 57 proyectos europeos centrados en el ámbito de la salud, como parte del clúster 1. Salud del programa marco Horizonte Europa. Actualmente, 35 de estos proyectos permanecen activos.

En los últimos tres años, se nos concedieron 6 proyectos europeos en 2021, 12 en 2022 y 7 en 2023.

Proyectos que han sido concedidos en el 2023:

PREDICTOM (<https://cordis.europa.eu/project/id/101132356>)

HYPIEND (<https://cordis.europa.eu/project/id/101137440>)

ARTEMIS (<https://cordis.europa.eu/project/id/101136299>)

BETTER (<https://cordis.europa.eu/project/id/101136262>)

NextMRI (<https://i3m.csic.upv.es/research/stim/nextmri-eic-mrilab/>)

METEV (se encuentra en la fase “Grant Agreement preparation”)

PROTEMIC “Grant Agreement preparation”)

4.3. Colaboraciones temáticas. Participación en RICORS

RICORS-SAMID

4.4. Participación en plataformas del ISCIII

Itemas; Biobancos y biomodelos; Sren

4.5. Participación en clúster

Clúster de salud

4.6. Colaboraciones internacionales. Redes internacionales.

EATRIS.

EURO-BIOIMAGING

ECRIN. European Clinical Research Infrastructures Network.

INNOLIFE.

EIP ON AHA. Asociaciones Europeas para la Innovación (EIP),

EU-OPENSREEN.

HONEUR. (Hematology Outcomes Network en Europa)

Otras redes: EHDEN y Transbionet

4.7. Colaboración con empresas de base tecnológica

“ProCanAid. Gemelo digital para la detección, el diagnóstico del cáncer de próstata y la simulación de los efectos y la eficacia de diferentes tratamientos oncológicos. Empresa: QUIBIM SL; “TARTAGLIA. “METASMART. “SINUÉ. “Terapia Diabetes. “FUNGISENS. SEQPLEXING SL. SOLUTEX SL “BIOCARDIOTOX.

IIS INCLIVA - Instituto de Investigación Sanitaria INCLIVA

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías,
2. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Nuevos métodos de profilaxis, detección y tratamiento,

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Farmacología, farmacogenómica, nuevos fármacos y terapias,
2. Nuevos materiales biomédicos
3. Inteligencia Artificial,
4. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA, etc.

PLATAFORMA BID DATA E INTELIGENCIA ARTIFICIAL <https://www.incliva.es/incliva-desarrolla-un-proyecto-piloto-para-la-integracion-de-informacion-sanitaria-en-tiempo-real-en-el-departamento-de-salud-clinico-malvarrosa-de-valencia/> <https://valenciaplaza.com/integra-cloud-incliva-informacion-sanitaria-tiempo-real>

2.2. Unidades o plataformas acreditadas

1. Estructura de gestión (gestión científica y gestión económica)
2. Biobanco

3. Unidad de Ensayos clínicos y Estudios Clínicos
4. Unidad de ensayos clínicos de FASE I de oncología

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1 Canales de participación

1. Web
2. Redes sociales (twitter, linkedin, Instagram)
3. Clusters biotecnológicos: BIOVAL

Jornadas. ejemplo: <https://www.incliva.es/wp-content/uploads/2023/04/I-Encuentro-Donantes-DEF.pdf>

Presencia en Patronato de INCLIVA (Fero y FEDER)

Plan de mecenazgo y embajadores de honor y donantes: <https://www.incliva.es/colabora/>

3.2. Gestión de dato

Para la gestión de los datos de los proyectos nacionales e internacionales concedidos, el IIS INCLIVA pone a disposición de el/la IP un espacio en nuestros servidores (CPD) durante todo el proyecto. Se trata de un sistema de almacenamiento temporal. El objetivo es que, tras el proyecto, sean depositados en otros repositorios externos con características FAIR

3.3. Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual: **Técnicas de diagnóstico; Terapia; Dispositivos; Prevención; Oncología; Genética; Enfermedades infecciosas; Cirugía**

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM/CiberOBN/CiberDEM/CiberER/CiberES/CiberFES/CiberCV/CiberONC

4.2. Participación en plataformas del ISCIII

Biobancos y biomodelos; Sclero

4.3. Participación en clúster

Clúster salud; Clúster tecnológico

4.4. Colaboraciones internacionales. Participación en partenariados europeos

10 partenariados

4.5. Colaboraciones internacionales. Redes internacionales

- BDVA-DAIRO <https://bdva.eu/>

- I SPACES <https://bdva.eu/task-forces/i-spaces/>

- RSCN <https://www.rscn.eu/> - EATRIS <https://eatris.eu/>

- ECRIN/SCREN <https://www.scren.eu>
- WIN consortium <https://www.winconsortium.org/>
- EHDEN <https://ehden.eu/>
- EU-OPENSREEN (hasta 2023) <https://www.eu-openscreen.eu/> - 1+ Million Genomes

4.6. Colaboración con empresas de base tecnológica

Seqplexing, Epidisease, Nela BioDynamics, ARTHEx BIOTECH, Cella, Avamed, Airbiometrics, Quibim, Tucuvi, Tetraneuron, Freshmedical, entre otras.

ISABIAL - Instituto de Investigación Sanitaria y Biomédica de Alicante

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Nutrición y dieta personalizadas
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y reemergentes causadas por hongos, bacterias y virus
3. Vacunas
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
5. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
6. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Nuevos materiales biomédicos
5. Inteligencia Artificial
6. Nuevas técnicas quirúrgicas
7. Salud digital

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)

2. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
3. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías ómicas

Secuenciadores masivos de segunda generación: MiSeq y NexSet 550

Secuenciador masivo de tercera generación: MinION y GridION

2.2. Tecnologías de imagen.

Microscopio Electrónico de Barrido FESEM GeminiSEM 460 Zeiss y Microscopio de Fluorescencia invertido Zeiss Axio Observer 7 con Apotome3

2.3. Servicios e infraestructuras singulares de interés en investigación clínica

Unidad de Ensayos Clínicos en Fase I (<https://isabial.es/plataforma/unidad-de-ensayos-clinicos-de-fase-i-ueca/>)

2.4. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

Laboratorio de Simulación e Inteligencia Artificial (SimIA): <https://isabial.es/simialab>

2.5. Otros equipos, unidades o infraestructuras

Unidad de Datos, Historia Clínica y Salud Digital (en desarrollo): <https://isabial.es/apoyo-de-gestion/unidad-de-datos/>

2.6 Infraestructuras, unidades o plataformas acreditadas

Biobanco: ISO 9001; Unidad de Microbiología: ISO 9001

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Web, participación en jornadas (comité evaluador, sesiones propias, invitados), Comisión participativa en desarrollo)

3.2. Gestión de dato.

Política de Open Science reciente

3.3. Repositorio documental en abierto

Comunidad en ZENODO: <https://zenodo.org/communities/isabial/records>

3.4. *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Dispositivos
- Cardiovascular
- Enfermedades infecciosas

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberOBN / CiberEHD / CiberER / CiberNED

4.2 Colaboraciones temáticas. Participación en RICORS

RIAPAd /RICAPPS /RICORS REI /RICORS TERA V /RICORS-SAMID

4.3. Participación en plataformas del ISCIII

Scren

4.4. Participación en clúster

Clúster tecnológico

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

4 proyectos internacionales

4.6. Colaboración con empresas de base tecnológica

Principalmente empresas de la región, mayoritariamente start-ups y spin-offs, dado que es un requisito de las convocatorias competitivas promovidas a nivel regional.

GALICIA

IDIS - Instituto de Investigación Sanitaria de Santiago de Compostela

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Nutrición y dieta personalizadas
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Vacunas
4. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen
2. Farmacología, farmacogenómica, nuevos fármacos y terapias

3. Terapia génica
4. Medicina regenerativa
5. Nanotecnología aplicada a la biomedicina
6. Implantes y órganos artificiales

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías ómicas

Centro Nacional de Genotipado de la Fundación Pública Gallega de Medicina Genómica (CeGen-FPGMX).

Servicios singulares CeGen: servicios de genotipado de SNV (Single Nucleotide Variants), CNV (Copy Number Variations) y pequeñas InDels (Insertions and Deletions) y análisis de metilación a gran escala.

Equipos singulares CeGen: Plataforma de genotipado de alto rendimiento: OpenArray / TaqMan Genotyping Systems (Applied Biosystems), MassArray system (Agena Bioscience) y Genechip y GeneTitan System (ThermoFisher Scientific).

Detección molecular directa: Equipo nCounter MAX (Nanostring) <https://nanostring.com/resources/ncounter-analysis-system-quick-tour-max-flex/>

Servicio singular de la plataforma de Epigenómica: análisis de metilación del ADN en múltiples muestras biológicas: tejidos, muestras paraфинadas, células y biopsia líquida (plasma, saliva, etc)

2.2. Tecnologías de imagen.

-Microscopio Multifotón Olympus FVMRE-RS, equipado con un láser Insight X3 de Spectra Physics, unidad de barrido para fotoestimulación con 3 láser de Coherent, 4 detectores, kit de estereotaxia para manipulación de animal pequeño, kit para medidas FLIM de picoquant (<https://www.olympus-lifescience.com/es/laser-scanning/fvmpe-rs/>)

-Unidad de Resonancia Magnética preclínica de alto campo (9.4 T); Bruker BIOSPEC 94/20 (sistema de gradientes de 440 mT/m); Software ParaVision®6. (<https://www.idisantiago.es/plataformas-de-apoyo-comun/imagen-por-resonancia-magnetica/>)

-Unidad de Imagen Experimental: MicroPET-CT Albira (Bruker) que permite obtener imágenes moleculares (empleando isótopos emisores de radiación β , como el Flúor-18) y estructurales en pequeños roedores; Equipo de autoradiografía BeaQuant

2.3. Unidades de experimentación animal. Equipos singulares

CEBEGA oferta servicios y equipos singulares

(<https://www.usc.gal/es/servicios/area/infraestructuras-investigacion/cebega/servicios-instalaciones-equipos>), como el sistema de imagen óptica IVIS Spectrum: imagen óptica 2D in vivo de alta sensibilidad para fluorescencia y bioluminiscencia.

2.4. Servicios e infraestructuras singulares de interés en investigación clínica

Producción de radiofármacos (<https://galaria.sergas.gal/Contidos/Produccion-radiofarmacos?idioma=es>).

Centro de Protonterapia en construcción: primer centro público en España

2.5. Infraestructuras, unidades o plataformas acreditadas

Unidad de Biopsia Líquida - UNE-EN ISO 15189: 2013

Unidad de Epigenómica - UNE-EN ISO 15189: 2013

Unidad de Ensayos Clínicos en Fases Tempranas, acreditada.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

- -Formulario web
- -Jornadas celebradas en días específicos sobre determinadas patologías.
- -Comité Científico Interno – 6 actores clave no científicos: empresas (Finsa, Frinsa, Afundación) asociaciones de pacientes (AECC y Fegerec) y consejo social de la Universidad de Santiago de Compostela

3.2. Gestión de dato.

FUNDANET. Sistema de almacenamiento de datos en proceso de creación/implementación que estará a disposición de los usuarios próximamente.

3.3. Repositorio documental en abierto.

RUNA- Repositorio del SERGAS/Xunta de Galicia gestionado por Bibliosaúde

MINERVA – Repositorio de la Universidad de Santiago de Compostela

3.4 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Prevención
- Cardiovascular
- Oncología
- Reumatología
- Nutrición o metabolismo
- Genética
- Enfermedades infecciosas
- Cirugía
- Epidemiología

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberOBN / CiberESP / CiberER / CiberES / CiberCV / CiberONC / CiberNED

4.2. Colaboraciones temáticas. Participación en RICORS

RIAPAd/RICAPPS/RICORS REI/RICORS2040 (KIDNEY DISEASE)/RICORS-ICTUS/RICORS TERAIV/RICORS-SAMID

4.3. Participación en plataformas del ISCIII

Itemas; Scleren

4.4 Participación en clúster

Clúster de salud; Clúster tecnológico

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

16 activos como partners, 3 más como affiliated entity: -MultiLab (<https://cordis.europa.eu/project/id/101135435>); -NEUROATLANTIC (www.neuroatlantic.eu); -DIAMONDS (<https://www.diamonds2020.eu/>); -EULAT Eradicate GBC (<https://cordis.europa.eu/project/id/825741/es>); -RELECOV 2.0 (<https://releco.isci.es/proyecto-releco-2/>); -PAINLESS (<https://palliativeprojects.eu/painless/>); -COLOMARK MSCA – DN (<https://cordis.europa.eu/project/id/101072448/es>); -TETRIS (<https://www.project-tetris.eu/>); -TIMELY (<https://www.timely-project.com/>); -PRomISE (<http://promise-project.org/>); -Recon4IMD (<https://www.recon4imd.org/>); -ENDOTARGET (<https://endotargetproject.eu/>); -Collaborative Network for European Clinical Trials for Children - c4c (<https://conect4children.org/>); -APTADEGRAD. (<https://aptadegrad.es/>);

4.6. Colaboraciones internacionales. Redes internacionales.

EATRIS; ECRIN; EU OPENSREEN; COST Actions

4.7. Colaboración con empresas de base tecnológica

Por lo menos 18 a nivel nacional. A nivel internacional: Humanitas Mirasole SPA; Hybrigenics Services SAS; GTP Nano; Surgeonmate LDA; Inova+-innovation Services SA; SYNABS S.A.; Neuroconn GMBH; Software Imagination & Vision SRL; QST Lab; Mentalab GMBH.

IIS Galicia Sur- Instituto de Investigación Sanitaria Galicia Sur

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
2. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
3. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y reemergentes causadas por hongos, bacterias y virus
3. Vacunas
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
5. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
6. Nuevos métodos de profilaxis, detección y tratamiento
7. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Terapia génica
5. Medicina regenerativa
6. Nuevos materiales biomédicos
7. Inteligencia Artificial
8. Nanotecnología aplicada a la biomedicina
9. Implantes y órganos artificiales
10. Nuevas técnicas quirúrgicas
11. Salud digital
12. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
4. Desarrollo integrado de programas multidisciplinares desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina
5. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías de imagen

Microscopio multifotón, infraestructura compartida entre los 3 IIS de Galicia IDIS, INIBIC e IIS Galicia Sur

2.2. Servicios e infraestructuras singulares de interés en investigación clínica

Unidad de Farmacotecnia y Elaboración de Medicamentos en Investigación Clínica (UFEMIC), para fabricación de medicamentos de investigación clínica. La UFEMIC cuenta con: Sala blanca, Dos unidades de elaboración de estériles con presión positiva, Dos unidades de elaboración de estériles con presión negativa, Una unidad de elaboración no estéril, Una unidad de control de calidad, Una unidad de acondicionamiento, Una unidad de validación y registro farmacéutico.

2.3. Otros equipos, unidades o infraestructuras

Unidad de Cultura Científica y de la Innovación (UCC+I), acreditada por la FECYT

2.4 Infraestructuras, unidades o plataformas acreditadas

El Instituto de Investigación Sanitaria Galicia Sur y la Fundación Pública Galega de Investigación Biomédica Galicia Sur han implementado un sistema de gestión de I+D+I, certificado según la norma UNE 166002 desde noviembre de 2023, en relación con las actividades de investigación, desarrollo e innovación tecnológica en el ámbito de la biomedicina.

La Fundación Pública Galega de Investigación Biomédica Galicia Sur dispone del reconocimiento de la Estrategia de Recursos Humanos en Investigación (HRS4R) desde 2022.

El Biobanco del IIS Galicia sur tiene implementado un sistema de gestión de calidad certificado según la norma UNE-EN ISO 9001 con fecha 11 de septiembre de 2021.

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Web UCC+I - Unidad de Cultura Científica y de la Innovación. Proyectos de Ciencia Ciudadana FECYT:
4. Consello Reitor del IISGS (representación de asociaciones de pacientes)

Jornadas Anuales de Participación de Pacientes; Jornada Anual de Encuentro de Grupos del IISGS (participación de asociaciones de pacientes); Curso de formación en atención a la discapacidad visual, Jornada Biointegrasaúde 2024 (conferencia de la European AIDS Treatment Group - EATG); II Jornada Nacional sobre el Síndrome de Joubert ; Diversas actividades #11F 2024

Visitas y talleres con centros escolares. Visitas de asociaciones de pacientes. Convenios con asociaciones de pacientes vigentes: 15

3.2. Repositorio documental en abierto.

RUNA: Repositorio Institucional del Sergas

INVESTIGO: Repositorio Institucional de la UVigo

3.3. *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Prevención

- Cardiovascular
- Oncología
- Reumatología
- Genética
- Enfermedades infecciosas
- Cirugía

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberES

4.2 Colaboraciones temáticas. Participación en RICORS

RICAPPS

4.3. Participación en plataformas del ISCIII

Items; Biobancos y biomodelos; Scleren

4.4 Participación en clúster

- Clúster de salud
- Clúster tecnológico

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

SINFONIA (GA945196): <https://www.sinfonia-appraisal.eu/>

PAINLESS (GA101057367): <https://palliativeprojects.eu/painless/>

REVERSE (GA965265): <https://www.reverseproject.eu/>

RELECOV 2.0. (GA 101113109): <https://releco.isciii.es/es/proyecto-releco-2/>

TRANSITION (GA101101261): F&T Portal; <https://www.europeancancer.org/eu-projects/resource/transition>

INTERACT-EUROPE (GA101129375): F&T Portal; <https://www.europeancancer.org/eu-projects/impact/interact-europe>

IBEROS+ (0072_IBEROS_MAIS_1_E): <https://2007-2020.poctep.eu/es/2014-2020/instituto-de-bioingenier%C3%ADa-en-red-para-el-envejecimiento-saludable>

ICAREWOUNDS (AC23_2/00031): Página web en construcción

UP4HEALTH (GA888003) <https://up4health.eu/>

BIOCELLPHE (GA965018) <https://www.biocellphe.eu/>

WHEATBIOME GA101084344 (WHEATBIOME) <https://www.wheatbiome-project.eu/>

3DSecret (GA101099066) <https://www.3dsecret.eu/>

IN-ARMOR (GA101080889) <https://inarmor-project.eu/>

4.6. Colaboraciones internacionales. Redes internacionales.

European Infrastructure for translational medicine (EATRIS - Biomarkers Platform): <https://eatris.eu/>

CCI4EU fights against cancer: <https://cci4eu.eu/>

European General Practice Research Network (EGPRN): <https://www.egprn.org/>

4.7. Colaboración con empresas de base tecnológica

MIwendo; Amadix; Hifas da Terra ; Quibim ; TUCUVI.

INIBIC - Instituto de Investigación Biomédica de A Coruña

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Vacunas
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
5. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Terapia génica
5. Medicina regenerativa
6. Nuevos materiales biomédicos
7. Inteligencia Artificial
8. Implantes y órganos artificiales
9. Nuevas técnicas quirúrgicas

10. Salud digital

11. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina
4. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías ómicas. Equipos singulares

Espectrómetro de masas 4800 MALDI-TOF/TOF™ Proteomics Analyzer, Sistema de cromatografía líquida Tempo™ nanoLC-2D acoplado a espectrómetro de masas QTRAP5500, Secuenciador automático de ADN de tecnología capilar, La plataforma también dispone de un equipo de secuenciación masiva Ion S5XL y un robot para la elaboración automática de librerías de secuenciación y template, el Ion Chef.

”Estereolitografía (SLA) mediante la impresora Form 3BL, primera impresora de sus características puesta en servicio en el mercado europeo. Permite el uso de resinas biocompatibles específicas y aporta unos resultados más consistentes y precisos en toda la plataforma de impresión mediante la avanzada tecnología de SLA de baja fuerza. Modelado por deposición fundida (FFF) mediante la impresora Ultimaker S5 Pro Bundle.

2.2 Tecnologías de imagen.

PLATAFORMA DE IMAGEN MULTIMODAL, ECOGRAFÍA DE ULTRA ALTA FRECUENCIA, para uso en modelo animal "in vivo" Modelo: Vevo F2 de Fujifilm

2.3 Unidades de experimentación animal.

BIOMÓDULO DE BARRERA PARA EXPERIMENTACIÓN EN MODELO ANIMAL CON MODIFICACIÓN GENÉTICA

Área de microcirugía con equipamiento completo para microscopía quirúrgica, Sala multiusos con capacidad para ocho puestos completos en cirugía simultánea en modelo animal “in vivo”, dotados de conexiones de video y monitor docente centralizado en matriz, Dos quirófanos equipados para cirugía en modelo animal “in vivo”

2.4. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

Bioinformática, Unidad de Apoyo a la Investigación

2.5 Otros equipos, unidades o infraestructuras

Área de Impresión 3D. Combina cuatro tipos de tecnologías 3D:

a. Impresión 3D mediante fabricación por filamento fundido (FFF) y estereolitografía (SLA), para ofrecer productos y biomodelos fabricados en más de una veintena de materiales con distintas propiedades, como biocompatibilidad, transparencia, radiolucidez/radiopacidad o elasticidad.

b. Escaneado 3D, para la oferta de servicios de ingeniería inversa a partir de modelos reales.

c. Realidad virtual (RV), para ofrecer biomodelos digitales manipulables e inmersivos.

3. Área de Simulación.

2.6 Infraestructuras, unidades o plataformas acreditadas

Licencia de Fabricante de Producto Sanitario A Medida con el número 15-2022-001-C3D, La plataforma está certificada con la UNE-EN ISO 13485:2018 "Productos Sanitarios. Sistemas de Gestión de la Calidad, UNE-EN ISO 14001:2015 "Sistemas de gestión ambiental" y la UNE-EN ISO 9001:2015 "Sistemas de gestión de la calidad, La Central de Esterilización del CHUAC, también se encuentra certificada con la UNE-EN ISO 9001:2015.

Certificación ISO 9001:2015: El Biobanco obtuvo la certificación ISO 9001:2015, reacreditado 2023. Implantación de ISO 20387

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1 Canales de participación

Via Web y Comisión de participación de pacientes, jornadas

3.2 Gestión de dato

Aplicación propia

3.3 Repositorio documental en abierto

Runa

3.4 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Prevención
- Oncología
- Reumatología
- Genética
- Cirugía

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberBBN / CiberCV / CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICORS REI/ RICORS-ICTUS

4.3. Participación en plataformas del ISCIII

- Biobancos y biomodelos
- Scleren

4.4 Participación en clúster

- Clúster de salud
- Clúster tecnológico

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

IDERHA, IDEA4RC

4.6 Colaboraciones internacionales. Redes internacionales.

EATRIS, ECRIN, COST, SCReN

4.7. Colaboración con empresas de base tecnológica

Microsoft, ITG, CTAG, Bahia Soeware, ARSOFT, Aguiar

MADRID

Instituto i+12 - Instituto de Investigación Sanitaria Hospital 12 de Octubre

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Nutrición y dieta personalizadas
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y reemergentes causadas por hongos, bacterias y virus
3. Vacunas
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Medicina regenerativa
4. Nuevos materiales biomédicos

5. Inteligencia Artificial
6. Salud digital
7. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
2. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Servicios e infraestructuras singulares de interés en investigación clínica

Servicio de Medicina Nuclear H120 y Servicio de Oncología Radioterápica H120

2.2. Otros equipos, unidades o infraestructuras

Unidad de Impresión en 3D (UTADI – H120)

2.3. Infraestructuras, unidades o plataformas acreditadas

Unidad de Genómica: IDO 9001

Unidad de Impresión 3D: ISO 9001

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Jornadas de investigación

Actividades de divulgación científica

3.2. Gestión de dato.

Sistema general de almacenamiento de datos genómicos. QUIMERA. Uso para investigación de los datos de la historia clínica HCIS (INFOBANCO). Uso de CMAG (Centro Madrileño de Análisis Genómico) para genética clínica (almacenamiento de dato genómico).

3.3 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Oncología
- Nutrición o metabolismo

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberBBN / CiberESP / CiberER / CiberES / CiberFES / CiberCV / CiberONC / CiberNED / CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RIAPAd/RICAPPS/RICORS REI/RICORS-ICTUS/RICORS TERAIV/RICORS-SAMID

4.3. Participación en plataformas del ISCIII

Itemas; Biobancos y biomodelos; Scleren

4.4 Participación en clúster

Clúster de salud

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

Participan en 23 proyectos de investigación (financiados o activos en 2023) de los programas:

- - DIGITAL (Uso de Tecnologías digitales en la sociedad)
- - HORIZON (Investigación y desarrollo en Salud)
- - EU4HEALTH (Mejora y promoción de la salud y los sistemas sanitarios)
- - EIT HEALTH (Innovación en salud y sistemas sanitarios)

4.5 Colaboraciones internacionales. Redes internacionales.

EATRIS, ELIXIR, ECRIN, BBMRI

4.6. Colaboración con empresas de base tecnológica

ALTUM SECUENCING; NUTRI GENOMICS; STAB THERAPEUTICS

IDIPAZ - Instituto de Investigación Hospital Universitario La Paz

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Nutrición y dieta personalizadas
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
5. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune

2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Zoonosis
4. Vacunas
5. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
6. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
7. Nuevos métodos de profilaxis, detección y tratamiento
8. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
1. Nuevas técnicas diagnósticas basadas en imagen
2. Farmacología, farmacogenómica, nuevos fármacos y terapias
3. Terapia génica
4. Medicina regenerativa
5. Nuevos materiales biomédicos
6. Inteligencia Artificial
7. Implantes y órganos artificiales
8. Nuevas técnicas quirúrgicas
9. Salud digital
10. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
4. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías de imagen. Equipos singulares

Microscopia confocal y de fluorescencia TAC multicore, Resonancia magnetica. Varios equipos.

2.2 Unidades de experimentación animal. Equipos singulares

Animalario. Animalario para animales inmunodeprimidos.

2.3. Unidades de Biología Celular. Infraestructuras o equipos singulares

Sí, Sala Blanca.

2.4. Servicios e infraestructuras singulares de interés en investigación clínica

Protonterapia en proyecto.

2.5. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

Bioinformática, Bioestadística, IA, Tecnología 3D.

2.6 Infraestructuras, unidades o plataformas acreditadas

Sí. <https://www.idipaz.es/PaginaDinamica.aspx?IdPag=573&Lang=ES>

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Comisión humanización. Jornadas de divulgación. Jornadas de interacción con asociaciones con pacientes, Página Web, Participación en proyectos.

3.2. Gestión de dato.

Unidad integral de apoyo a la investigación. Unidad del dato H La Paz 5.0.

3.3. Repositorio documental en abierto.

www.idipaz.es

3.4 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Cardiovascular
- Oncología
- Reumatología
- Nutrición o metabolismo
- Genética
- Enfermedades infecciosas
- Cirugía

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

- CiberDEM
- CiberBBN
- CiberESP

- CiberEHD
- CiberER
- CiberES
- CiberCV
- CiberONC
- CiberNED
- CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

- RICORS2040 (KIDNEY DISEASE)
- RICORS-ICTUS
- RICORS-SAMID

4.3. Participación en plataformas del ISCIII

- Items
- Biobancos y biomodelos
- Sren

4.4 Participación en clúster

- Clúster de salud
- Clúster tecnológico

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

<https://www.idipaz.es/PaginaDinamica.aspx?IdPag=637&Lang=EN>

4.5 Colaboraciones internacionales. Redes internacionales.

21 redes.

4.6. Colaboración con empresas de base tecnológica

Sí, múltiples.

IDIPHISA - Instituto de Investigación Sanitaria Puerta de Hierro - Segovia de Arana

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas,
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.,
3. Nutrición y dieta personalizadas,
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías.

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune,
2. Vacunas,
3. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes,
4. Vigilancia de la salud y epidemiología.

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Farmacología, farmacogenómica, nuevos fármacos y terapias,
2. Inteligencia Artificial,
3. Nuevas técnicas quirúrgicas.

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

En este anexo se incluyen las infraestructuras, equipos y/o servicios **singulares**, no los generales

2.1 Tecnologías ómicas

Estudio de biomarcadores en biopsia líquida <https://investigacionpuertadehierro.com/laboratorio-biopsia-liquida/>

Unidad de Secuenciación de Adn y Biología Molecular <https://investigacionpuertadehierro.com/unidad-de-secuenciacion-de-adn-y-biologia-molecular/>

2.2 Infraestructuras, unidades o plataformas acreditadas

- Laboratorio de Biopsia Líquida: ISO 15189 Laboratorios clínicos.
- Unidad Apoyo a la Innovación: UNE 166002:2021

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual: **Terapia, Prevención, Cardiovascular, Oncología, Nutrición o metabolismo, Genética, Enfermedades infecciosas.**

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberEHD / CiberCV

4.2. Colaboraciones temáticas. Participación en RICORS

RICORS TERA

4.3. Participación en plataformas del ISCIII

Biobancos y biomodelos; Sren.

4.4. Colaboraciones internacionales. Participación en partenariados europeos.

- ORTHO-ALLO-UNION
- CLARITY
- RETENTION
- HALT-RONING
- DCM-NEXT

4.5. Colaboración con empresas de base tecnológica

- Atrys Health
- GAMERA NEST SL
- LEADARTIS SL

IdISSC - Fundación para la Investigación Biomédica del Hospital Clínico San Carlos

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen
2. Farmacología, farmacogenómica, nuevos fármacos y terapias
3. Medicina regenerativa
4. Inteligencia Artificial
5. Nuevas técnicas quirúrgicas

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

Perfiles moleculares del envejecimiento saludable

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Infraestructuras, unidades o plataformas acreditadas

Unidad de Terapias Experimentales en Cáncer (UTEC): <https://www.idissc.org/espacio-de-apoyo/unidad-de-terapias-experimentales/>

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

1. X
2. LinkedIn
3. Web
4. Clínico Informa
5. Boletín interno IdISSC
6. Encuentro IdISSC: Sociedad y Ciencia se dan la mano.

3.2. Gestión de dato

1. FUNDANET
2. Sistema documental del Hospital Clínico San Carlos
3. Sistema de Información Madrid Digital

3.3. Repositorio documental en abierto

Repositorio de publicaciones Comunidad de Madrid

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1. Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM/CiberDEM/CiberBBN/CiberESP/CiberCV/CiberINFEC

4.2. Colaboraciones temáticas. Participación en RICORS

RICAPPS/RICORS REI

4.3. Participación en plataformas del ISCIII

1. Items
2. Biobancos y biomodelos
3. Sclera

4.4 Participación en clúster

1. Clúster de salud
1. Clúster tecnológico

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

Detallado en el siguiente enlace: <https://www.idissc.org/proyectos-publicos-de-idi/>

4.6 Colaboraciones internacionales. Redes internacionales.

Detallado en el siguiente enlace: <https://www.idissc.org/colaboraciones/>

IIS FJD- Instituto de Investigación Sanitaria Fundación Jiménez Díaz

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Zoonosis
2. Vacunas
3. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
4. Nuevos métodos de profilaxis, detección y tratamiento
5. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Farmacología, farmacogenómica, nuevos fármacos y terapias
3. Terapia génica
4. Medicina regenerativa
5. Nuevos materiales biomédicos
6. Inteligencia Artificial
7. Nanotecnología aplicada a la biomedicina
8. Nuevas técnicas quirúrgicas
9. Salud digital
10. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

Desarrollo de biomateriales para su uso en implantes y prótesis

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías ómicas. Equipos singulares

- 2 Secuenciador masivo (NextSeq500 de Illumina)
- 2 Secuenciador masivo (NextSeq2000 de Illumina)

Plataforma de Arrays: 1 Horno de hibridación y 1 lector de arrays SureScan de Agilent.

Equipo integrado de nano/capilar/micro HPLC (1200 Series) para análisis proteómico y metabolómico.

Instrumentación para cromatografía líquida mono- y multi-dimensional a escala nano, micro o capilar para la separación de muestras biológicas complejas de péptidos, proteínas y/o metabolitos. La instrumentación MS-QQQ está diseñada para un análisis dirigido (target) por SRM (Selected Reaction Monitoring) <https://www.fjd.es/iis-fjd/es/unidades-apoyo/unidades-apoyo-investigacion/unidad-genomica> <https://www.fjd.es/iis-fjd/es/unidades-apoyo/unidades-apoyo-investigacion/unidad-proteomica>.

2.2 Tecnologías de imagen.

Laboratorio de manipulación de emisores Gamma

Laboratorio de manipulación de emisores Beta. Cuarto de Instrumentación.

Cuarto de manipulación de emisores Beta de baja Energía y estudios metabólicos. Posibilidad de realización de estudios metabólicos en cultivos celulares con radioisótopos

2.3 Unidades de experimentación animal.

Equipamiento: - Arco de Rayos X - Sistema de ecografía con sondas para roedores y animales de gran tamaño - Sistema de endoscopia para cirugías en animales grandes (gastroskopias, colonoscopias,...) - Sistema IVIS de fluorescencia y quimioluminiscencia para roedores asociado a sistema de anestesia - 2 Campanas de flujo para manipulación de pequeños animales en condiciones de esterilidad - Sistema de control de aire hermético para estudios pulmonares - Equipos de anestesia para roedores (4), y grandes mamíferos (3) - Cajas de control de aire para sacrificio de roedores. - Neveras, congeladores para medicación y animales. - caja fuerte para medicación "sensible" - 3 salas de almacén - Balanzas para roedores y grandes animales. - Equipamiento quirúrgico para micro cirugía y para grandes cirugías. - Salas de lavado y esterilización de cubetas, biberones y lecho de animales Además el animalario tiene unas instalaciones ("STAR") independientes para estabulación y manipulación de animales inmunosuprimidos completamente equipadas: Racks de estabulación, campanas de flujo, sistemas de esterilización,

<https://www.fjd.es/iis-fjd/es/unidades-apoyo/unidades-apoyo-investigacion/experimentacion-animal-cirugia-experimental>

2.4. Unidades de Biología Celular.

Citómetros: citómetro digital de dos láseres y cuatro detectores de fluorescencia (FACSCanto II), de Becton Dickinson.

Sorters: clasificador de células (sorter) que contiene tres láseres (azul, rojo y violeta) y ocho detectores de fluorescencia (FACSMelody), de Becton Dickinson.

Confocal TCS SP5 de Leica configurado con detectores SP (cinco canales simultáneamente), un escáner en tándem (convencional y resonante para adquisición de imágenes a alta velocidad), y sistema AOBS para separación dinámica de luz. Líneas láser de excitación: 405 nm, 458 nm, 476 nm, 488 nm, 496 nm, 514 nm, 561nm, 594 nm y 633 nm.

Microscopio DMI6000 invertido de Leica, automático, con pletina motorizada, incubadora de temperatura y suministro de CO₂. Como fuentes de iluminación dispone de una fuente EL6000 (Leica) para la visualización de las muestras con fluorescencia; y luz transmitida para campo brillante y contraste diferencial de interferencia (DIC). <https://www.fjd.es/iis-fjd/es/unidades-apoyo/unidades-apoyo->

investigacion/unidad-biologia-celular-microscopia-citometria-flujo

Cultivos celulares: laboratorio con nivel de contención II, un laboratorio de mayor seguridad para la producción de vectores virales y una sala GMP para la producción de Medicamentos de Terapia Avanzada acreditada por la Agencia Española de Medicamentos y Productos Sanitarios <https://www.fjd.es/iis-fjd/es/unidades-apoyo/unidades-apoyo-investigacion/cultivos-celulares>

2.5. Servicios e infraestructuras singulares de interés en investigación clínica

El Grupo de Protonterapia es un grupo de investigación externo asociado al IISFJD <https://www.quironsalud.com/protonterapia>

2.6. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

Servicio Business Intelligence, IA y Big Data Objetivo Recolectar, organizar y analizar los datos de los distintos centros para la ayuda a la toma de decisiones estratégicas de compañía basadas en la interpretación de dichos datos. Además de la utilización de estos datos, para automatizar procesos, detectar patrones de comportamiento que ayuden a la toma de decisiones clínicas, desarrollo de modelos predictivos. Descripción • Servicio de Data Warehouse • Servicio de Data Marts • Creación de métricas en dashboards • Informes basados en los modelos de datos implementados. • Procesamiento de grandes volúmenes de datos • Automatización de procesos • Desarrollo de modelos predictivos (Machine Learning) • Inteligencia Artificial (Procesamiento de imágenes, NLP)

2.7 Infraestructuras, unidades o plataformas acreditadas

ISO45001, ISO9001 norma específica de Biobanco ISO 20387. Certificación de Calidad ISO 9001:2008 Servicio de Documentación Clínica. ISO 15189, unidad de Genómica EFQM, Joint commission international.

- Laboratorio con nivel de contención II, un laboratorio de mayor seguridad para la producción de vectores virales y una sala GMP para la producción de Medicamentos de Terapia Avanzada acreditada por la Agencia Española de Medicamentos y Productos Sanitarios

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Consejo asesor de agentes sociales; Jornadas asociaciones de pacientes

3.2. Gestión de dato.

FUNDANET

3.3 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Dispositivos
- Enfermedades infecciosas
- Otro: EXPERIENCIA DEL PACIENTE

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberDEM/CiberER/CiberES/CiberCV/CiberONC/CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICORS REI/RICORS2040 (KIDNEY DISEASE/RICORS TERA V

4.3. Participación en plataformas del ISCIII

Biobancos y biomodelos/Scren

4.4 Participación en clúster

Clúster de salud

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

10 participaciones en partenariados. <https://selnet-h2020.org/>; <https://www.idea4rc.eu/idea4rc-project/>; <https://amelie-project.eu/>; <https://rita-mi2.eu/>; <https://www.ushter.eu/>

4.6 Colaboraciones internacionales. Redes internacionales.

EATRIS, ECRIN, EASI GENOMICSTRANSBIONET, BEYOND 1M GENOMES, ACCION COSTIMPACT: GENOMICA, DATA, INFRAESTRUCTURA DE MEDICINA DE PRECISION ASOCIADA A LA CIENCIA Y TECNOLOGIA

4.7. Colaboración con empresas de base tecnológica

EVOMED KIJ THERAPEUTICS ROCKET PHARMACEUTICALS DANAUS

IISGM - Instituto de Investigación Sanitaria de Gregorio Marañón

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Nutrición y dieta personalizadas
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
5. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Zoonosis
4. Vacunas

5. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
6. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas
7. Nuevos métodos de profilaxis, detección y tratamiento
8. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Terapia génica
5. Medicina regenerativa
6. Nuevos materiales biomédicos
7. Inteligencia Artificial
8. Nanotecnología aplicada a la biomedicina
9. Implantes y órganos artificiales
10. Nuevas técnicas quirúrgicas
11. Salud digital
12. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
4. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina
5. Fragilidad y prevención de la discapacidad

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías ómicas. Equipos singulares

Unidad de Genómica: secuenciadores de ácidos nucleicos tanto convencionales (Sanger ABI 3130xl y ABI 3730xl) como masivos de nueva generación Illumina (2 MiSeq, un NextSeq y un NovaSeq)

Laboratorio de Genética Hematológica:

Procesamiento de las muestras: Auto-MACS (Miltenyi Biotec) purificación de linajes leucocitarios

Estudios de Citogenética y Citogenómica: Sistema para la realización del mapeo óptico del genoma,

junto con un servidor y software específico para el análisis de datos (Bionano)

Biología Molecular: PCR digital (dPCR, QIAcuity, Qiagen)

Todo lo necesario para la realización de NGS incluyendo la preparación automática de librerías (Hamilton Company, USA)

2.2 Tecnologías de imagen.

Equipamiento para pequeño animal: PET/CT de alta resolución (SuperArgus, Sedecal), SPECT y CT de alta resolución (b-Cube and x-Cube, Molecubes), Resonancia magnética de 7 Teslas (Bruker Bioespec 70/20 USR), Sistema de imagen óptica IVIS Lumina Serie III (PerkinElmer), Microscopio de haz plano (SPIM) 3D con 5 láseres (405, 488, 532, 590, 649), Irradiador de rayos X (Sedecal), Sistema de autorradiografía (BAS-5000, Fujifilm) y Unidad de Radiofarmacia para la producción “in situ” de radiotrazadores

2.3. Unidades de Biología Celular. Infraestructuras o equipos singulares

- - Citómetro de flujo MACSQuant Analyzer 16 MILTENYI N°LOTE: 5201100727 SN/40251 <https://www.miltenyibiotec.com/ES-en/products/macsqquant-analyzer-16.html>
- - Sorter MACSQuant_Tyto cell sorter (A42046) Ref: 120-048-865 MILTENYI SN/10208 <https://www.miltenyibiotec.com/ES-en/products/macsqquant-tyto.html>
- - Cuantificador de citoquinas. ELLA Protein Simple. Bio-technne SN/ SN18040286 https://www.bio-technne.com/p/simple-plex/ella-automated-immunoassay-system_600-100
- - Gentle MACS Dissociator Ref: 130-093-235 MILTENYI MODELO: Dispomix Drive N° LOTE: 1204 SN/ 1080
- <https://www.miltenyibiotec.com/ES-en/products/gentlemacs-dissociator.html>
- - CliniMACS PRODIGY MILTENYI REF: 200-075-301 MODELO: 1555
- <https://www.miltenyibiotec.com/ES-en/products/clinimacs-prodigy.html>
- - AutoMACS PRO Ref: 120-002-682 MILTENYI 120-002-682 MODELO: 2657
- <https://www.miltenyibiotec.com/ES-en/products/automacs-pro-separator-starter-kit.html>
- - Gentle MACS Dissociator octo MILTENYI [REF: 130-096-427](https://www.miltenyibiotec.com/ES-en/products/gentlemacs-dissociator-octo.html)

2.4. Servicios e infraestructuras singulares de interés en investigación clínica

Fabricación de modelos anatómicos para docencia y comunicación. Fabricación de instrumental quirúrgico y prototipos paciente-específicos. Consultoría de fabricación aditiva biomédica. Plataforma ISCII de Biomodelos y Biobancos y apoyo a la investigación e innovación gracias a diferentes acuerdos de colaboración

2.5. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

Living Lab de Tecnologías Asistenciales e Inteligencia Artificial: Una granja de computación compartida que consta de una primera infraestructura con 1240 Cores, 5.3TByte de memoria distribuida, 40TBytes de almacenamiento centralizado y otros 40TBytes de almacenamiento distribuido para tareas de procesamiento BigData, HPC basado en MPI y procesos monolíticos. 128 Cores y 20 GPUs de última generación, para desarrollo de métodos de Deep Learning. Esta infraestructura está interconectada a través de una red privada e independiente de alta velocidad, para reducir la latencia de comunicaciones e interferencia de la red

departamental. 16 servidores de alto rendimiento (256 cores Intel x64), 928 GBytes de memoria distribuida, para la ejecución de tareas de propósito general, 3 servidores dedicados con 4 GPUs cada una para procesamiento matricial intensivo.

Todos estos equipos están interconectados a un servidor de almacenamiento de 32TBytes de capacidad.

2.6. Infraestructuras, unidades o plataformas acreditadas

- Unidad de Citometría de Flujo y Sorter. SO 9001:2015
- ISO 9001:2015 Web: <https://umce.hggm.es/sai/imagen-preclinica>
- La Unidad UPAM3D / SAI 3D está integrada en la Plataforma de Biobancos y Biomodelos del ISCIII, dentro del HUB de 3D Printing. La unidad tiene certificado su sistema de gestión de calidad bajo la norma internacional ISO 1348:2018 para dispositivos médicos y cuenta con licencia de fabricante de producto sanitario a medida (PSM) concedida por la Comunidad de Madrid.
- Unidad de Apoyo a la Innovación: Certificación sistemas de gestión de I+D+i UNE 166002

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Jornada anual de Investigación e Innovación. Programa 4ºESO + empresa. Científicos en prácticas - CSIC. Semana de la Ciencia y la Innovación. Noche europea de I@s Investigador@s. Día internacional de la Mujer y la Niña en la Ciencia. DNA day. Web del IiSGM. LinkedIn. Twitter (X). YouTube

3.2. Gestión de dato.

RecCap. Repositorio Comunidad de Madrid

3.3. *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

Técnicas de diagnóstico; Terapia; Dispositivos; Prevención; Cardiovascular; Oncología; Reumatología; Genética; Enfermedades infecciosas; Cirugía

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM/CiberBBN/CiberEHD/CiberES/CiberFES/CiberCV/CiberONC/CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICORS REI/RICORS2040 (KIDNEY DISEASE)/RICORS TERAVID/RICORS-SAMID

4.3. Participación en plataformas del ISCIII

Items/Biobancos y biomodelos/Screen

4.4. Colaboraciones internacionales. Partenariados de proyectos europeos

EIT Health <https://eithealth.eu/>

4.5 Colaboraciones internacionales. Redes internacionales.

European Network of Paediatric Research at the European Medicines Agency Pediatric Resuscitation Quality Collaborative PedResQ

European Narcolepsy Network

EURL (The European Union Reference Laboratory)

4.6. Colaboración con empresas de base tecnológica

Corify Care, THYTECH, Telara Pharma, Ownmed Innovation y Evidence Based Behaviour

IIS Princesa - Instituto de Investigación Sanitaria Princesa

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Vacunas
4. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica
2. Nuevas técnicas diagnósticas basadas en imagen
3. Farmacología, farmacogenómica, nuevos fármacos y terapias
4. Inteligencia Artificial
5. Salud digital
6. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
2. Desarrollo integrado de programas multidisciplinares desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías ómicas

NGS Myseq, Illumina

2.2. Tecnologías de imagen

Dentro de la Unidad de Videomicroscopía: plataforma ISRET (Spatial and Temporal Super-Resolution Imaging; Leica Microsystems, GmbH)

2.3 Unidades de experimentación animal. Equipos singulares

Animalario de protección P3 dentro del campus de la UAM

2.4. Infraestructuras, unidades o plataformas acreditadas

- Biobanco acreditación ISO 203087
- Unidad de Ensayos Clínicos fase I acreditada en ISO 9001 y tiene Certificación de la Comunidad de Madrid de cumplimiento de BPCs

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Página web del Instituto (<https://www.iis-princesa.org>).

Talleres que se organizan durante la Semana de la Ciencia en la que participan alumnos. (En la última edición participaron más de 700 alumnos)

Jornadas de Puertas Abiertas para pacientes, como por ejemplo la Jornada de "Tu dolor nos importa" o la Jornada de Esofagitis Eosinofílica organizada junto con AEDESEO (Asociación de pacientes con esofagitis Eosinofílica) entre otras.

Comisiones: Un representante de los pacientes en el Consejo Rector, en la Comisión Delegada hay 1 paciente y en el Comité de Ética de la Investigación con medicamentos 2 pacientes

3.2. Gestión de dato.

En la actualidad estamos realizando la solicitud para constituirnos en nod REDCap

3.3. Repositorio documental en abierto.

Hacemos uso de los existentes en la Comunidad Autónoma de Madrid

3.4 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Cardiovascular
- Reumatología
- Nutrición o metabolismo
- Otro: inmunología

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM/CiberOBN/CiberEHD/CiberCV/CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICORS REI/RICORS2040 (KIDNEY DISEASE)/RICORS-ICTUS/RICORS TERA

4.3. Participación en plataformas del ISCIII

- Sren

4.4. Colaboraciones internacionales. Partenariados de proyectos europeos.

- AIDA -. <https://cordis.europa.eu/project/id/101095359>
- ICOD. <https://www.icod-project.eu/>
- INTELLILUNG: <https://intellilung-project.eu/>
- SECURE <https://cordis.europa.eu/project/id/633765/es>
- SPIDERR <https://spiderr-project.eu/>
- TOGAS - https://health.ec.europa.eu/non-communicable-diseases/cancer/europes-beating-cancer-plan-eu4health-financed-projects/projects/togas_en
- unCoVer: <https://uncover-eu.net/>
- CORDIAL: <https://www.projectcordial.eu/en>
- SYNCHROS. <https://ecrin.org/projects/synchros#>
- EMPOWER: <https://empower-project.eu/>.

4.5. Colaboración con empresas de base tecnológica

Orgenesis (<https://orgenesis.com/#/>); Cytex (<https://cytekbio.com>); Pharmamar (<https://pharmamar.com/es/>); Immed; Catapult Therapeutics BV; Biohope (<https://biohope.eu/>) y Lilly (<https://www.lilly.com/es/>)

IRYCIS - Instituto Ramón Y Cajal de Investigación Sanitaria

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.
3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada
5. Otro: Medicina Personalizada en Enfermedades Raras, cardiovasculares y endocrinológicas

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Vacunas
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes
5. Nuevos métodos de profilaxis, detección y tratamiento
6. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Nuevas técnicas diagnósticas basadas en imagen
2. Farmacología, farmacogenómica, nuevos fármacos y terapias
3. Medicina regenerativa
4. Nuevos materiales biomédicos
5. Inteligencia Artificial
6. Nanotecnología aplicada a la biomedicina
7. Nuevas técnicas quirúrgicas
8. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer).
2. Desarrollo integrado de programas multidisciplinares desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina
3. Fragilidad y prevención de la discapacidad.

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Servicios e infraestructuras singulares de interés en investigación clínica

- Dos salas de hospitalización (4 camas y 8 sillones reclinables)
- Consulta médica con equipamiento necesario para examen completo.
- Laboratorio para procesamiento y archivo de muestras biológicas con centrífuga refrigerada, congeladores de -20° y -80°, autoclave, etc.
- Despacho de trabajo y archivo de documentación confidencial.
- Sala polivalente.
- Medidas de seguridad para garantizar el buen desarrollo del estudio
- Unidad Soporte en estudios clínicos y ensayos fase II-IV: 2 sillones en extracciones preferentes para ensayos clínicos, 6 sillones reclinables y 1 cama en el Hospital de Día Médico.

2.2. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

- Unidad Data Science: Microsoft Power BI, mETABASE Y aPACHE sUPERSET
- ProM/Disco (minería de procesos).
- Stack de computación científica de Python
- Stack de computación científica de R
- Otras herramientas de ingeniería de datos

2.3. Infraestructuras, unidades o plataformas acreditadas

- Biobanco UNE-EN ISO 9001:2015. Certificado por SGS ICS (Nº. ES13/14407).
- Unidad de Innovación: IDI-0008/2017. UNE 166002:2021

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Visibilidad IRYCIS, HRCInforma, Web IRYCIS, Canal Youtube

3.2. Gestión de dato.

Fundanet

3.3. Repositorio documental en abierto.

Repositorio CAM

3.4 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico
- Terapia
- Dispositivos
- Cardiovascular
- Oncología
- Enfermedades infecciosas
- Cirugía

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberDEM / CiberBBN / CiberESP / CiberEHD / CiberER / CiberES / CiberCV / CiberONC / CiberNED / CiberINFEC

4.2 Colaboraciones temáticas. Participación en RICORS

RICORS REI/ RICORS2040 (KIDNEY DISEASE)/ RICORS-ICTUS

4.3. Participación en plataformas del ISCIII

- Items
- Biobancos y biomodelos
- Scleren

4.4 Participación en clúster

- Clúster de salud
- Clúster tecnológico
- Otros

4.5. Colaboraciones internacionales. Partenariados de proyectos europeos.

ERANET TRANSCAN 2, ERANET-EURONANOMED, EULAC, JPIAMR, EDCTP2

4.6. Colaboraciones internacionales. Redes internacionales.

EULOGH, COST, EATRIS, ELIXIR, ECRIN, JPI

4.7. Colaboración con empresas de base tecnológica

APTUS, APTATARGET, ISQUAEMIA, EYEGRESS, +50 ACUERDOS

MURCIA

IMIB - Instituto Murciano de Investigación Biosanitaria

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus
3. Nuevos métodos de profilaxis, detección y tratamiento
4. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Farmacología, farmacogenómica, nuevos fármacos y terapias
2. Medicina regenerativa
3. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Otro: enfermedades neurodegenerativas

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1. Tecnologías ómicas. Equipos singulares

Secuenciador NextSeq 2000 (Illumina) : <https://emea.illumina.com/systems/sequencing-platforms/nextseq-1000-2000/specifications.html>

2.2. Unidades de experimentación animal. Equipos singulares

El Instituto dispone de un animalario libre de patógenos

2.3. Unidades de Biología Celular.

IMIB cuenta con una sala blanca dentro de la cual los equipos singulares son SEPARADOR CELULAR SEPAX, CLINIMACS PRODIGY

2.4. Servicios e infraestructuras singulares de interés en investigación clínica

El grupo de Radiofarmacia del Hospital Virgen de la Arrixaca es responsable de la preparación de radiofármacos para uso asistencial y para la colaboración en estudios de investigación. El hospital núcleo básico del Instituto dispone de un ciclotrón.

2.5. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

El instituto cuenta entre sus plataformas con la de Informática Biomédica y Bioinformática. También se presta un servicio de apoyo metodológico y estadístico a los investigadores.

2.6. Infraestructuras, unidades o plataformas acreditadas

La plataforma de biobanco (norma ISO 9001:2015) y Ensayos clínicos (ISO 9001:2015)

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1. Canales de participación

Jornadas del IMIB, Jornadas de Investigación para la vida, redes sociales, escuela de salud, eventos con asociaciones de pacientes, presencia en medios de comunicación, Semana de la Ciencia, participación en jornadas dirigidas a ciudadanos (Salón del Manga entre otros)

3.2. Gestión de dato.

Base propia desarrollada por la plataforma de Informática biomédica y bioinformática del IMIB

3.3. Repositorio documental en abierto

Portal de transparencia, en la página web del Instituto se pueden encontrar en acceso abierto los documentos de funcionamiento del Instituto así como sus memorias científico-económicas

3.4 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.

- Técnicas de diagnóstico

- Terapia
- Dispositivos
- Cardiovascular
- Oncología
- Genética
- Enfermedades infecciosas
- Cirugía
- Otro: Escala de valoración carga de trabajo enfermería

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

- CiberESP /CiberER /CiberCV

4.2 Colaboraciones temáticas. Participación en RICORS

- RICORS REI /RICORS TERAVID/ RICORS-SAMID

4.3. Participación en plataformas del ISCIII

- Items
- Biobancos y biomodelos
- Scleren

4.4. Colaboraciones internacionales. Partenariados de proyectos europeos.

2 participaciones en partenariados

4.5. Colaboraciones internacionales. Redes internacionales.

COST, ERN

4.6. Colaboración con empresas de base tecnológica

Abamed Medsynergy, Cela Medical Solutions, Inbentus, Cetem, D'Enginy biorem S.L., Biocrosmo S.L., Laboratorio Reig Jofre S.A., Peaches Biotech S.L.

NAVARRA

IDISNA - Instituto de Investigación Sanitaria de Navarra

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica.
2. Nutrición y dieta personalizadas.

3. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías.
4. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada.

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune.
2. Enfermedades emergentes y re-emergentes causadas por hongos, bacterias y virus.
3. Zoonosis.
4. Vacunas.
5. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes.
6. Efectos medioambientales sobre aparición y difusión de enfermedades infecciosas.
7. Nuevos métodos de profilaxis, detección y tratamiento.
8. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica.
2. Nuevas técnicas diagnósticas basadas en imagen.
3. Farmacología, farmacogenómica, nuevos fármacos y terapias.
4. Terapia génica.
5. Medicina regenerativa.
6. Nuevos materiales biomédicos.
7. Inteligencia Artificial.
8. Nanotecnología aplicada a la biomedicina.
9. Implantes y órganos artificiales.
10. Nuevas técnicas quirúrgicas.
11. Salud digital.
12. Car-T.

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable,
2. Impacto del envejecimiento en la enfermedad.
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable.
4. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina.
5. Fragilidad y prevención de la discapacidad.

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

2.1 Tecnologías ómicas

Unidad Genómica:

1. Equipos Maxwell (Promega) para la extracción automatizada de ácidos nucleicos.
2. Equipos Qubit (Thermo Fisher) y TapeStation (Agilent) para la caracterización de ácidos nucleicos.
3. Equipos de secuenciación de segunda generación (NGS) MiSeq (Illumina) e Ion S5 (ThermoFisher).

Unidad Proteómica:

1. Espectrómetro de masas Exploris 480 acoplado a nanocromatógrafo Ultimate 300 (Thermo).
2. Espectrómetro de masas 5600+ TripleTof acoplado a nanocromatógrafo Eksigent (Sciex)

2.2 Tecnologías de imagen

Equipos de imagen animal:

1. Tomografía axial computarizada Quantum GX microCT, Perkin Elmer.
2. Equipo de ultrasonografía de alta resolución Visualsonics VEVO 3100.
3. Equipo de bioluminiscencia y fluorescencia para animales PhotonImager Optima, Biospace Labs.

Equipos de microscopía:

1. Microscopio láser de barrido confocal Zeiss LSM 800 (captura de imagen 3D en muestras fijadas con fluorescencia).
2. Microscopio confocal multifotón Zeiss LSM 880 NLO; Microscopio confocal rápido de disco giratorio (Spinning disk) Cell Observer Z1 (captura de imagen multidimensional 3D + tiempo en cultivos celulares vivos).
3. Microscopio automatizado Zeiss Axio Imager M1Esc (automatización de la adquisición y el análisis de muestras microscópicas).

Equipos MicroPET:

1. Tomógrafo microPET (rata, ratón, mono),
2. Equipo microSPECT/CT (rata y ratón),

2.3 Unidades de experimentación animal

Equipo MicroPet:

1. Técnicas de imagen metabólica in vivo
2. Estudios de biodistribución ex vivo
3. Marcajes de células, péptidos o nanopartículas con distintos radioisótopos (in vivo y/o ex vivo).

2.4. Unidades de Biología Celular. Infraestructuras o equipos singulares

1. Laboratorio GMP de Terapia Celular (LTC)
2. Laboratorio GMP-TG para la elaboración de productos celulares ingenierizados con adenovirus.

2.5. Servicios e infraestructuras singulares de interés en investigación clínica

1. Radiofarmacia-Laboratorio PET GMP.
2. Unidad de desarrollo de fármacos.
3. Instalaciones Radiactivas (Micro CT e Irradiador)

2.6. Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA.

1. Laboratorio del Instituto de Smart Cities¹.
2. Impresora 3D DWS 020X. Impresora 3D de estereolitografía (SLA) de la marca Digital Wax Systems (DWS) y modelo 020X.2.
3. Sala limpia. Sala de limpia ISO 7 para la fabricación de circuitos microelectrónicos.
4. Equipamiento de THz.
5. Clúster de Computación: Consta de 27 nodos con procesadores, núcleos que permiten realizar procesos paralelos. Entre los nodos destacan el Maestro, el de Bigdata, el de cálculo, y los GPU 1 y 2.

2.7. Otros equipos, unidades o infraestructuras

Laboratorio del Instituto de Investigación de Materiales Avanzados

2.8 Infraestructuras, unidades o plataformas acreditadas

1. ISO 9001:2015. Los dos Biobancos, la Unidad de Proteómica y la Unidad de Gestión de EECC de uno de los centros que forma parte de IdiSNA.
2. ISO7: la Sala limpia del Laboratorio Instituto Smart Cities.
3. GMP: el laboratorio GMP de Terapia Celular (LTC)

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1 Canales de participación

Web, el mail, invitación a jornadas, charlas. IdiSNA ha constituido el **Órgano de Participación Ciudadana** (con diferentes representantes de la población Navarra)

3.2 Know How. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual. Destaca el área de **Oncología**

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberOBN / CiberESP/ CiberEHD / CiberFES / CiberCV/ CiberONC/ CiberNED

4.2 Colaboraciones temáticas. Participación en RICORS

RIAPAd/ RICAPPS /RICORS REI /RICORS2040 (KIDNEY DISEASE)/ RICORS-ICTUS/ RICORS TERAV/ RICORS-SAMID

4.3. Participación en plataformas del ISCIII

ITEMAS

4.4 Participación en clúster

1. Clúster de salud
2. El Gobierno de Navarra participa en la ERA-PERMED y participamos con las entidades del mismo que coordinan la Estrategia de Medicina Personalizada de Navarra (SODENA, NASERTIC, ADITECH, etc.)

4.5 Colaboraciones internacionales. Redes internacionales.

EATRIS; BBMRI

4.6. Colaboración con empresas de base tecnológica

Clúster de Salud y CEIN, el Centro Europeo de Empresas e Innovación de Navarra que aglutinan entre ambas tanto a empresas asentadas del ámbito de la salud y de la biotecnología como a las empresas/startups de nueva creación de base tecnológica y/o sector salud.

PAÍS VASCO

IIS Biobizkaia

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas,
2. Integración de tecnologías de proteómica, genómica, epigenómica, metabolómica, etc.,
3. Nutrición y dieta personalizadas,
4. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías,
5. Aspectos sociológicos, psicológicos, económicos, éticos, inteligencia artificial, salud digital en la medicina personalizada
6. Otro: Tecnologías avanzadas en Medicina Personalizada: Robótica, Neuroimagen, Realidad Virtual, 3D, etc.

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune,
2. Enfermedades emergentes y reemergentes causadas por hongos, bacterias y virus,
3. Vacunas,
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes,
5. Nuevos métodos de profilaxis, detección y tratamiento,
6. Vigilancia de la salud y epidemiología
7. Otro: Enfermedades infecciosas en la edad pediátrica y neonatal

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica,
2. Nuevas técnicas diagnósticas basadas en imagen,
3. Farmacología, farmacogenómica, nuevos fármacos y terapias,
4. Terapia génica,
5. Medicina regenerativa,
6. Nuevos materiales biomédicos,
7. Inteligencia Artificial,
8. Nanotecnología aplicada a la biomedicina,
9. Implantes y órganos artificiales,
10. Nuevas técnicas quirúrgicas,
11. Salud digital,
12. Car-T
13. Otro: CAR-NK y Terapia Celular

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer)
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable
4. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina
5. Fragilidad y prevención de la discapacidad
- 6.

EJE 2. CAPACIDADES TECNOLÓGICAS/SERVICIOS

En este anexo se incluyen las infraestructuras, equipos y/o servicios singulares, no los generales

2.1 Tecnologías ómicas

Genética: Novaseq; Cytoscan, Cytoassist, ChromiumX, S5 ,Genetitan y Genechip

Metabolómica: UHPLC, Cromatógrafo

Proteómica: Cromatógrafo líquido ULTA-ALTO (UHPLC); Espectrómetro de masas

2.2 Tecnologías de imagen

Equipo singular microscopía: Microscopio confocal; Microscopio in vivo; Estación de célula viva

Citometría singular: MAcsQuant; LSR Fortessa, Luminex

2.3 Unidades de experimentación animal

Cajas metabólicas; Arco en C; Criostato; Vibratomo

2.4 Unidades de Biología Celular. Infraestructuras o equipos singulares

Escáner de infrarrojos (Odyssey); Estación de trabajo en hipoxia, Aislador, Prodigy, Jess; Chemidoc

2.5 Servicios e infraestructuras singulares de interés en investigación clínica

Participación en el consorcio CERTERA con 2 nodos en Bizkaia.

- - En fase de acreditación de Sala Blanca
- - Laboratorio de investigación en oncología pediátrica:
- - Unidad Mixta de Investigación en oncología pediátrica (H. Cruces-H. Donostia)

2.6 Servicios o equipos singulares de apoyo metodológico, bioinformática, estadística, IA, etc.

Laboratorio de Realidad Virtual.

2.7. Otros equipos, unidades o infraestructuras

Banco de Pruebas del Sistema Nervioso Central para neurorehabilitación de lesionados medulares, niños con parálisis cerebral infantil y enfermedades neurológicas (ictus, E. Parkinson, esclerosis múltiple...)

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1 Canales de participación

- Participación del Director de la Plataforma de organización de pacientes POP en la Comisión de Investigación.

- Participación de los investigadores en las comisiones de asesoramiento de asociación de pacientes (ACCB, ADEMBI, ASPARBI)

3.2 *Know How*. Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual.
Todas las áreas indicadas, y además Ginecología y Reproducción Humana

EJE 4. CAPACIDADES DE COLABORACIÓN

4.1 Colaboraciones temáticas. Participación en consorcios CIBER

CiberSAM / CiberDEM/ CiberESP / CiberER/ CiberNED/

4.2 Colaboraciones temáticas. Participación en RICORS

RICAPPS; RICORS REI; RICORS-ICTUS; RICORS TERA V

4.3. Participación en plataformas del ISCIII

ITEMAS; Biobancos y biomodelos; Scleren

4.4 Participación en clúster

Clúster salud, clúster tecnológico

4.5 Colaboraciones internacionales. Redes internacionales.

Conect 4 Children, COST, ICHOM, ECRIN, Euronet, Endo- ERN, Antiphospholipid Syndrome Alliance, Transbionet, IPDN, EGG, PERN, Treat NMD neuromuscular network, European society for pediatrics nephrology EATRIS

4.6. Colaboración con empresas de base tecnológica

53 Proyectos activos en la convocatoria MEDTECH con empresas vascas, la mayoría pertenecientes al Basque Health Cluster

IIS Biogipuzkoa

EJE 1. CAPACIDADES CIENTÍFICAS

Línea estratégica 1. Medicina de precisión

1. Medicina personalizada, más allá de técnicas ómicas
2. Medicina personalizada en cáncer, enfermedades raras, salud mental y otras patologías

Línea estratégica 2. Enfermedades infecciosas

1. Respuesta inmune,
2. Enfermedades emergentes y reemergentes causadas por hongos, bacterias y virus,
3. Vacunas,
4. Resistencia a los antibióticos, enfermedades por bacterias multirresistentes,
5. Efectos medioambientales (cambio climático, migraciones, globalización) sobre aparición y difusión de enfermedades infecciosas,
6. Nuevos métodos de profilaxis, detección y tratamiento,
7. Vigilancia de la salud y epidemiología

Línea estratégica 3. Nuevas técnicas diagnósticas y terapéuticas

1. Ingeniería biomédica,
2. Nuevas técnicas diagnósticas basadas en imagen,
3. Farmacología, farmacogenómica, nuevos fármacos y terapias,
4. Terapia génica,
5. Medicina regenerativa,
6. Nuevos materiales biomédicos,
7. Inteligencia Artificial,
8. Nanotecnología aplicada a la biomedicina,
9. Implantes y órganos artificiales,
10. Nuevas técnicas quirúrgicas,

11. Salud digital,

12. Car-T

Línea estratégica 4. Cáncer y gerociencia: envejecimiento, enfermedades degenerativas

1. Perfiles moleculares del envejecimiento saludable,
2. Impacto del envejecimiento en la enfermedad (neurodegenerativa, cardiovascular, metabólica, cáncer),
3. Interacción del medio ambiente, nutrición y factores psico-sociológicos en el envejecimiento saludable,
4. Desarrollo integrado de programas multidisciplinarios desde la biología celular y molecular del envejecimiento a biología de sistemas y a la medicina,
5. Fragilidad y prevención de la discapacidad

EJE 3. CAPACIDADES DE TRASLACIÓN A LA SOCIEDAD / PACIENTE

3.1 Canales de participación

1. Web
2. Comité Científico Interno
3. Proyectos de participación ciudadana (como co-investigadores)
4. Proyectos de investigación (como financiadores, donantes o en sesiones divulgativas)
5. Ensayos Clínicos
6. Jornadas formativas de puertas abiertas
7. Iniciativas de outreach y educación científica

3.2. *Know How.* Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual: **Técnicas de diagnóstico; Terapia; Dispositivos; Prevención; Oncología; Genética; Enfermedades infecciosas; Cirugía**

1. vas de outreach y educación científica³

3.2 *Know How.* Tipología y áreas de conocimiento en las que el IIS ha generado propiedad intelectual: **Técnicas de diagnóstico; Terapia; Dispositivos; Prevención; Oncología; Genética; Enfermedades infecciosas; Cirugía**

GDT5. INTELIGENCIA ARTIFICIAL

SUBGRUPO DE TRABAJO 1: DOCUMENTO DE POSICIONAMIENTO: IA EN LA INVESTIGACIÓN SANITARIA

ANEXO I: GLOSARIO DE TÉRMINOS Y ACRÓNIMOS

- **Anonimización:** Proceso de transformación irreversible de datos personales de modo que impida la identificación del individuo, convirtiendo los datos en no personales bajo el RGPD.
- **Aprendizaje automático (Machine Learning):** Conjunto de técnicas que permiten a los sistemas aprender de los datos y mejorar su rendimiento sin ser explícitamente programados para cada tarea específica.
- **Aprendizaje federado (Federated Learning):** Técnica de aprendizaje automático donde un modelo se entrena utilizando datos distribuidos en múltiples sitios sin centralizar los datos, preservando la privacidad.
- **Aprendizaje profundo (Deep Learning):** Subconjunto del aprendizaje automático basado en redes neuronales artificiales con múltiples capas que pueden representar información de manera jerárquica.
- **Big Data:** Conjuntos de datos caracterizados por gran volumen, alta diversidad y velocidad de generación, cuyo análisis requiere infraestructuras y técnicas específicas.
- **CHART:** Chatbot Assessment Reporting Tool, guía para reportar estudios de sistemas conversacionales basados en IA.
- **CONSORT-AI:** Extension de las guías CONSORT para reportar ensayos clínicos que involucran intervenciones basadas en IA.
- **DECIDE-AI:** Guía para evaluar sistemas de IA en etapas tempranas de uso clínico.
- **EHDS:** European Health Data Space (Espacio Europeo de Datos Sanitarios), iniciativa de la UE para facilitar el acceso y uso secundario de datos de salud.
- **IA explicable (XAI - Explainable AI):** Técnicas que permiten comprender cómo los sistemas de IA llegan a sus conclusiones o recomendaciones.
- **IA generativa:** Modelos de IA capaces de producir contenido novedoso como textos, imágenes o datos sintéticos a partir del aprendizaje de patrones en datos de entrenamiento.
- **Inteligencia Artificial (IA):** Conjunto de técnicas computacionales que permiten a los sistemas realizar tareas que típicamente requieren razonamiento, aprendizaje, percepción o interacción adaptativa.
- **Interoperabilidad:** Capacidad de diferentes sistemas de intercambiar datos y utilizarlos de manera efectiva mediante estándares técnicos y semánticos comunes.
- **LOPDGDD:** Ley Orgánica de Protección de Datos y Garantía de Derechos Digitales (España).
- **Modelo multimodal:** Sistema de IA que integra y procesa diferentes tipos de datos (texto, imágenes, audio, datos estructurados) simultáneamente.
- **Privacidad diferencial:** Técnica matemática que proporciona garantías cuantificables de privacidad al

añadir ruido controlado a los datos o resultados.

- **RGPD:** Reglamento General de Protección de Datos de la Unión Europea.
- **Sesgo algorítmico:** Tendencia sistemática de un algoritmo a producir resultados injustos o discriminatorios para ciertos grupos.
- **Seudonimización:** Proceso de sustitución de identificadores directos por códigos, reduciendo el riesgo de identificación pero manteniendo la utilidad analítica de los datos.
- **SPIRIT-AI:** Guía para elaborar protocolos de ensayos clínicos que involucren intervenciones basadas en IA.
- **STARD-AI:** Guía para reportar estudios de precisión diagnóstica que utilizan IA.
- **Supervisión humana:** Principio que requiere que sistemas de IA, especialmente los de alto riesgo, mantengan la intervención y control de profesionales capacitados.
- **TRIPOD-AI:** Guía para reportar estudios de desarrollo y validación de modelos predictivos basados en IA.
- **Validación externa:** Evaluación del rendimiento de un modelo en datos completamente independientes de una población o contexto diferente al utilizado para su desarrollo.

ANEXO II: TABLA RESUMEN DE RESPONSABILIDADES POR ACTOR

Actor	Responsabilidades principales	Acciones clave
Investigadores individuales	Formación continua en IA, ética y protección de datos; Diseño riguroso de estudios; Gestión responsable de datos; Comunicación transparente de resultados	Completar formación específica en IA; Aplicar guías SPIRIT-AI, TRIPOD-AI, CONSORT-AI; Evaluar modelos con criterios de equidad; Publicar en acceso abierto
Grupos de investigación	Colaboración interdisciplinar; Participación de pacientes; Evaluación de impacto ético y social; Reproducibilidad	Formar equipos multidisciplinarios; Incorporar representantes de pacientes; Realizar análisis de impacto; Compartir datos y código cuando sea posible
Institutos de investigación	Políticas institucionales; Unidades de apoyo especializadas; Infraestructuras seguras; Formación de personal; Igualdad y diversidad	Aprobar políticas sobre IA; Crear unidades de ciencia de datos y protección de datos; Invertir en infraestructuras; Implementar planes de igualdad
Comités de ética	Evaluación ética específica para IA; Supervisión continua; Formación especializada	Desarrollar criterios de evaluación para IA; Realizar seguimiento de proyectos; Incorporar expertos en IA y representantes de pacientes
Direcciones científicas	Estrategia institucional; Asignación de recursos; Promoción de buenas prácticas; Rendición de cuentas	Priorizar inversiones en IA; Reconocer contribuciones interdisciplinarias; Reportar actividades de IA; Participar en redes nacionales e internacionales
Agencias financiadoras	Políticas de financiación alineadas con principios éticos; Promoción de estándares; Requisitos de transparencia	Incluir criterios de equidad en evaluación; Requerir planes de gestión de datos; Financiar infraestructuras compartidas; Promover ciencia abierta
Autoridades sanitarias	Marco regulatorio apropiado; Coordinación interinstitucional; Protección de derechos fundamentales	Desarrollar normativas equilibradas; Facilitar participación en EHDS; Armonizar requisitos; Supervisar cumplimiento
Pacientes y ciudadanos	Participación informada; Aportación de perspectivas; Ejercicio de derechos	Participar en diseño de proyectos; Expresar prioridades y preocupaciones; Solicitar información sobre uso de datos

ANEXO III: LISTA DE VERIFICACIÓN PARA PROYECTOS DE IA EN INVESTIGACIÓN SANITARIA

Fase de diseño

- ☐ ¿Se ha justificado el uso de IA frente a métodos más simples?
- ☐ ¿El equipo incluye expertise en IA, clínica, ética y protección de datos?
- ☐ ¿Se han incluido representantes de pacientes en la planificación?
- ☐ ¿Se ha realizado un análisis de riesgos éticos y de privacidad?
- ☐ ¿El protocolo sigue las guías SPIRIT-AI cuando corresponda?
- ☐ ¿Se ha planificado la gestión de datos desde el inicio?

Fase de datos

- ☐ ¿Los datos son representativos de la población diana?
- ☐ ¿Se ha verificado la calidad de los datos?
- ☐ ¿Se han implementado medidas de seudonimización o anonimización?
- ☐ ¿Se ha obtenido consentimiento informado apropiado?
- ☐ ¿Existe documentación completa del origen y transformaciones de los datos?
- ☐ ¿Se cumplen los requisitos del RGPD y LOPDGDD?

Fase de desarrollo

- ☐ ¿Se han considerado estrategias de mitigación de sesgos?
- ☐ ¿Se utilizan conjuntos separados para entrenamiento, validación y prueba?
- ☐ ¿Se han definido métricas apropiadas incluyendo medidas de equidad?
- ☐ ¿Se documenta exhaustivamente el desarrollo del modelo?
- ☐ ¿Se ha realizado validación externa cuando sea posible?
- ☐ ¿Se evaluó el rendimiento desagregado por subgrupos relevantes?

Fase de implementación

- ☐ ¿Existe un plan de supervisión humana efectiva?
- ☐ ¿Se ha diseñado monitorización continua del rendimiento?
- ☐ ¿Hay procedimientos claros para gestionar incidentes?
- ☐ ¿Se ha formado adecuadamente a los usuarios del sistema?
- ☐ ¿Existe un comité de supervisión para la implementación?

Fase de comunicación

- ☐ ¿Se ha registrado el protocolo en repositorio público?
- ☐ ¿El manuscrito sigue las guías apropiadas (CONSORT-AI, TRIPOD-AI, etc.)?

- ☐ ¿Se reportan limitaciones y resultados negativos honestamente?
- ☐ ¿Se facilita acceso a código, modelos o datos cuando sea posible?
- ☐ ¿La autoría refleja todas las contribuciones sustanciales?
- ☐ ¿La comunicación pública es clara sobre beneficios y limitaciones?

ANEXO IV. FIGURAS Y TABLAS

Figura 1



Figura 2

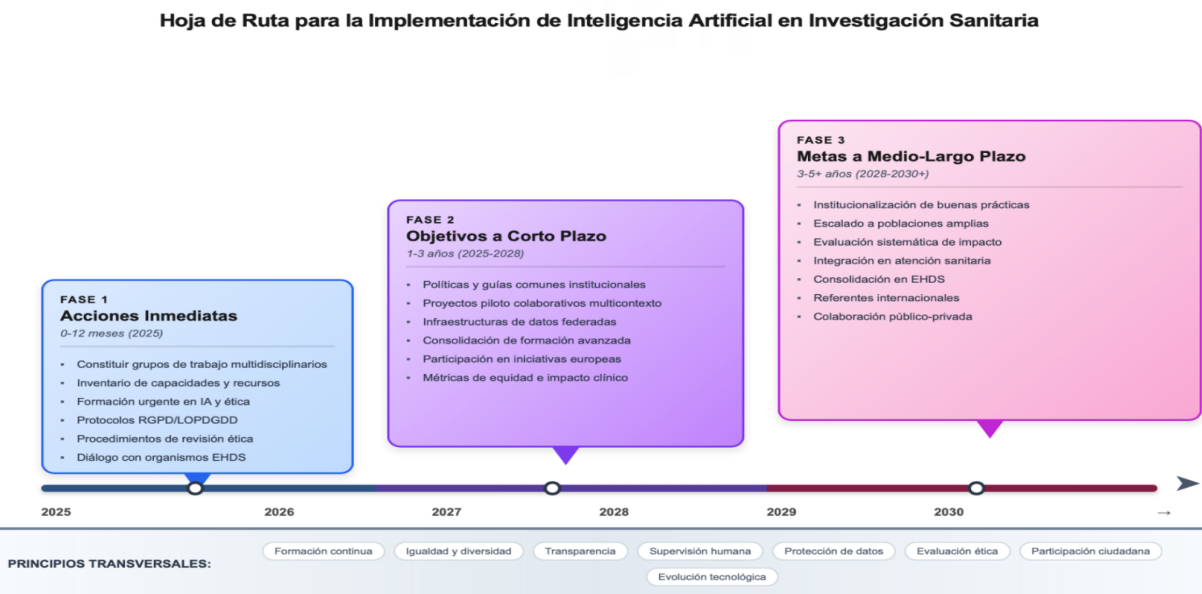


Figura 2. Representación visual de la implementación progresiva de inteligencia artificial en investigación sanitaria. Las fases se muestran como bloques ascendentes que reflejan el aumento en complejidad y alcance, sustentadas por principios transversales que permanecen constantes durante todo el proceso.

Tabla 1. Definiciones operativas de conceptos fundamentales

Concepto	Definición operativa	Aplicación en investigación sanitaria
TECNOLOGÍAS DE IA		
Inteligencia Artificial	Conjunto de técnicas que permiten a sistemas realizar tareas que requieren razonamiento, aprendizaje, percepción o interacción adaptativa	Análisis de imágenes médicas, predicción de riesgos, apoyo a decisiones clínicas
Machine Learning <i>(Aprendizaje automático)</i>	Algoritmos que encuentran patrones en datos y mejoran con la experiencia sin programación explícita	Estratificación de pacientes, predicción de respuesta a tratamientos
Deep Learning <i>(Aprendizaje profundo)</i>	Redes neuronales con múltiples capas que representan información jerárquicamente	Diagnóstico por imagen, análisis genómico, procesamiento de historias clínicas
IA Generativa	Modelos que producen contenido novedoso (textos, imágenes) a partir de datos de entrenamiento	Generación de datos sintéticos, asistencia en redacción científica, simulaciones
Big Data	Conjuntos de datos caracterizados por gran volumen, diversidad y velocidad de generación	Integración de datos multi-ómicos, registros clínicos poblacionales, vigilancia epidemiológica
Sistemas Predictivos	Modelos que estiman probabilidad de eventos futuros a partir de datos históricos	Predicción de desenlaces clínicos, modelización de brotes, pronóstico de enfermedades
MODALIDADES DE INVESTIGACIÓN SANITARIA		
Investigación Básica	Profundiza en mecanismos biológicos fundamentales a nivel molecular, celular o sistémico	Identificación de dianas terapéuticas, comprensión de patogénesis
Investigación Clínica	Estudios con personas o muestras biológicas humanas para evaluar intervenciones	Ensayos clínicos, estudios observacionales, validación de biomarcadores
Investigación Traslacional	Traslada hallazgos de investigación básica a aplicaciones clínicas	Desarrollo de nuevas terapias, medicina de precisión
Investigación Epidemiológica	Estudia distribución y determinantes de enfermedades en poblaciones	Vigilancia de salud pública, identificación de factores de riesgo
Investigación de Servicios de Salud	Analiza organización y eficiencia de sistemas sanitarios	Optimización de recursos, mejora de procesos asistenciales

Nota: La IA puede actuar en todas las modalidades de investigación sanitaria, aunque con consideraciones metodológicas y éticas específicas en cada caso. La comprensión compartida de estos conceptos facilita la comunicación efectiva entre clínicos, científicos de datos, bioestadísticos, especialistas en ética, juristas y otros profesionales que deben colaborar en proyectos multidisciplinarios.

Tabla 2. Guía de buenas prácticas en el ciclo de vida de la investigación con IA

Fase	Principios clave y acciones	Guías específicas y consideraciones
1. Planificación y Diseño	<ul style="list-style-type: none">Ética desde el diseño<ul style="list-style-type: none">Justificar el uso de IA frente a alternativasIdentificar riesgos potenciales tempranamenteIncluir análisis de impacto ético y socialMultidisciplinariedad<ul style="list-style-type: none">Equipos con científicos de datos, clínicos, epidemiólogos, especialistas en ética y pacientes	SPIRIT-AI Protocolos de ensayos <ul style="list-style-type: none">Descripción detallada del algoritmoInformación sobre datos de entrenamientoEstrategias de validaciónPlan de actualización del modeloProcedimientos de supervisión humana
2. Recolección y Gestión de Datos	<ul style="list-style-type: none">Calidad y representatividad<ul style="list-style-type: none">Diversidad en edad, género, etnia, nivel socioeconómicoMinimizar errores, valores perdidos, inconsistenciasEstandarizar procedimientos de recolecciónCumplimiento normativo<ul style="list-style-type: none">Minimización de datos (solo lo necesario)Seudonimización tempranaConsentimiento informado específico para IA	Requisitos RGPD/LOPDGDD: <ul style="list-style-type: none">Documentar origen y contexto de datosRegistrar transformaciones aplicadasImplementar medidas de seguridad multicapaPlanificar preservación o destrucción segura Interoperabilidad: <ul style="list-style-type: none">Estándares: HL7 FHIR, DICOM, SNOMED CT, LOINC
3. Desarrollo y Validación	<ul style="list-style-type: none">Mitigación de sesgos<ul style="list-style-type: none">Repesado de muestras para compensar desequilibriosTécnicas de aprendizaje justo (fairness-aware ML)Calibración por subgruposValidación rigurosa<ul style="list-style-type: none">Separación: entrenamiento/validación/pruebaValidación externa en datos independientesEvaluación desagregada por subgrupos	TRIPOD+AI Modelos predictivos (27 elementos) <ul style="list-style-type: none">Datos fuente y variables predictorasArquitectura del algoritmo e hiperparámetrosProcedimientos de preprocesamientoMétricas de rendimiento y equidadValidación interna y externa Métricas de equidad: Paridad demográfica, igualdad de oportunidades, paridad predictiva
4. Implementación Experimental	<ul style="list-style-type: none">Supervisión continua<ul style="list-style-type: none">Comenzar en entornos controladosComités de supervisión con informes periódicosMonitorización del impacto y derechosSupervisión humana efectiva<ul style="list-style-type: none">Información comprensible sobre prediccionesAlertas ante alta incertidumbreIntervención humana fácil y rápida	DECIDE-AI Evaluación temprana <ul style="list-style-type: none">Evaluación en etapas tempranasReporte transparente para replicabilidadCapacidad de retirar o ajustar el modelo Gestión de incidentes: <ul style="list-style-type: none">Procedimientos claros de reporteInvestigación de causasAcciones correctivas y preventivas
5. Publicación y Difusión	<ul style="list-style-type: none">Transparencia y reproducibilidad<ul style="list-style-type: none">Registro previo de protocolosDescripción detallada de algoritmos, datos, métricasDiscusión honesta de limitacionesFacilitar acceso a código y modelosAutoría responsable<ul style="list-style-type: none">Reconocer contribuciones técnicas sustancialesIncluir participación de pacientes	CONSORT-AI Resultados de ensayos STARD-AI Precisión diagnóstica CHART Sistemas conversacionales <ul style="list-style-type: none">Acceso abierto a publicacionesCompartir datos: sintéticos, acceso controlado, enclaves segurosRepositorios: GitHub (código), Hugging Face (modelos), Zenodo (datos) Comunicación: Clara y honesta sobre beneficios y limitaciones

Principio transversal: La colaboración entre científicos de datos y clínicos debe mantenerse a lo largo de todo el ciclo de vida. Los clínicos aportan conocimiento del dominio y criterio sobre utilidad clínica; los científicos de datos contribuyen comprensión de capacidades y limitaciones algorítmicas, técnicas avanzadas de validación, e implementación eficiente.

ANEXO IV DOCUMENTACIÓN ADICIONAL.GDT5. INTELIGENCIA ARTIFICIAL

SUBGRUPO DE TRABAJO 3: GUÍA DE REQUISITOS TÉCNICOS Y REGULATORIOS PARA PROYECTOS CON BIG DATA E IA EN SALUD

ANEXOS OPERATIVOS

CHECKLISTS TRANSVERSALES (VERIFICACIÓN RÁPIDA)

Proyecto / Sistema de IA: _____

Versión del documento: _____

Fecha de revisión: ____ / ____ / ____

Revisor(es): _____

Observaciones generales: _____

Uso: marcar **SI** (cumplido), **No** (pendiente), **N/A** (no aplica). Añadir enlace a evidencia.

A) Datos y gobernanza

- Existe **DMP** aprobado y versionado.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Diccionario de variables y linaje/documentación **ETL/ELT**.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Informe de calidad y representatividad (subgrupos).
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Plan de retención/eliminación y copias (**RPO/RTO**).
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

B) Protección de datos (RGPD/LOPDGDD)

- **Base jurídica** definida y Registro de actividades de tratamiento.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

- **DPIA/EIPD** realizada y firmada.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Seudonimización/anonimización y control de acceso por rol.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Contratos de encargo/corresponsabilidad y transferencias internacionales, si procede.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

C) Regulación/ética

- Cualificación del software (¿PS? clase y justificación).
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Gestión de riesgos (ISO 14971) y plan de evaluación clínica/desempeño.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Aprobaciones **CEIm/organizativas** y, cuando proceda, interacción con **AEMPS**.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Mapeo de requisitos **AI Act** (alto riesgo) y cronograma.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

D) Diseño/validación

- Protocolo de validación con métricas (incluida **calibración**). Evidencia: ____
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- **Validación externa** (al menos una) y análisis por subgrupos.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Reproducibilidad (versionado de datos/código/artefactos).
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

E) Explicabilidad y trazabilidad

- Guía de explicabilidad por rol (clínico, datos, auditor). Evidencia: ____
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Política de **logging** de inferencias y conservación.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

F) Monitorización y MLOps

- Plan de métricas (servicio y clínicas), **drift** y recalibración.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- **Changelog**, criterios de **cambio significativo** y **CI/CD**.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

G) Interoperabilidad e integración

- Perfiles **HL7 FHIR** y **DICOM** definidos y validados.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Catálogo de interfaces, pruebas **end-to-end** y modo **shadow**.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

H) Seguridad del paciente y operación

- Análisis de peligros, salvaguardas y **override** clínico.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)
- Plan de incidentes y notificación; **SLA/SLO**.
 - Sí ☐ No ☐ N/A ☐
 - Evidencia: (añadir enlace a evidencia)

I) Verificación rápida de ciberseguridad (SBOM/VDP/backups)

- **SBOM** por versión:
 - Sí ☐ No ☐ N/A ☐
 - referencia de versión: _____

- **VDP publicado** (divulgación de vulnerabilidades):

- Sí ☐ No ☐ N/A ☐
- url/correo: _____ — sla: _____

- **Parcheo de CVES críticas < 30 días:**

- Sí ☐ No ☐ N/A ☐
- evidencias/fecha: _____

- **Prueba de restauración (< 12 meses):**

- Sí ☐ No ☐ N/A ☐
- fecha última prueba: _____
- resultado:
- OK ☐
- con incidencias ☐

- **Gestión de claves (kms/hsm) y rotación:**

- Sí ☐ No ☐ N/A ☐
- Periodicidad: _____

- **Registro/auditoría de accesos e inferencias:**

- Sí ☐ No ☐ N/A ☐
- Retención: _____ meses

J) Sostenibilidad y contratación

- **TCO/ROI** y plan de financiación/compra.

- Sí ☐ No ☐ N/A ☐
- o Evidencia: (añadir enlace a evidencia)

- **Contratos/licencias** (propiedad, portabilidad y salida).

- Sí ☐ No ☐ N/A ☐
- Evidencia: (añadir enlace a evidencia)

FORMULARIO DE EVALUACIÓN PI (TRL 1–3)

Identificación del proyecto: título, IP, centro, línea clínica, TRL objetivo.
Resumen no técnico (≤ 200 palabras): ____

Bloques y puntuación (0–3 por ítem):

- Diseño científico y relevancia clínica (8 pts) → /8
- Datos: calidad y representatividad (10 pts) → /10
- Metodología y rendimiento (8 pts) → /8
- Ética y protección de datos (4 pts) → /4
- Plan de madurez y transferencia (4 pts) → /4
- Innovación y encaje estratégico (2 pts) → /2
-

Total PI (36): __/36 → No viable / Viable / Viable y financiable

Evidencias adjuntas (enlaces): protocolo, DMP, informe de calidad, resultados, DPIA, etc.

Acciones recomendadas y plazos: ____

FORMULARIO DE EVALUACIÓN ICPS (TRL ≥ 4)

Proyecto / Sistema de IA: _____

TRL actual: _____

TRL objetivo: _____

Fecha de revisión: ____ / ____ / ____

Revisor(es): _____

Identificación del estudio: título, promotor/fabricante legal, centro/es, clase de PS, intended purpose, TRL. (≤ 200 palabras): ____

Autorizaciones/Registros: CEIm (fecha y referencia), AEMPS (notificación/autorización, si aplica), EUDAMED (si aplica).

Diseño del estudio: tipo (exploratorio/confirmatorio; pre/post-market), población, endpoints, tamaño muestral y análisis.

Integración y flujo del estudio: datos requeridos, integración con HCE/FHIR/DICOM si procede, procedimientos y roles.

Riesgos y salvaguardas: gestión de riesgos, GSPR, plan de incidentes y supervisión humana. **Datos/Equidad:** calidad y representatividad, subgrupos, *DataSheet/ModelCard*.

Operación y seguridad: bloqueo de versiones para protocolo, *logging* y auditoría, protección de datos (RGPD/LOPDGDD, DPIA).

Transición posestudio: plan de PMS/PMCF o despliegue asistencial, condiciones para adopción.

Bloques y puntuación (0–3 por ítem):

- Valor clínico y seguridad del paciente (10 pts) → /10
- Regulación y conformidad (10 pts) → /10
- Interoperabilidad e integración (8 pts) → /8
- Monitorización y MLOps (8 pts) → /8
- Datos y equidad (6 pts) → /6
- Sostenibilidad y escalabilidad (6 pts) → /6
-

Total ICPS (48): ____/48 → No viable / Viable / Viable y financiable

Evidencias adjuntas: validación externa, CEIm/AEMPS, perfiles FHIR/DICOM, plan de monitorización, contrato/SLAs, evaluación económica.

Condiciones de despliegue (si aplica): ____

PLANTILLA DATASHEET (DATASET)

- **Origen y periodo:** ____
- **Población y criterios:** inclusión/exclusión, centros.
- **Variables y terminologías:** diccionario, codificaciones (SNOMED CT, LOINC, ICD-10-ES, etc.).
- **Procesos de limpieza/etiquetado:** reglas y validaciones.
- **Representatividad y sesgos conocidos:** análisis por subgrupos.
- **Limitaciones y calidad:** *missingness*, *outliers*, coherencia temporal.
- **Acceso y licencias:** restricciones y procedimiento de solicitud.
- **Versionado y linaje:** identificadores y cambios respecto a versiones previas.

1.1. PLANTILLA MODEL CARD (MODELO)

- **Objetivo clínico e finalidad prevista (intended use):** ____
- **Población diana y contexto de uso:** ____
- **Datos y preprocesado:** versiones y filtros.
- **Arquitectura y entrenamiento:** resumen reproducible.
- **Métricas clave:** rendimiento y **calibración** global y por subgrupos.
- **Riesgos, salvaguardas y supervisión humana:** ____
- **Usos permitidos/prohibidos:** límites explícitos.
- **Monitorización y mantenimiento:** métricas en producción, umbrales y criterios de **cambio significativo**.
- Limitaciones conocidas y escenarios no recomendados:
 - o Limitaciones técnicas: _____
 - o Condiciones clínicas o contextos donde no se recomienda su uso: _____
- **Versionado:** identificador de modelo y fecha.

PLAN DE MONITORIZACIÓN POSDESPLIEGUE (PLANTILLA)

- **Objetivos y responsables:** comité, roles y RACI.
- **Métricas clínicas y de servicio:** disponibilidad, latencia, fallos, rendimiento por subgrupos, tasa de **override**.
- **Detección de *drift*:** tests y ventanas; umbrales y tiempos de reacción.
- **Recalibración/actualización:** procedimiento, entorno *shadow*, criterios de aceptación.
- **Reporte y periodicidad:** tablero, informes y comunicación a usuarios/órganos de supervisión.

GESTIÓN DE CAMBIOS Y HOMOLOGACIÓN POR VERSIÓN (PLANTILLA)

- **Clasificación del cambio:** menor / mayor / **significativo**.
- **Riesgo e impacto:** clínica, seguridad, rendimiento, integración.
- **Pruebas requeridas:** unitarias, integración, *end-to-end*, usabilidad.
- **Aprobaciones:** comité técnico/ético; ventana de mantenimiento.
- **Despliegue y rollback:** plan y validación post-despliegue.
- **Documentación:** *changelog*, versiones de datos/modelo/servicio.

DOSSIER DE INTEROPERABILIDAD (PLANTILLA)

- **Perfiles y recursos:** HL7 FHIR (recursos y perfiles nacionales), DICOM/DICOM SR.
- **Mapeos terminológicos:** SNOMED CT, LOINC, ICD-10-ES, ATC/RxNorm (según entorno).
- **Interfaces y eventos:** endpoints, autenticación (OIDC/OAuth2), CDS Hooks/SMART si aplica.
- **Pruebas y conformidad:** validadores, casos de prueba y resultados.
- **Seguridad y auditoría:** cifrado, trazas y retención de logs.

EXPEDIENTE REGULATORIO MÍNIMO (SI CUALIFICA COMO PS)

- **Intended purpose y clasificación** (MDR/IVDR) con justificación.
- **Gestión de riesgos** (ISO 14971) y **IEC 62304** (ciclo de vida software).
- **Evaluación clínica/desempeño y plan *post-market***.
- **Cumplimiento AI Act** para alto riesgo (gobernanza, datos, trazabilidad, supervisión humana).
- **Vigilancia y seguridad:** incidentes, tendencias y acciones correctivas.

DPIA/EIPD (ESQUELETO)

- **Descripción del tratamiento y finalidad:** ____
- **Bases jurídicas y necesidad/proporcionalidad:** ____
- **Riesgos para derechos/libertades:** catálogo y evaluación.
- **Medidas de mitigación:** técnicas y organizativas (incluye seudonimización/anonimización).
- **Conclusión y firma:** DPD, responsables y fecha.

CASO DE NEGOCIO Y EVALUACIÓN ECONÓMICA (PLANTILLA)

- **Problema y alternativas:** ____
- **Costes:** CAPEX/OPEX, datos e integración.

- **Beneficios:** clínicos, operativos y económicos.
- **Análisis:** TCO, ROI, ICER (si aplica) y sensibilidad.
- **Plan de financiación/compra:** convocatoria, CPI, licencias/uso/resultado.

REPORTES TIPO

- **Informe a CEIm:** sinopsis, población, datos, riesgos/beneficios, consentimiento/ información y salvaguardas.
- **Comunicación a AEMPS (cuando proceda):** cualificación/clase, riesgos, evaluación clínica/desempeño, plan poscomercialización.
- **Informe a financiadores (p. ej., ISCIII):** objetivos, TRL, evidencias, plan de madurez, presupuesto y KPIs.
- **Informe operativo interno:** estado, incidencias, **drift**, recalibraciones y acciones.

POLÍTICA SBOM Y BOLETÍN DE VULNERABILIDADES (PLANTILLA)

- **Alcance y formato SBOM** (CycloneDX/SPDX), responsable, periodicidad de emisión.
 - **Flujo de revisión de CVEs** (umbral CVSS), parcheo y comunicación.
 - **Boletín de vulnerabilidades:** versión afectada, CVE, impacto, workaround, fecha de parche.
- Salida: SBOM firmada por versión + boletín vigente.

PROCEDIMIENTO DE DIVULGACIÓN DE VULNERABILIDADES (VDP)

- Canal público (URL/correo), PGP, alcance, no-legal-threats clause.
 - SLA de acuse (≤ 7 días) y de corrección (según severidad).
 - Coordinación con CSIRTs y notificación regulatoria cuando proceda.
- Salida: VDP publicado + registro de casos y tiempos.

PLANTILLA DE MODELADO DE AMENAZAS (STRIDE) Y MATRIZ 14971

- Catálogo inicial STRIDE (spoofing, tampering, repudiation, information disclosure, denial of service, elevation of privilege) por componente.
 - Matriz **requisito ↔ amenaza ↔ control ↔ evidencia** enlazada a **ISO 14971** y verificación (7.4).
- Salida: diagrama de datos/flujo + matriz firmada y versionada.

Salida esperada del apartado 12: *checklists* cumplimentados, formularios **PI/ICPS** con puntuación, *DataSheet/ModelCard* actualizados, planes de monitorización y cambios aprobados, dossier de interoperabilidad, expediente regulatorio (si aplica), **DPIA**, caso de negocio y reportes tipo

