• Biobanking is a young discipline...
  ... We are still looking for a good definition.
• It is also time to rethink our mission and strategies.

• What are the basis of our work?
• Networking is one of the keys for future.
• The Spanish National Biobank Network - ISCIII
Biobanking is an ancient activity and a young discipline, and therefore it is especially necessary to establish its position in biomedical research in these changing times.

Biobanks are not a goal, but rather a scientific tool for accomplishing the real objective of gaining knowledge by performing research of excellence.

Biobanking activity is mediated by a fourfold commitment: social, ethical, technical, and scientific.
Social commitment refers to the promotion of knowledge (basic science) and, in case of human samples and biobanking-based research, health and translational biomedical research.

Preserving life, biodiversity and human health is a social and historical dimension to be care.

Social biobanking dimension is not against commercial activities, but is more than a simple market activity.

**Biobanking is not for us, but for others.**
The **ethical commitment** refers to the guarantee of donors’ rights and the chain of custody of samples and personal data to be protected.

Commitment with live, health and welfare is the centre of our activity.

**Ethics means more than an informed consents.** An IC without an adequate ethical background is only a paper, a SOP for defensive working.

Ethics also refers to solidarity and justice including **respect for very diverse cultures**.

Ethics not only affect to human samples and subjects.
Due to these two previous commitments, biobanks are obliged to use the most suitable methodology in order to ensure the highest quality of service, this being their technical commitment.

**Harmonization** is one of our most urgent duties including not only experts consensus, but adequate training of new biobanker generations.

Technology is, once again, not a goal in itself, but a tool.
Finally, **biobanking should be directly linked to scientific challenges, interests, and advances**.

For these reasons, new technologies used or developed in the scientific scenario should be of the greatest interest for biobanking professionals, who are compelled to collect, preserve, and provide samples not only for current studies but also for those to be promoted in the coming 5 or 10 years.
These aren’t four independent dimensions or commitments.

All they are necessarily interconnected. All they should be viewed together.

A biobank design or activity excluding one of them is not a correct design:

- Technical & scientific excellence without ELSI is pure utilitarism.
- ELSI development are pure philosophy and/or biopolitics if are no oriented to technical & scientific excellence.
Keys for a better future in biobanking

- Harmonization.
- International societies and platforms open dialog.
- Robust methods accepted by consensus.
- Research in Biobanking methodology, ethics, economy ...
- Biobank training and professionalization.
- Applying new technologies (i.e. IT) with respect of donor’s rights.
- Dialog in Ethics based on the new paradigm.
- Legal international harmonization based on the new ethic paradigm and accepting the experts advices.
- Commitment with emerging countries.
- Better use of resources in a time of economical crisis.
- Respect for collectors and stakeholders

• NETWORKING
We are living in the networks era

- Computer networks
- Biology networks
- Communication and broadcast networks
- Social networks
- Terror networks
- Politic networks
- Etc...

It is a novel issue open to academic study from the mathematical and social perspective.

**What means networking in biobanking?**
Biobank Networking

Why biobank networking?

• Technical developments have renewed the need for high-quality tissue samples, especially when this technology is of increasing clinical value.

• To identify new parameters of clinical value we are obliged to run large-scale molecular studies with large numbers of cases.

• To transfer from basic to clinical research requires homogeneous tissue-sampling protocols for multi-centre studies.

• Treatment response prediction must be based on multicentre and multi-national clinical trials. However, these trials must include the acquisition of suitable clinical samples for molecular studies.
Biobank networks usually have a main promoter but, to be sustainable, should be based in freedom and respect of each biobank autonomy:

- **Nobody should be obliged to participate** in the network.
- **Nobody should be obliged to collaborate** in a specific project.
- **Each Centre's samples should belong to the corresponding Hospital**, where it can then be used for the welfare, teaching and research activities of each individual hospital.
- The Network should be coordinated and managed by a **coordination office as a service**, placing particular emphasis on harmonization, **common quality control policies and best practices**, bringing a service at the entire national and International Scientific Community.
Networks based on contracts could ensure only short term goals, and always depending on the promoter.

Networks based on robust and friendly interpersonal relationships is a guaranty for long term activities.

In networking, attitudes are more important than aptitudes.
The Spanish National Biobank Network is an initiative of the National Institute of Health Charles III (ISCIII) oriented to promote the coordination of the Spanish Biobanks, mainly those hospital-based, and their effective integration in international platforms (BBMRI) in terms of public service. (BBMRI-ERIC.es)

- It was officially created in December 22th 2009, for 2010 to 2013 period.
The Network initially integrates 63 institutions based on 15 from the 17 Spanish Autonomous Regions.
Spanish National Biobank Network (ISCIII)

MISSION

- To provide the Scientific Community access to quality sample collections and associated data through a cooperative structure of public service.
- To integrate existing initiatives related to biobanks 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 of patients and donors.
- To promote technological innovation in biobanks.
- To assist in the development of the pan-European platform BBMRI, and promote the Spanish participation (BBMRI-ERIC.es).

http://www.redbiobancos.es
Initially funded with 6,000,000 euro/year, this budget has decreased to 33% due to Spanish and international economical situation.

Median investment per institution was 103,000 € / year for 2010 & 2011 applicable to:
- Infrastructures (2,675,000 €)
- Personnel (2,340,000 €)
- Mobility (197,000 €)
- Indirect costs, 15% (780,000 €)

Coordination core office is independently funded.
Spanish National Biobank Network (ISCIII)

Complexity

- ReTBioH
- 63

- NHS Hospitals
- 52

- Associates
- 11

- BB regional networks

- National DNA Bank

- Private Hospitals and research institutes

- Andalusia

- Castilla & León

- Basque Country

- Valencia

- Asturias

- Catalonia

- CNIO
Spanish National Biobank Network (ISCIII)

Complexity

Only human samples and hospital based biobanks
Structure

- Spanish national coordination hub
- Members: Hospitals and other institutions
- Regional and/or thematic coordination hubs
- Other institutions and service providers
- Groups and alliances of strategic thematic interest
Spanish National Biobank Network (ISCIII)

Strategic lines

Integration
- Hospital
- Regional
- NATIONAL
- INTERNATIONAL

Harmonization
- Technical Procedures
- Ethic requirements
- Quality management policies

Public Service
- Efficient broker between researchers and biobanks
- Certified high quality technical platforms for derivates
- Guaranties for patients & donors
- Documentation service & Advisory actions
- Dialog with Society
Thematic Working Groups- 2011-13

- CANCER
- BLOOD DERIVATIVES
- BRAIN BANKS
- ADN & POPULATION

Minimum data set to share
Standardised Operative Procedures
Markers for future specific quality controls
Instrumental Working Groups – 2011-13

- Biomedical research law:
  - Practical guide for application

- INFORMED CONSENTS:
  - Information & consent templates catalog.

- QUALITY MANAGEMENT POLICIES:
  - Basic Guide and advisory permanent service.

- GOOD PRACTICES GUIDE:
  - Good Practices general document.

- COST ANALYSIS:
  - Cost recovery studies and models.

- SNOMED-CT:
  - Applicability of SNOMED-CT to biobank activity
Finalized documents

Participants:
151 people from 65 institutions
University Master on biobanking

University Master on Biobanking & human samples use in biomedical research

- **TRENDS ON BIOMEDICAL RESEARCH**
- **BIOBANKS: ETHICS**
- **BIOBANKS: LEGAL ASPECTS**
- **BIOBANKS: TECHNICAL PROCEDURES**
- **BIOBANKS: MANAGEMENT**
- **MASTER FINAL PERSONAL WORK (THESIS)**

www.ucv.es/master_biobancos
University Master on biobanking

**I Edition 2011-12:**
- September 2011-September 2012
- 25 participants
- High satisfaction reports

**II Edition 2012-13:**
- Started at September 2012
- 13 participants

**Looking to the future:**
- On-line version for Spain and Latin-America
- International European Master
  - 3-4 universities from different European countries (UK, France, Spain...)
  - Erasmus Program (?)
  - ESBB participation (?)
Informatic platform for interoperability

- **Layered by activity:**
  - Brain Banks,
  - Solid tissue,
  - Population, etc.

- **Layered by greatest lines:**
  - Rare diseases,
  - Neurodegenerative,
  - Cancer, etc.

- **SNOMED-CT based ontology.**
- **SPREC pre-analytical code**
New challenges

- Centralised Quality Controls
- Great strategic projects:
  - International Rare Disease Research Consortium (IRDiRC)
  - Human Proteome Project.
  - EU Joint Programme for Neurodegenerative Diseases Research (JPND)
  - Participation in activities promoted by Spanish scientific networks and societies
  - Promotion of concrete collections of high strategic value.
- Definitive and active integration in BBMRI-ERIC
- Active participation in ISBER and ESBB
A new legal framework for biobanking is in force from December 2011.

- Most of our activities in 2012 are oriented to promote the knowledge on this new law and facilitate to our associates its implementation.
- More than 12 monographic meetings around the country.
In summary, the Spanish Biobank Network aims to provide added value to the whole Spanish Biobank system, being a meeting point for diverse local initiatives.
Thanks and enjoy Granada