The Strategic Plan 2010-2013 of the Spanish National Biobank Network was approved by the network Plenary Board and by Instituto de Salud Carlos III Director in December, 2010
INDEX

1. Introduction
2. Origin of the network
3. Model definition
   3.1. Definition
   3.2. Mission
   3.3. Vision
4. Organizational Structure
   4.1. Title Holder
   4.2. Members
   4.3. Collaborating institutions
   4.4. General Coordinator of the network
   4.5. Plenary Board
   4.6. Executive Board
   4.7. Internal Committees
   4.8. External Scientific Advisory Board
   4.9. Working Groups
   4.10. Coordination Office
   4.11. Organizational chart
5. Analysis of the current situation
   5.1. The global scientific environment
   5.2. The Spanish scientific environment
   5.3. Biobanking in Spain
   5.4. Analysis
      5.4.1. Strengths
      5.4.2. Weaknesses
6. Legal Framework
7. Strategic Plan 2010-2013
   7.1. Integration
   7.2. Harmonization
   7.3. Public Service
Annexe List of institutions
STRATEGIC PLAN

1. INTRODUCTION

In order to promote translational research and the application of advances in knowledge and technology from research and innovation, it is very useful to build easily accessible infrastructures that facilitate rapid experimental demonstration of a hypothesis (“theory”) or testing of a previously simulated model. Among the many biomedical and health platforms, biobanks are among the most attractive in helping to build bridges between basic, translational, and clinical research and care practice.

Throughout history, the availability of biological samples and associated information of high quality has been a constant that has been at the root of many of the most important advances in Medicine of our time, including currently recognized definitions of anatomical and molecular entities.

Typically, the collection of significant numbers of human biological samples and quality information involves a major effort in planning, construction, and finally operation, which consumes a significant amount of time and which slows the development of experimental research. Therefore, the promotion and implementation of biobanks that facilitate access to quality samples (and associated data) by researchers who present a project with the appropriate scientific organization and with the proper ethical and legal safeguards for the donor represents an essential milestone in shortening the time that normally elapses between research and the application of its results and in improving the effectiveness of research.

For this effort to have the desired impact, constant coordination and collaboration between biobanks and conceptually related initiatives is required, and within each of them among the different professionals involved in processing the samples and their associated information: identification and phenotyping of donors, sampling, processing, storage, distribution, transfer, use of samples and associated information, and overall management of these proceedings.

Based on what was just stated, it is essential to include hospitals in a stable structure, the biobank, provided with an infrastructure and personnel specialized in the handling of samples and associated data for transfer to biomedical research in an adequate ethical-legal framework.

The main distinguishing feature of biobanks, as currently understood, with respect to the classical concept of a collection of samples and associated data (collection of a research group, institutional collection, or private collection), is its commitment to transferring samples and associated information to research groups in an open, transparent, and generous way for the benefit of science and, above all, the patient. This distinguishing feature is unambiguously reflected in the current definition of a biobank drawn up by the OECD as a Biological Resource Centre. \(^1\),\(^2\)

On the other hand, today’s biomedical excellence research is organized largely as a global phenomenon around the study of large series of samples organized with well-defined and detailed criteria regarding the identification of patients, with the specific information required in each case. This is especially important in:


Processes such as cancer where the most recent evidence shows the genetic heterogeneity among different patients;

- Infectious diseases where both the agent causing the disease and the genetic characteristics of the patient are important;

- Rare diseases where the participation of multiple institutions is essential to achieve assessable caseloads; and

- Epidemiological studies, where it is necessary to have representative series of personal/collective environmental and genetic differences involved in the development of the disease.

All this justifies the growing interest in developing cooperative networks of biobanks to minimize biases arising from heterogeneity in the quality of biological samples by means of protocols for procedures, policy development, quality assurance, and promotion of collaborative environments. In the same sense, an efficient effort to integrate the various information systems that manage patient identification, clinical data, and samples is required.

In addition, Society is increasingly aware of the importance of biomedical research and the value of biological samples and associated information to enable a greater degree of health and, therefore, a more effective medical care. Fruit and reflection of this interest is the formulation of specific legislative frameworks in this area, among which should be mentioned The Recommendation Rec(2006) of the Committee of Ministers to members states on research on biological materials of human origin, and Law 14/2007 on Biomedical Research (Spanish abbreviation: LIBM).

Based on the provisions of the LIBM, biobanks are called to guarantee:

- The rights of patients and donors.

- The quality of biological samples and associated data made available to the Scientific Community.

- A transparent, regulated, and effective management process of these samples.

- A proper use of biological samples and associated data in accordance with this framework.

To meet these requirements in Spain, the Spanish Ministry of Science and Innovation (Spanish abbreviation: MICINN), through the Instituto de Salud Carlos III (The Carlos III Health Institute; ISCIII) has decided to create and develop a network of hospital biobanks (n = 52) to which other biobanks (n = 11) have been associated that are not affiliated with hospitals, as a platform to support the development of biomedical research. These institutions are listed in Annexe 1.

The present document aims to establish a strategic plan for the design, construction, and implementation of this network, based on the initiative of the ISCIII and on an analysis of the current situation at the level of the different institutions and their environment.

### 2. ORIGIN OF THE NETWORK

The Spanish National Biobank Network (Red Nacional de Biobancos) is an initiative of the Instituto de Salud Carlos III (ISCIII) of the Spanish Ministry of Science and Innovation, within the Subprogram of Thematic Networks of Cooperative Research on Health (Spanish abbreviation: RETICs), and its aim is

"To regulate the procedure for awarding grants to fund specific stable cooperative research structures in areas considered strategic for the NHS, to promote a better positioning of our country in the European Research Area in those fields."

A RETIC is defined as a

---


4 http://www.coe.int/t/e/human_rights/equality/01_overview/1_annual_reports/

"Group of professionals from different institutions, with common research, development, and innovation lines and objectives, in order to promote complementarity of actions by sharing goals and resources."

The creation of the Spanish National Biobank Network is contained in the Resolution of March 20, 2009, jointly by the Secretariat of State for Research and the Carlos III Health Institute, for which in 2009 a call for proposals was published to grant funding through the Strategic Action in Health, under the National Plan R&D+I 2008-2011 (BOE No. 71, Tuesday March 24, 2009).

Based on this call, the Network is defined as a stable structure of cooperative research (art. 133) corresponding to a new vision of RETICs characterized by a transversal nature and whose primary objective is not the generation of knowledge, but the establishment of service platforms.

This initiative of the ISCIII is based on a two-fold need:

- The legal need for development and implementation of Biobanks according to Law 14/2007 for Biomedical Research.
- The operational need to provide added value to the system in the categories of integration and public service.

3. DEFINITION OF THE MODEL

3.1 DEFINITION

The Spanish Biobank Network was established as a stable network of scientific cooperation of biobanks for biomedical research:

- Promoted and funded by the ISCIII through its RETICs Program,
- Essentially hospital-based,
- With the objective of public service,
- Committed to its own ethical principles and with a strict observance of the effective legislation.

The network is ordered and structured to function as a stable instrument of coordination between its various component institutes.

The network is based on the greatest respect for regional and territorial initiatives or initiatives by each centre, and can only fully meet its objectives by working with and from those territorial initiatives.

3.2 MISSION

Based on the foregoing definition, the main mission of the Spanish National Biobank Network focuses on developing a cooperative network of public service, especially directed towards the Spanish Scientific Community, made up of hospital biobanks and associated biobanks in different Autonomous Communities and other related institutions with activities related to sample management to allow the following:

- To provide the Scientific Community access to quality sample collections and associated data through a cooperative structure of public service, first and foremost implemented in hospitals.
- To integrate existing initiatives related to biobanks and the use of human samples in biomedical research, by establishing a functional map of the biobanks.
- To promote the creation of qualitatively varied collections, fitting current needs of researchers and those that can be foreseen for the future.
- To harmonize their bases and functional strategies, technical processes, and procedures derived from the ethical and legal requirements.
To contribute to ensuring respect for the fundamental rights and freedoms of patients and donors in general, with special reference to the protection of the dignity and identity of the individual, from which the principle of autonomy derives, and of the treatment of their personal data.

To promote technological innovation in biobanks.

To assist in the development of the pan-European platform BBMRI, and promote the Spanish participation in said infrastructure (BBMRI-ERIC.es).

In summary, the Biobank Network aims to provide the system with added value by creating a harmonious cooperative framework for the benefit of the Scientific Community, favouring the growth of scientific production in Biomedicine in quantity and especially in quality, guaranteeing the rights of patients with respect to donation, management, and transfer of biological samples and associated information within the frameworks of ethical standards and the legislation.

The network activity does not compete with the responsibilities of the Health Authorities or the institutions that host the biobanks, but rather complements their actions, in an open and efficient cooperative framework, through the implementation of harmonized protocols regarding procurement, processing, and storage of the samples, as well as the application of diagnostic criteria and stages of the pathologies, in a way consented by international standards, so as to optimize the quality of the samples and to minimize individual differences inherent to the characteristics of each biobank.

### 3.3 VISION

The Thematic Network of Hospital Biobanks was established as a Cooperative Network of Biobanks of human biological samples for research, promoted and funded by the ISCIII as part of its RETICs program, and is characterized by:

- Being a public service of the highest quality in its field of activities.
- Being a cooperative state reference on biobanks through harmonization of procedures, institutional integration, and organization as a public service of samples and associated data within the framework of Law 14/2007 on Biomedical Research.
- Basically having a territorial and functional design that reflects a structure of a "network of networks" similar to that established in the preliminary design of the European network of biobanks BBMRI (Biobanking and Biomolecular Resources Research Infrastructure).
- Showing a strong commitment to its own ethical principles and with a strict observance of the effective legislation.

### 4. ORGANIZATIONAL STRUCTURE

#### 4.1 TITLE HOLDER

The Spanish National Biobank Network (RETIC of Hospital Biobanks) is an initiative of the Instituto de Salud Carlos III (ISCIII) included in its subprogram Thematic Networks of Cooperative Research. The Institute acts as the title holder of the Network.

The objective of this subprogram is to regulate the procedure for awarding grants to fund specific stable cooperative research structures in areas considered strategic for the NHS, to promote a better positioning of our country in the European Research Area in those fields.  

Among its functions are:

---

• Selection of members of the network through specific calls.
• Funding support for the implementation and optimal operation of the network members and their coordination structures.
• Assessment of the achievements of its members, based on the goals and commitments of each one of them.
• Appointing the coordinator of the Network.
• Providing the coordination office with the resources necessary to carry out its duties.
• Approving the Strategic Plan of the Network and its annual developments.

4.2 MEMBERS

• Network members are those institutions included in the resolution(s) of specific calls to join the Biobank RETIC published by the ISCIII.

• According to the above call, there are two basic types of members, subject to the provisions of paragraph 4.3 of the present Strategic Plan:
  o NHS hospital centres
  o Associated centres, defined as public or private non-profit centres that are not affiliated with hospitals.

• For operational purposes the associate members are considered full members.

• Annex 1 provides a list of institutions that make up the network at the time of its formation.

4.3 COLLABORATING BIOBANKS

• Because of the characteristics of the initial call and its resolution, various institutions with biobank activity whose participation, experience, activity, and cooperation would be very enriching to achieve the objectives of the network are not members of the network.

• These institutions include various institutional CIBERs, RETICs, and biobanks that are currently not part of the network according to the procedures described, but could be included in territorial or cross-territorial networks as full members.

• These institutions may participate in the activities of the network as Collaborating Biobanks, but without access to funding.

• To be collaborating members of the network, interested institutions should submit a request to the coordinator of the Network including information similar to that required in the initial call by the ISCIII, which includes:
  o Its functional structure
  o The samples and information it contains
  o The technical means it has available for functioning as a biobank.

• A justified acceptance or refusal of the application is the responsibility of the Executive Commission.

• Collaborating Biobanks will be considered for all purposes members of the Plenary Board of the Network.

• As with hospital and associated members, collaborating centres shall appoint a site coordinator, meaning a professional belonging to the staff of the applicant institution to carry out the activities related to the scientific coordination of network activities in that centre.

4.4 GENERAL COORDINATOR OF THE NETWORK

• Directs the coordination office of the network.
The network will have a coordinator who will for all purposes be in charge of the scientific coordination and the monitoring of the network, and will generally act in its representation.

The coordinator is appointed by the Director of the Instituto de Salud Carlos III.

On behalf of the Director of the Instituto de Salud Carlos III, the coordinator may assume representation of the ISCIII in international biobank platforms, especially at the European level (BBMRI-ERIC, etc.).

The general coordinator will have a specific budget for the maintenance of the coordination office of the network.

Functions:

a. Organize and coordinate the activities of the network, and establish service objectives.

b. Represent the network.

c. Represent the ISCIII in biobanking initiatives in which the Institute participates.

d. Direct the human resources of the coordination office of the network.

e. Assume obligations and authorize payments for equipment, supplies, and services with the restrictions arising from the annual budget and in accordance with the procedures established by the Management Guidelines of the Node to which it belongs.

f. Determine future needs for equipment depending on the technical and scientific developments, and document and defend proposed acquisitions of equipment.

g. Draft the Annual Report of Activities of the network, which must contain a summary of the results of its technical and administrative management.

h. Ensure optimal quality of services provided according to the established specifications.

i. Contribute to compliance with the regulations on occupational health and safety by all personnel of the coordination office.

4.5 PLENARY BOARD OF NETWORK MEMBERS

Made up of:

- The coordinators of each participating institution in the network (hospital biobanks, associated biobanks, collaborating biobanks), or other delegated members of the node.

- Representatives of other collaborating institutions with relevant activities in the field of biobanks, whose participation has been requested with proper documentation and approved by the Executive Commission of the network.

It shall meet at least once a year. In case of voting, the criterion of a single vote per network member will be used.

Given the complexity of this network and the high number of nodes participating in it, the following support structures for its operation and for the general coordinator are considered:

- Executive commission.

- Internal scientific commission.

- External Scientific Advisory Committee.

4.6 EXECUTIVE COMMISSION

Appointed by the board of directors of the ISCIII at the proposal of the Coordinator according to operational criteria, training, and representation of the different scientific and territorial fields in the network and the various work areas.
• It is chaired by the coordinator of the network.
• The number of members shall not exceed 15.
• Its functions are to collaborate in the tasks of the coordinator in the various areas of cooperation among network centres, as well as the tasks of monitoring and fulfilling the planned objectives.
• The Executive Committee shall meet in person at the proposal of the General Coordinator at least once every six months, maintaining constant communication via e-mail or other means of telecommunication.
• Annually, and starting from the second year, at least 20% of its members must be renewed.
• This commission will assume the functions of the Internal Scientific Committee, for which relevant researchers proposed by the general coordinator could be invited.

4.7 INTERNAL COMMITTEES: ETHICS ADVISORY COMMITTEE AND INTERNAL SCIENTIFIC COMMISSION

• The mission of the Ethics Advisory Committee is to assess current or future needs regarding the activity in the field of biobanking, with the aim of protecting the fundamental rights of individuals, and respecting the bioethical principles and commitments made by the scientific community. This function will be assumed by the Research Ethics and Animal Welfare Committee of the ISCIII.
• The Internal Scientific Committee is responsible for assessing current or future needs regarding the activity in the field of biobanking, with the aim of ensuring the excellence of the technical performance of the network, its adjustment to the needs of the researchers, and any other scientific and technical issues that may arise.
• Both committees will be of an advisory nature.

4.8 EXTERNAL SCIENTIFIC ADVISORY COMMITTEE

• The External Scientific Advisory Committee of the network is an independent body made up of recognized experts in the field of Hospital biobanks and other related disciplines, under the patronage of the ISCIII through the network coordinator.
• The Committee’s main mission is to provide objective evidence, information, and scientific and technical advice to the network and its coordinator about its designs, objectives, and results.
• Among the functions of the External Scientific Advisory Committee of the network are:
  o Offer advice on the planning and organization of the network contained in its Strategic Plan.
  o Conduct periodic evaluation of the different strategic lines and working groups.
  o Participate in the preparation of the annual report on the scientific activity of the network, providing conclusions and future goals within its scope of action.
  o And, ultimately, provide support and expertise to increase the efficiency and productivity of the Biobank Network.
• This committee is of an advisory nature.
• The Committee will meet regularly once a year to assess the activity of the network, but it is also contemplated that there may be special meetings.
• For the election of its members, it should be strived for that they are opinion leaders in the field of biobanks and/or related disciplines:
  o Ensuring an appropriate balance of specialists in biomedical research, quality policy, bioethics, management and networking, and legislative development.
  o Including different technical fields such as, for example, cancer, neurosciences, serum banks, etc.
Linking prominent members of the main international scientific societies and international biobank initiatives or international bodies.

- Representing different countries, especially at the European level.

- They are appointed by the Director of the Instituto de Salud Carlos III at the proposal of the Network Coordinator.

- At least 30% of its members will be renewed every 4 years.

### 4.9 WORKING GROUPS

- Are appointed by the General Coordinator of the Network at the Executive Committee's proposal to develop specific strategic issues within the framework of strategic design lines of the network, and can vary over time.

- They are composed of members of the network nodes, and other experts in the corresponding fields may be invited.

- It is advisable that they are coordinated by a member of the Executive Commission.

### 4.10 COORDINATION OFFICE

- It will be headed by the General Coordinator of the Network.

- Its actions include:

  - Creating and maintaining a management system of biological samples and associated data to facilitate access by the Scientific Community to biological samples deposited in member biobanks.

  - Creating a web site that enables to transmit the network activity to the Scientific Community, its objectives and services, and to serve as a means of communication between its members and researchers.

  - Preparation of monographs and agreed upon technical papers that bring together the results of the working groups.

  - Permanent advisory activity on ethical and legal aspects related to biobank activities. When necessary this activity will take place in close contact with the Bioethics Committee of the Instituto de Salud Carlos III.

  - Networking and cooperation with health authorities in charge of licensing and maintenance of biobanks, both at the regional level and at the level of the General State Administration.

  - Strengthening and coordination of the network of technical platforms.

  - Training activities for staff in order to achieve a progressive professionalization of the activity in hospitals and nodes.

  - Joint activities with patient associations and public media to achieve a quality divulgation about the importance of biobanks for translational research.

  - Implementation and coordination of internal policies of quality assurance of the network.

  - Promoting joint activities with Scientific Societies and Cooperating Groups.

  - Cooperation with other National Banks that are promoted by or could be promoted from the Instituto de Salud Carlos III.
5. ANALYSIS OF THE CURRENT SITUATION

5.1 THE GLOBAL SCIENTIFIC ENVIRONMENT:

- New high-throughput technologies allow a better understanding of complex diseases and susceptibility to their development, and are the basis of concepts and disciplines such as personalized medicine and pharmacogenomics.

- In fact, knowledge of the etiological complexity of a disease is a challenge based on the presence of a large number of small additive effects including genetic predisposition, lifestyle, and environmental conditions. To know and understand these complex interactions, it is critical to facilitate access of researchers to large numbers of biological samples that are well documented and selected with appropriate scientific criteria for the research at hand.

- On the other hand, a critical point in the design, construction, and development of a biobank or a network of biobanks is the ability to predict the future needs of researchers and to be able to update the service portfolio in a timely way. This means having a detailed knowledge of the research reality and its environment and the legal and ethical framework, while taking into account:
  
  a) the critical mass of research groups that use these resources,
  
  b) the areas in which they are working and will be working in the future, and
  
  c) the information they seek and will try to obtain from the resources (biological samples and associated data) available in the biobank.
5.2 THE SPANISH SCIENTIFIC ENVIRONMENT:

- Biomedical research in Spain has undergone significant development over the last decade, not only in quantity but also in quality, which has allowed the Spanish research community to become the ninth power in terms of scientific output.

- The increased participation of Spanish groups in international high complexity projects and the creation of high performance scientific institutions are indicators of this process in biomedical research.

- The advocacy and resource management of the Instituto de Salud Carlos III has played a decisive role in this development through the establishment of collaborative scientific platforms (RETICs, CIBERS, CAIBER, Health Research Institutes, etc.). Likewise, in the last decade several national and local monographic research centres were created (CNIO, CNIC, etc.).

- This development has facilitated a remarkable increase in Spanish participation in international projects, especially in Europe, and in the main pan-European infrastructures of the ESFRI program.

- Translational research in the field of health has undergone a special development, based largely on the use of high quality biological samples and associated information, particularly focused on the use of the following methods:
  
  - Techniques for high throughput analysis of gene expression, massive sequencing, epigenetic analysis, proteomics, etc.
  
  - Microscopy and cytometry techniques that require tissues and cells in which, besides the nucleic acids and proteins being preserved, cells must have retained integrity and even be viable.
  
  - Functional techniques with which molecular interactions, signalling pathways, and cellular response are evaluated.

- Spanish biomedical research is fully matched to that of its neighbouring countries, and in some fields it holds a position of international leadership. But to continue these upward dynamics, it appears necessary to endow the system with a stable network of infrastructures that will allow addressing new scientific challenges.

5.3 BIOBANKS IN SPAIN

The initiative of the ISCIII to promote a RETIC specific for Hospital Biobanks (National Biobank Network) consolidates and acknowledges the cooperative working dynamics developed in our country over the past decades and more intensely so in the last 10 years, and makes a greater degree of integration, harmonization, and public service possible. Based on previous experiences and the current status of cooperative development of biobanks in Spain, the following already existing initiatives should be mentioned:

1. Hospital Biobank Networks for Cancer Research (Tumour Banks).
2. Central Nervous System Tissue Banks, usually known as Brain Banks.
3. National Banks promoted by the ISCIII and other public agencies.
4. Other territorial initiatives, especially those of cooperative networks.
5. Other cooperative platforms within the framework of and promoted by other ISCIII initiatives in its CIBER and RETIC programs, and that include sample collections.

This development regarding biobanks is not an isolated phenomenon, but must be seen within the framework of scientific-technical developments in our country.

---

Ministerio de Ciencia e Innovación. Construyendo la ciencia del siglo XXI: Estrategia española para la participación en infraestructuras científicas y organismos internacionales. Febrero, 2010
5.4 ANALYSIS

Biobank activity, especially in hospitals, has been defined as a traditional activity that is rapidly being organized as a new scientific discipline in its own right\(^8\). It is from this perspective that the current situation of our country should be seen. Without attempting an exhaustive analysis, the following strengths and weaknesses are noteworthy:

5.4.1 Strengths

Among the main strengths of the Spanish reality in biobanks, the following stand out:

- **Very good cooperative development**, especially in relation to hospital biobanks directed at cancer research, infectious processes, and other areas.

- **Growing number of hospital biobanks and collaborative research networks**. In a survey conducted by the Spanish Society of Anatomic Pathology (SEAP) it was concluded that in 2007 41% of Spanish Pathology services developed some type of biobank activity, compared with 23% of services that did so a decade earlier.\(^9\)

- **Specific legal framework**. The approval, publication, and entry into force of Law 14/2007 on Biomedical Research were key events in regulating the sector by promoting its standardization.

- **Increase of biomedical research in Spain**, in quantity of resources, infrastructure, and high impact results, with a growing interest in translational research.

- **Emergence of international initiatives in the field of biobanks** including scientific societies and organizations (*The International Society of Biological and Environmental Repositories* - ISBER-, *The Public Population Project in Genomics* - P3G-, *The Federation of International Biobanking Organization* - FIBO-, *The Marble Arch International Working Group in Clinical Biobanking*, etc.), as well as numerous projects financed by the European Union through its Framework Programs, chief among them the ESFRI platform called *Biobanking and Biomolecular Resources Research Infrastructure* (BBMRI).

5.4.2 Weaknesses

On the other hand, these same characteristics of previously established activity and a new discipline are at the basis of several weaknesses, among which the following may be cited as particularly relevant:

- **Insufficient integration** of biobanks and collections, both at the intra-hospital level and at the regional and national levels.

- **Lack of cohesion** of the whole, as a result of the aforementioned lack of integration.

- **Persistence of undesirable habits**, with special emphasis on a mistaken notion of ownership, inadequate routes of access to samples, contempt for ethical and legal requirements, lack of quality policies, etc.

- **Horizontal structures** developed around the sample, its processing, and its storage, and not around the source individual.

- **Poor use of funds** of biobanks. In the aforementioned survey of the SEAP it became clear that less than a third of the biobanks had transferred samples to groups outside their institution.

- **Lack of standardization of the data associated with biological samples**.

- **Existence of a legal framework that is difficult to apply**, especially in relation to obtaining informed consent and the external evaluation of transfers.


Insufficient provision of resources, both material and human resources, to adequately develop biobanking activities. Especially important is the absence of staff and technical personnel who are exclusively or preferentially dedicated to the management and activities of hospital biobanks; these activities normally fall upon professionals who have a lot of pressure and attendance overload, and whose activity in hospital biobanks is secondary.

Irregular involvement of the regional health authorities in the development and promotion of excellence Hospital biobanks and the establishment of cooperative networking.

But it is important to mention that, although the weaknesses mentioned above are specific to our system and evolution, there are other equally important global weaknesses arising from the recent development of biobank activities, such as:

- Need for a better understanding by the Scientific Community of the meaning of the vocation and the responsibility of biobanks as a public service to the Scientific Community.
- Insufficient strategic appraisal of hospital-based biobanks by the public media and agencies and foundations sponsoring research.
- Lack of formal and accredited training, which causes the absence of appropriately trained professionals.
- Lack of international standards for certification and/or accreditation specific for biobanks.
- Need for own research in the field of biobanks, addressing current inconsistencies such as the incomplete development of robust markers of quality and integrity of deposited samples and the quality of the associated information.  
- Need for a paradigm shift in the bioethics discussion, and as a consequence legal changes, concerning the use of human samples in research in response to the scientific paradigm shift that took place in the past 15 years due to the accessibility of personal genetic information.
- Problems of sustainability of biobanks. Currently, biobanks tend to be financed by research programs that last three to five years, but the material they contain has the potential to supply researchers for many years more. It is therefore necessary to ensure long-term funding, looking for ways to mobilize domestic, European, and private funds to ensure the long-term sustainability of the infrastructure.

6. LEGAL FRAMEWORK

This network is the result of the 2009 call for proposals to obtain funding by the Strategic Action in Health, under the National Plan R&D+i 2008-2011 (Joint Resolution of the State Secretary of Research and the Carlos III Health Institute, by which the aforementioned call was published in the BOE No. 71 of March 24, 2009. The call was resolved by resolution of the Director of the ISCIII, dated December 22, 2009.

---


The following legislation is directly applicable to the activities of the National Biobank Network:

- Article 44.2 of the Spanish Constitution, which entrusts public authorities with the promotion of science and scientific and technical research in the public interest.
- Law 15/1999 of 13 December on the Protection of Personal Data.
- Law 41/2002 of 15 December, regulating the patient’s autonomy and rights and obligations regarding clinical information and documentation.
- Law 14/2007 of 3 July, on biomedical research, and Royal Decree, not yet published, which will develop the Biomedical Research Act on Biobanks.
- Royal Decree 1720/2007, of 21 December, approving the implementing Regulation of Law 15/1999, of 13 December, on the protection of personal data.
- The various legislative developments made by the Autonomous Communities.

The following conventions, directives, and declarations also apply:

- Convention on the protection of individuals with regard to automatic processing of personal data. Council of Europe, January 28, 1981.
- International Declaration on Human Genetic Data, UNESCO, October 2003.

7. STRATEGIC PLAN 2010-2013: GENERAL OBJECTIVES

The priority axes for the activities of the Spanish National Biobank Network are:

- Integration,
- Harmonization, and
- Public Service.

These axes are specified in the following objectives:

- **7.1 Integration**: Understood as the dynamics of progressive functional integration of all its components into cooperative structures. Within this axis five levels of integration with different strategic objectives are considered:

  1. **Intra-hospital integration**:

     **Objective**: To promote that hospital biobanks become the basic tool for managing biological samples and associated data for biomedical research.

     **Objective**: To promote the integration of different hospital collections of biological samples for research.

     **Objective**: To improve sample handling circuits in the healthcare system and promote the organization of the specimen archives such as biobanks as directed by the recently published norms and protecting the health care needs of patients.
Objective: To promote the implementation of the Law on Biomedical Research and its development in matters concerning biobanks.

2. Integration at the level of the Autonomic Communities:

Objective: To promote the creation of cooperative Biobank structures whose expenses are met by the regional authorities.

3. Integration at the National level (Primary scope of the network):

Objective: To implement the operational integration of the various biobanks and biobanking networks.

4. International Integration:

Objective: To promote the participation of the Network and its members in international initiatives and especially in the ERIC-BBMRI, which is included with high priority in the MICINN task list.

5. Thematic integration in specific areas:

Objective: To implement the creation and functionality of integration platforms in specific areas, such as brain banks, banks for neurodegenerative diseases, rare diseases, etc.

- 7.2 Harmonization: Referring to standard operating procedures and performance. Includes the work of the Network and its members, as part of its quality policy.

1. Harmonization at the technical level:

Objective: To harmonize the Standard Operating Procedures (SOPs).

2. Harmonization at the legal level:

Objective: Harmonization of documentation arising from the ethical and legal requirements under applicable laws.

3. Quality assurance Policies:

Objective: To harmonize and increase the degree of implementation of quality assurance policies.

- 7.3 Public service: Understood both in the internal dimension of the Network itself and in relation to the Scientific Community, including researchers and Biobank professionals, health authorities and agencies, without losing sight of patients, donors, and the rest of Society. This public service is aimed at:

1. The biobanks themselves:

Objective: To enhance and standardize the quality of the biological products of biobanks and their associated information in the context of the definition of the Biological Resource Centres proposed by the OECD.

Objective: To promote educational activities, including activities at the highest academic level, that allow the professionalization of the different actors involved in the work of biobanks and facilitate the harmonization of the terms described above.

Objective: To provide a scientific environment of cooperation and research specifically aimed at the activity of biobanks.

Objective: To provide advice on the formation of high-quality biobanks.

2. The Scientific Community:

Objective: To provide researchers with a channel that allows quick access to sets of samples, their products, and the associated data with quality assurance and ethical-legal adequacy.
Objective: To develop a continuous dynamics of analysis and a continuous assessment of the needs of biobank users.

3. Society:

Objective: To make the activity of the biobanks known to and appreciated by Society, especially in the field of associations of patients and affected persons.

The Executive Committee will develop and publicize on an annual basis specific activities to develop or update the general objectives set out above.
### ANNEXE 1: LIST OF INSTITUTIONS

<table>
<thead>
<tr>
<th>AUTONOMOUS REGION</th>
<th>EXPEDIENT REF.</th>
<th>CENTRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESTATE GENERAL ADMINISTRATION</td>
<td>RD09/0076/00108</td>
<td>Instituto de Enfermedades Raras - ISCIII</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00113</td>
<td>Centro Nacional de Investigaciones Oncológicas - CNIO</td>
</tr>
<tr>
<td>ANDALUCIA</td>
<td>RD09/0076/00043</td>
<td>Red de Bancos de Tumores de Andalucía</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00144</td>
<td>Hospital Reina Sofia</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00080</td>
<td>Hospital Virgen Macarena</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00085</td>
<td>Hospital Virgen del Rocio</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00112</td>
<td>Hospital Carlos Haya</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00147</td>
<td>Hospital Virgen de La Victoria</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00148</td>
<td>Hospital Universitario San Cecilio</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00165</td>
<td>Hospital Virgen de las Nieves</td>
</tr>
<tr>
<td>ARAGON</td>
<td>RD09/0076/00123</td>
<td>Hospital Miguel Servet</td>
</tr>
<tr>
<td>ASTURIAS</td>
<td>RD09/0076/00004</td>
<td>Hospital Central de Asturias</td>
</tr>
<tr>
<td>BALEARES</td>
<td>RD09/0076/00054</td>
<td>Hospital Son Dureta</td>
</tr>
<tr>
<td>CANTABRIA</td>
<td>RD09/0076/00076</td>
<td>Hospital Marques de Valdecilla</td>
</tr>
<tr>
<td>CANARIAS</td>
<td>RD09/0076/00072</td>
<td>Complejo Hospitalario Materno-Insular</td>
</tr>
<tr>
<td>CATALUÑA</td>
<td>RD09/0076/00010</td>
<td>Hospital Germans Trias i Pujol</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00036</td>
<td>Hospital del Mar</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00038</td>
<td>Hospital Clínico y Provincial de Barcelona - IDIBAPS</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00049</td>
<td>Hospital Joan XXIII</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00056</td>
<td>Hospital de Bellvitge</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00057</td>
<td>Hospital Juan de Dios Esplugues</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00059</td>
<td>Hospital Arnau de Vilanova</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00064</td>
<td>Fundación Puigvert</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00066</td>
<td>Hospital Valle de Hebron</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00081</td>
<td>Hospital de la Santa Cruz y San Pablo</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00104</td>
<td>San Juan de Dios. Servicios de Salud Mental</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00125</td>
<td>Hospital Dr. Josep Trueta</td>
</tr>
<tr>
<td>CASTILLA – LA MANCHA</td>
<td>RD09/0076/00047</td>
<td>Complejo Hospital General de Albacete</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00074</td>
<td>Hospital Virgen de la Salud</td>
</tr>
<tr>
<td>CASTILLA Y LEÓN</td>
<td>RD09/0076/00028</td>
<td>Centro de Investigación del Cáncer - BMCC</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00111</td>
<td>Hospital Universitario de Salamanca</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00130</td>
<td>Complejo Hospitalario de León</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00133</td>
<td>Universidad de Salamanca</td>
</tr>
<tr>
<td>GALICIA</td>
<td>RD09/0076/00011</td>
<td>Complejo Hospitalario de Vigo</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00032</td>
<td>Complejo Hospitalario Universitario de La Coruña</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00171</td>
<td>Complejo Hospitalario Universitario de Santiago</td>
</tr>
<tr>
<td>MADRID</td>
<td>RD09/0076/00002</td>
<td>Hospital de Getafe</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00008</td>
<td>Hospital Ramón Y Cajal</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00073</td>
<td>Hospital La Paz</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00084</td>
<td>Fundación MD Anderson International España</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00101</td>
<td>Fundación Jiménez Díaz</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00102</td>
<td>Hospital Clínico San Carlos</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00103</td>
<td>Hospital Gregorio Marañón</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00118</td>
<td>Hospital 12 de Octubre</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00127</td>
<td>Hospital de Fuenlabrada</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00142</td>
<td>Fundación Hospital Alcorcón</td>
</tr>
<tr>
<td>MURCIA</td>
<td>RD09/0076/00065</td>
<td>Hospital Virgen de La Arrixaca</td>
</tr>
<tr>
<td>NAVARRA</td>
<td>RD09/0076/00029</td>
<td>Hospital de Navarra</td>
</tr>
</tbody>
</table>
### Strategic Plan

**[Spanish National Biobank Network]**

<table>
<thead>
<tr>
<th>Region</th>
<th>Centre Name</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PAIS VASCO</strong></td>
<td>RD09/0076/00078 [Clinica Universidad de Navarra]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00068 [<em>Fundación INBIOMED</em>]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00088 [<em>Fundación Vasca de Innovación e Investigaciones Sanitarias</em>]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00149 [Hospital de Txagorritxu]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00150 [Hospital de Cruces]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00151 [Hospital de Basurto]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00154 [Hospital de Donostia]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00159 [<em>Centro Vasco de Transfusión y Tejidos Humanos</em>]</td>
</tr>
<tr>
<td><strong>VALENCIA</strong></td>
<td>RD09/0076/00021 [Hospital La Fe]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00041 [Hospital General de Elche]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00058 [<em>Centro Superior de Investigación en Salud Publica (CSISP)</em>]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00062 [Hospital General de Alicante]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00063 [<em>Centro de Investigación Principe Felipe</em>]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00132 [Hospital Clínico Universitario de Valencia]</td>
</tr>
<tr>
<td></td>
<td>RD09/0076/00163 [Instituto Valenciano de Oncología]</td>
</tr>
</tbody>
</table>

Associated centres are written in *italics*.

**Coordination**

Instituto de Salud Carlos III Director has designed to Dr Manuel M Morente, belonging to the Centro Nacional de Investigaciones Oncológicas (CNIO) node, as Coordinator of the Network.

**Constitution**

The Spanish National Biobank Network (Red Nacional de Biobancos) was officially constituted at March 3th, 2010.