



FONDAZIONE IRCCS CA' GRANDA  
OSPEDALE MAGGIORE POLICLINICO  
Milano - Istituto - Regione Lombardia



Fondazione Istituto Nazionale Genetica Molecolare



# Ca' Granda Lectures and Seminars in Molecular Medicine

**Biobanche: questioni giuridiche,  
casi pratici, opportunità**

Giovedì 20 novembre 2014 - ore 17.00 - 19.00 (puntuale)  
Aula Milano, Palazzo Uffici  
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

via F. Sforza, 28 - 20122 Milano

**Responsabile scientifico:**

**Pier Mannuccio Mannucci**  
Direttore Scientifico  
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

**Inquadramento della tematica, spunti introduttivi e conclusioni**

Paola Sangiovanni,  
Italy Legal Focus  
Francesco Pincirolì,  
Politecnico di Milano  
Laura Spinardi,  
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

**La Rete Internazionale di Biobanche**

Maria Luisa Lavitrano, Università degli Studi di Milano Bicocca

**Il percorso delle Biobanche oncologiche**

Maria Grazia Daidone, Fondazione IRCCS - Istituto Nazionale dei Tumori

**Biobanca POLI MI**

Lucilla Lecchi, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

**Esperienze italiane ed estere nelle biobanche**

Pasquale De Blasio, Integrated Systems Engineering s.r.l.



## La rete internazionale di Biobanche BBMRI-ERIC a gateway for Health

**Marialuisa Lavitrano**

**Coordinatore BBMRI.it**

**Co-Chair BBMRI-ERIC  
Management Committee**

[marialuisa.lavitrano@unimib.it](mailto:marialuisa.lavitrano@unimib.it)

[italy@bbmri.it](mailto:italy@bbmri.it)



**BBMRI-IT**  
Nodo Italiano della Infrastruttura  
di Ricerca Europea  
Biobanking and Biomolecular  
Resources Research Infrastructure



Time, March 13<sup>th</sup>, 2009

# Biobanks

*Think of it as an organic bank account. You put your biomaterial in and earn medical interest in the form of knowledge and therapies that grow out of that deposit — no monetary reward, just the potential that you might benefit from the accumulated data at some later date.*



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Biobanking and BioMolecular Resources Research Infrastructure  
of Italy

# L'Europa e le Biobanche



## EUROPEAN BIOBANKING AND BIOMOLECULAR RESOURCES

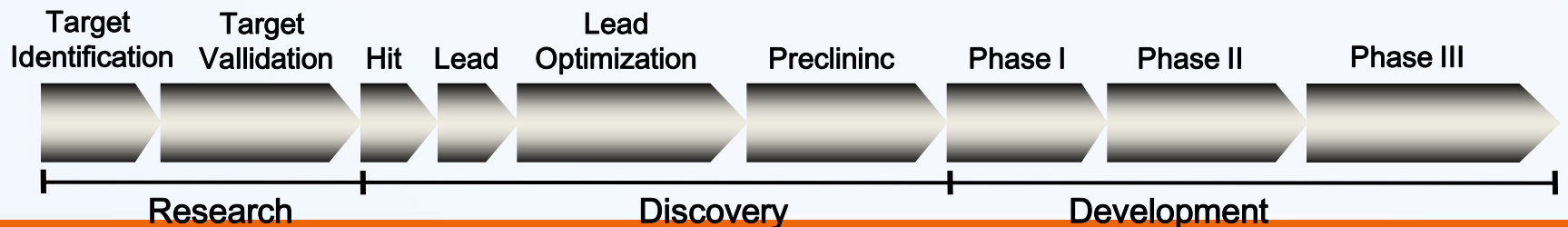
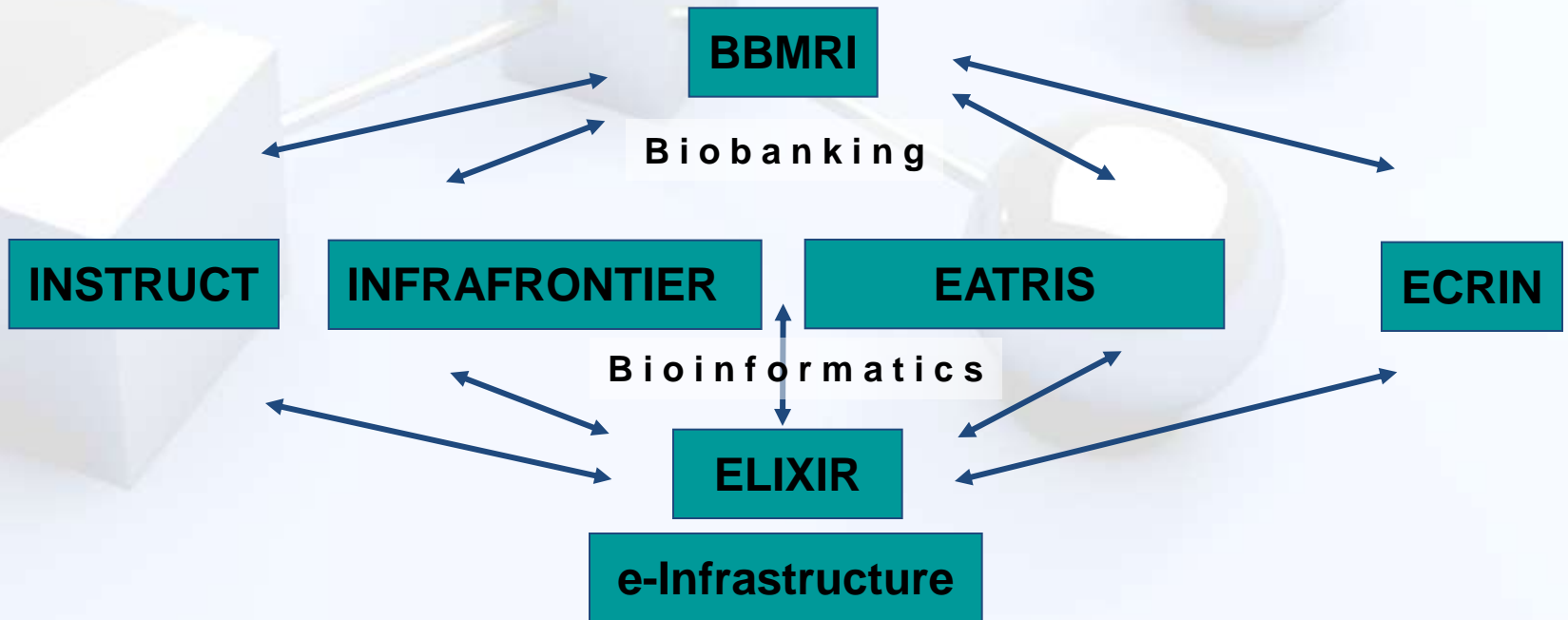
### The facility

A pan-European and broadly accessible network of existing and de novo biobanks and biomolecular resources. The infrastructure will include samples from patients and healthy persons, molecular genomic resources and bioinformatics tools to optimally exploit this resource for global biomedical research.

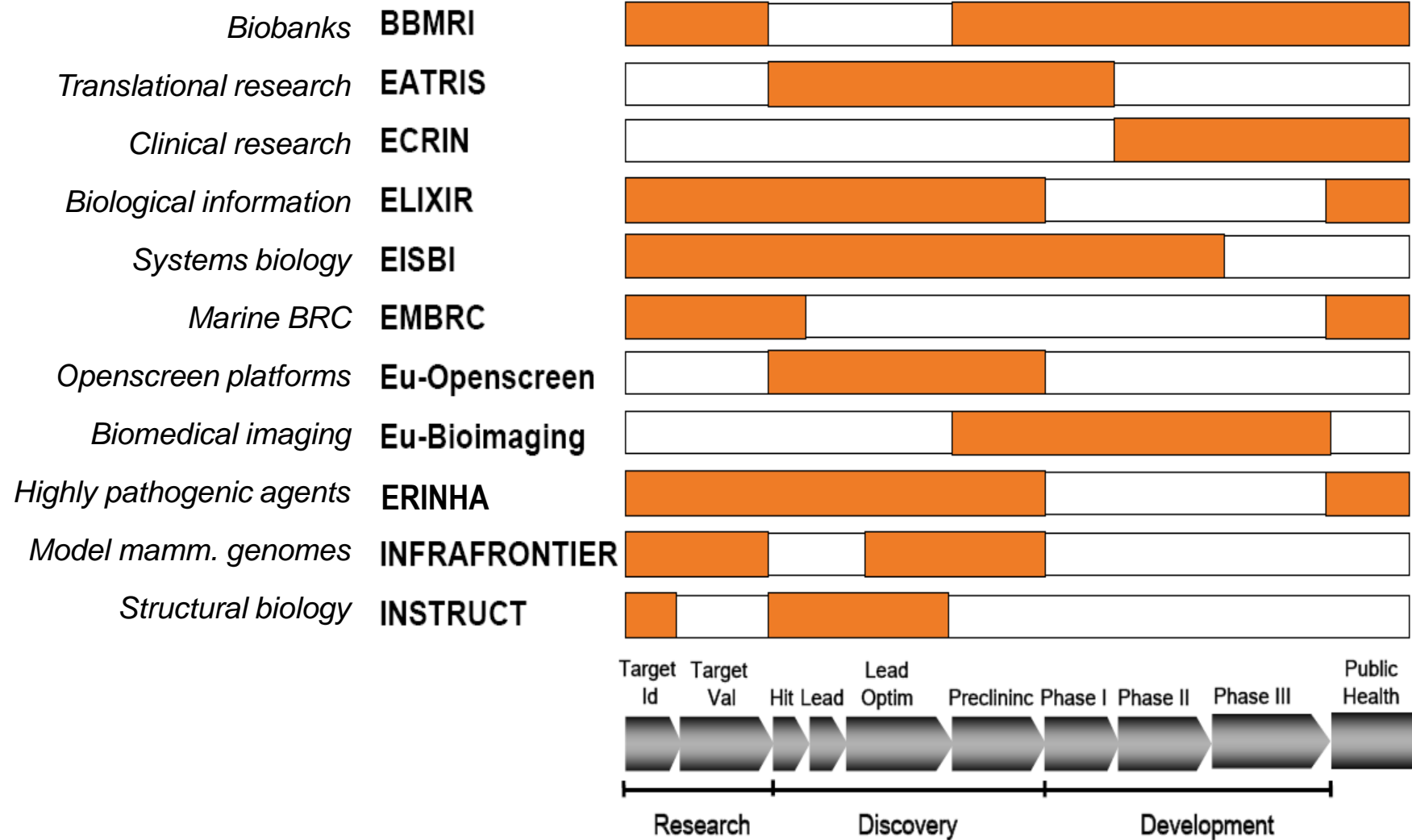
ESFRI Roadmap 2006: six research infrastructures for the lifesciences

FP7 supports the construction of European research infrastructures

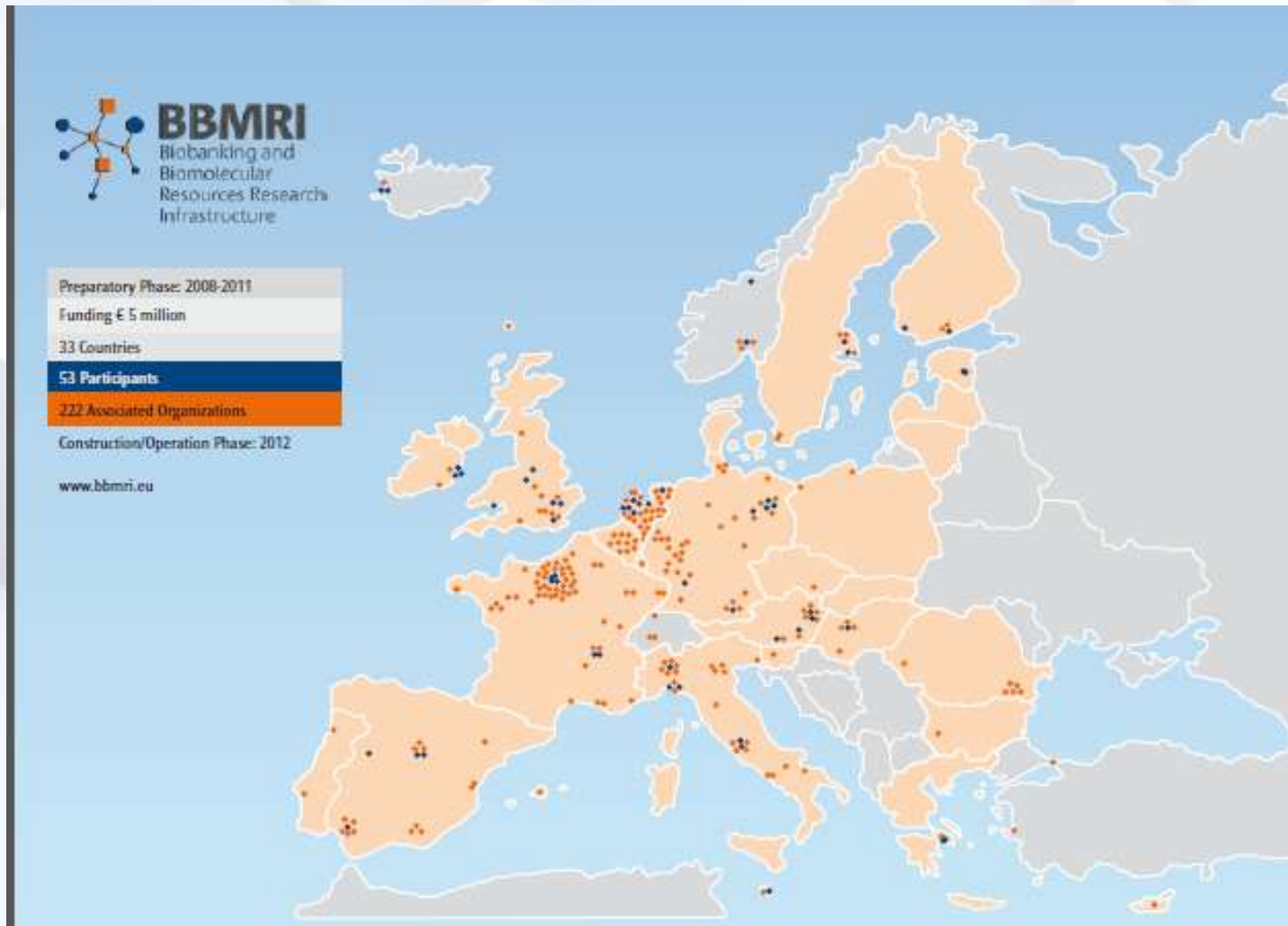
# BBMRI & ESFRI Biological and Bio-Medical Sciences Research Infrastructures



# Synergies of BMS RIs



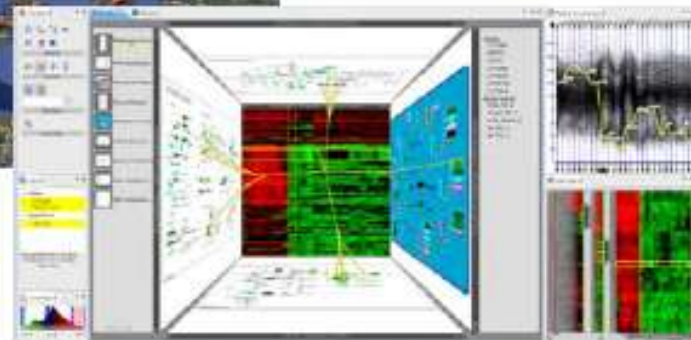
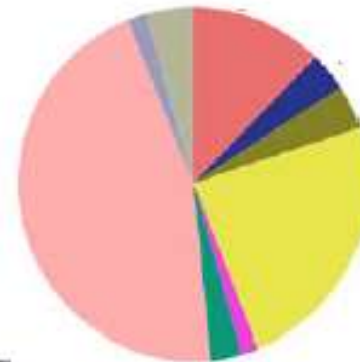
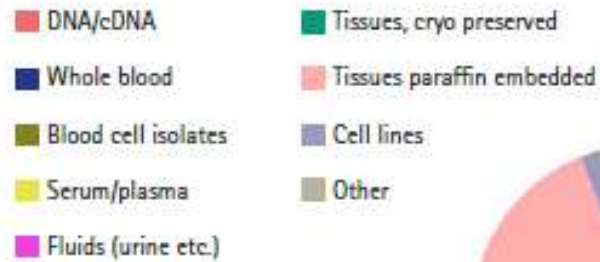
# Preparatory Phase



**Missione:** assicurare l'accesso equo e regolato alle risorse biologiche e garantire una gestione appropriata sia da un punto di vista etico che tecnologico, promuovendo la cultura della qualità dei campioni biologici e della innovazione biotecnologica. BBMRI funge da interfaccia tra le biorisorse (campioni e dati) e la ricerca biomedica di eccellenza.

**Struttura:** Infrastruttura di Ricerca diffusa con un Hub europeo (Graz, Austria) che si interfaccia con gli Hub Nazionali (nodi nazionali) e funge da erogatore di servizi attraverso i common services. Risponde alle esigenze del privato con piattaforme di eccellenza tecnologiche (cosiddetti Expert centers).

## Composition of 20 million human biological samples in Europe



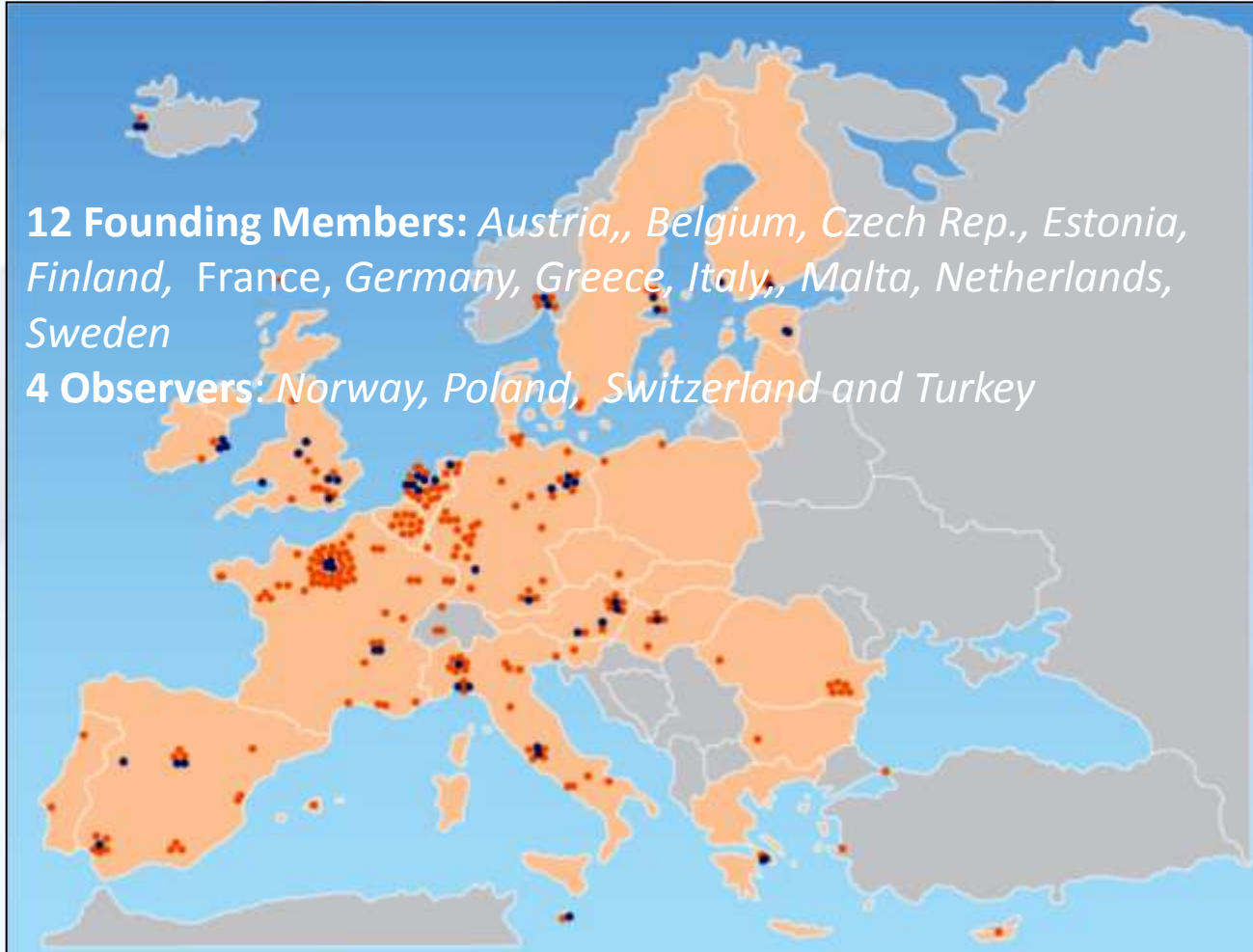


# BBMRI-ERIC:

## A pan-European Infrastructure

**12 Founding Members:** *Austria,, Belgium, Czech Rep., Estonia, Finland, France, Germany, Greece, Italy,, Malta, Netherlands, Sweden*

**4 Observers:** *Norway, Poland, Switzerland and Turkey*



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# *The ERIC Legal Framework*



Internationally recognized legal entity

Establishment of operational sites  
in different Member States that  
operate under one legislation

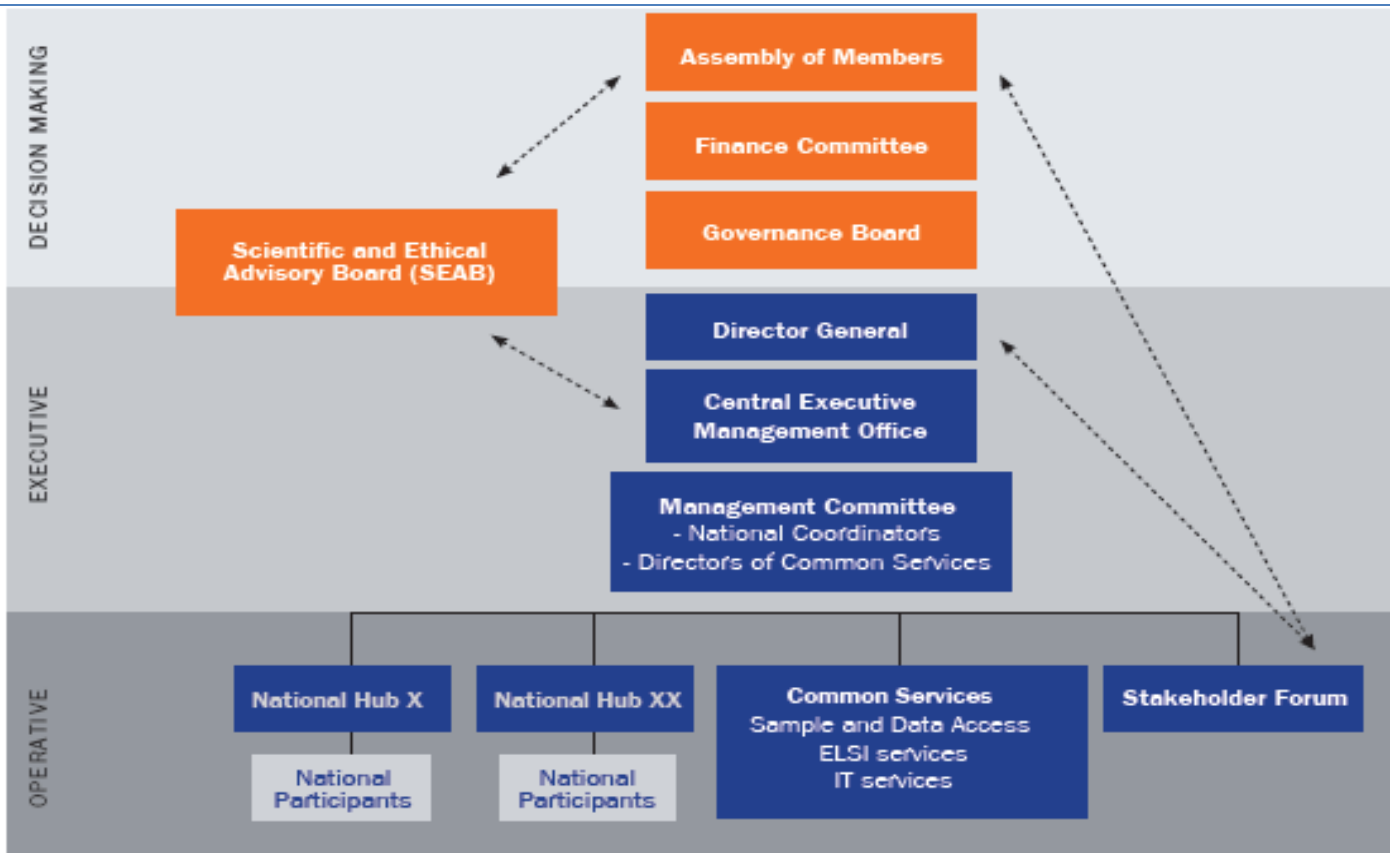
VAT exemption



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## Governance BBMRI-ERIC



■ Established under the ERIC legal framework



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# BBMRI.it

Biobanking and BioMolecular Resources Research Infrastructure of Italy



BBMRI-ERIC  
Biobanking and  
BioMolecular resources  
Research Infrastructure

**Programme**

**ESBB Annual Meeting**  
**October 8-11, 2013**

including BBMRI-IT Launch

Theme:  
**Biobanking for the Future**

Venue:  
**Palazzo Gran Guardia, Verona, Italy**



## BBMRI.it

Biobanking and BioMolecular Resources Research Infrastructure of Italy

**Ministry of Health**

**Ministry of University  
and Research**

**IRCCS**

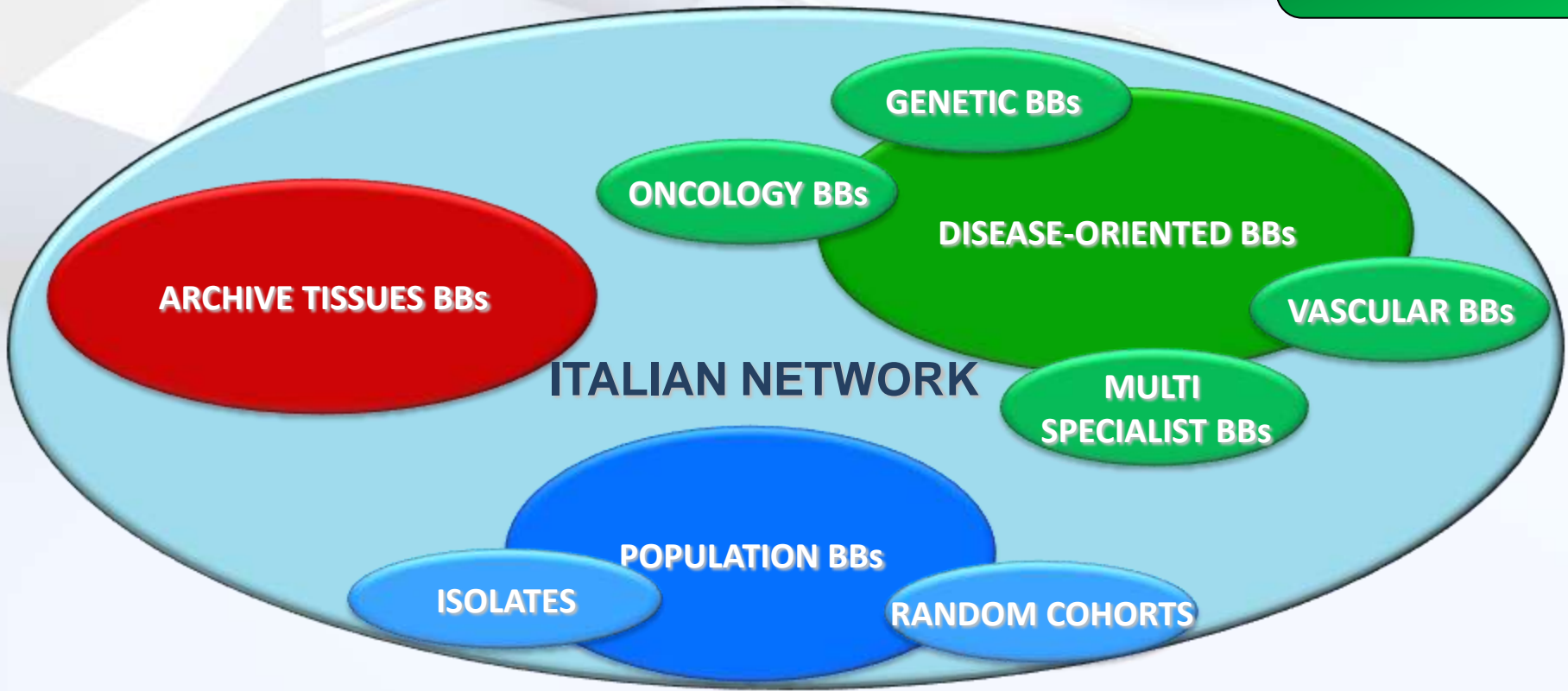
**Natl Institute  
of Health**

**Hospitals**

**Universities**

**Natl Research  
Council**

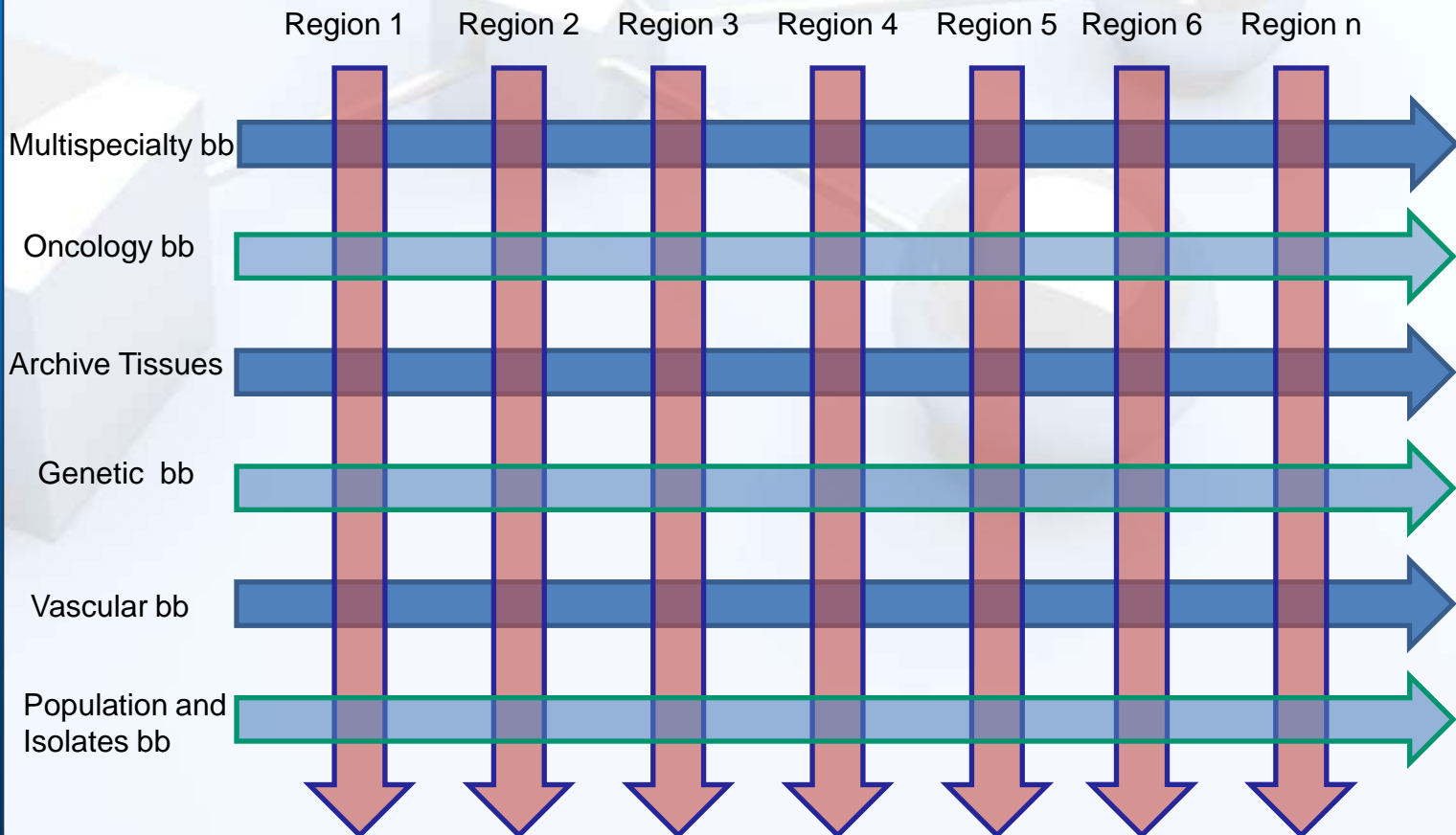
**Patient  
associations**



# BBMRI.it ARCHITETTURA A MATRICE

## Italian Regional Biobank Networks

Thematic and Multispecialty BB Networks



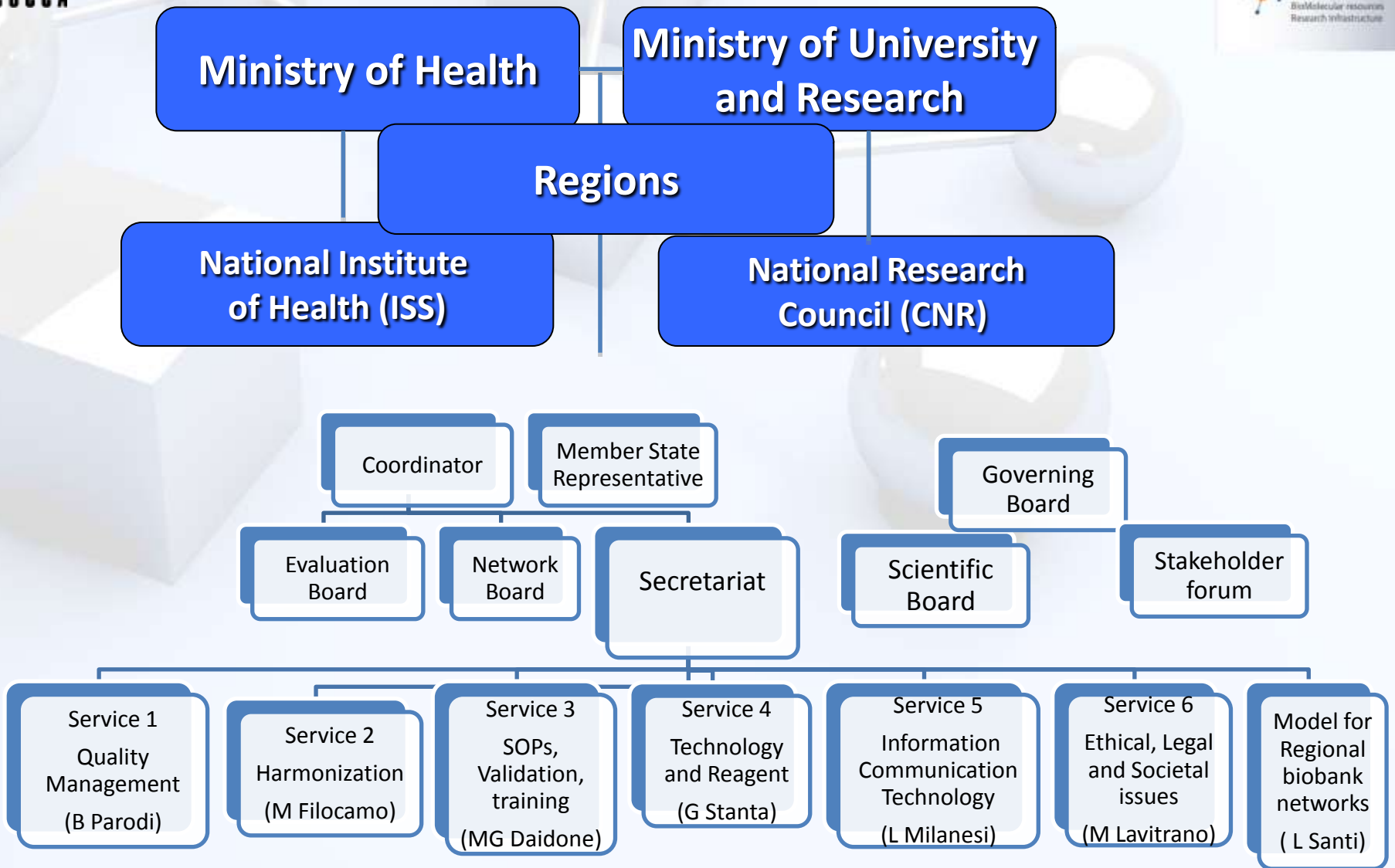
# BBMRI-IT Facts and figures

BBMRI.it è una infrastruttura distribuita che include BBs, Centri di risorse Biologiche e Collezioni collocati in diverse regioni italiane

- ➔ 18 Università
- ➔ 23 IRCCS
- ➔ 40 Ospedali
- ➔ 8 associazioni di Pazienti
- ➔ circa 90 BBs, Centri di risorse Biologiche e Collezioni

**290 GRUPPI DI RICERCA HANNO DICHIARATO INTERESSE AD ADERIRE A BBMRI-it**

# STRUTTURA DEL NODO ITALIANO





# BBMRI.it Obiettivi

## BBMRI.it obiettivi principali:

- **Portare le collezioni di risorse biologiche e le BBs italiane ad un nuovo livello di coordinamento e di efficienza**
- **Provvedere Common Services**
- **Offrire un migliore accesso agli utilizzatori del settore pubblico e privato**
- **Contribuire alla infrastruttura pan-Europea di ricerca BBMRI-ERIC**

# BBMRI.it Obiettivi

**per raggiungere gli obiettivi:**

- **Migliorare l'interoperabilità dei database di ricerca**
- **Facilitare la partnership pubblico/privata**
- **Sviluppare le condizioni per assicurare la sostenibilità delle BBs**
- **Armonizzare SOPs e elaborare tools appropriati**
- **Implementare i criteri di quality management**
- **Sviluppare il nodo nazionale nell'ambito di BBMRI-ERIC**



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## PATH OF BBMRI.it MEMBERSHIP

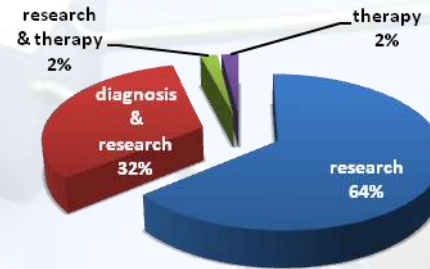
- **Prima fase: Censimento.** Mappare e selezionare le biobanche italiane e stratificarle in base al livello di qualità e di ricchezza in campioni e dati associati.
- **Seconda fase Valutazione.** Identificare le biobanche che non sono semplici collezioni di campioni. Questionario on-line, valutazione.
- **Terza fase: firma della BBMRI Partner Charter.** Ciascuna Biobanca / Centro di Risorse Biologiche compliant con le best practices nazionali e internazionali diviene membro effettivo di BBMRI.it

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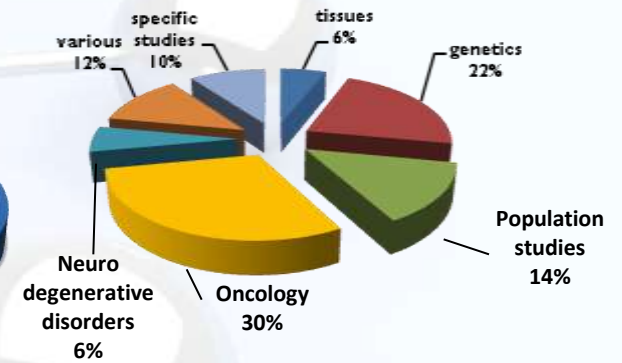
# Results of the first survey

- 16% were already operative before 1990, 56% were set up after 2001
- 43% have more than 10.000 cases collected
- 66% collect at least 3 different types of samples per subject (frozen samples, FFPE, blood derivatives, nucleic acids, cell lines)
- 77% participate in regional, National and/or International networks
- Most are disease oriented (about half cancer and genetic diseases)
- A vast majority is ready to offer services to the network (samples, data, molecular analysis, expertise, support in handling, preservation, transfer)

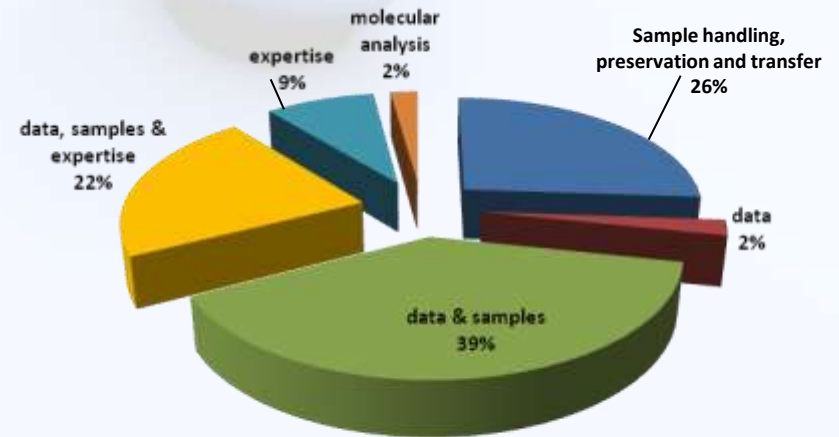
**Aims of the biobanks**



**Focus of the biobanks**



**Products and services offered to the network**



# SELF ASSESSMENT ON LINE QUESTIONNAIRE

## Aim 1

**Identifying Italian Biobanks who give assurance of:**

- ❖ **Service to the scientific community**
- ❖ **Interoperability**
- ❖ **Compliance with ethical and legal standards**
- ❖ **Compliance with National and International best practice**

## Aim 2

**Creating a network of Biobanks appropriate to sign the Partner Charter of BBMRI Europe**

# Outcome of the on-line self assessment of italian Biobanks

**83** applicants have compiled the questionnaire

**78** Biobanks have been selected as “real biobanks”,  
recognized by their host institutions and willing to sign the  
Partner Charter

**23** Biobanks have been directly contacted

**64** have a Quality system compatible with the requirements  
of the Partner Charter

**14** are improving their Quality system and are assisted by  
the Quality common service of the Italian node

**Purpose and applicability**

The BBMRI-ERIC Partner Charter should define the most important cornerstones for the participation of biobanks or biological resource centres (Partner) that are associated with BBMRI-ERIC to foster scientific excellence, guarantee interoperability, and compliance with ethical and legal requirements. The Partner Charter is binding for any Partner of the BBMRI-ERIC and shall be agreed between national BBMRI-ERIC nodes and the Partners. Participation of a Partner in BBMRI-ERIC is non-exclusive and has no effect on any activity of a Partner outside of BBMRI-ERIC.

**Principles****Primacy**

BBMRI-ERIC acknowledges the primacy of national and European legislation and respects the jurisdiction of competent authorities.

**Access policy**

Samples and data need to be accessible through a clear access procedure compliant with the general access procedures and conditions of BBMRI-ERIC. BBMRI-ERIC will foster the establishment of scientific collaborations between authenticated scientific users and Partners. Special access policies can be established for industrial users.

Access to samples and data will honour commitments to donors and follow the principles of "fair access" and scientific excellence. Access in the context of research projects performed within BBMRI-ERIC will only be provided for specified research projects, in accordance with the terms of the consent given by the participant and after approval of the research project by a Research Ethics Committee (REC). Access has to be compliant with regulations of BBMRI-ERIC Partner biobanks, and Partner biobanks have to decide whether access can be granted for a specific project. This decision has to follow transparent and non-discriminating decision making procedures. Noteworthy, the establishment of high quality research collaboration is the preferred format for access.

**Data protection and management policy**

BBMRI-ERIC and Partners will not make public any information of research projects performed through BBMRI-ERIC that can be directly related to an individual. Information on individuals will only be made accessible to authenticated scientific users in a coded or anonymized fashion in the context of specific research projects and upon approval by a competent Research Ethics Committee (REC) in compliance with national and EU legislation, and subject to the BBMRI data access conditions. Partners will support integration of their data management system with that of BBMRI-ERIC by complying with the BBMRI-ERIC information requirements. The initial information requirements are realised as the expected minimal common data content and data structure in relevant databases. No access will be provided for non-research purposes (such as forensic, insurance or employment purposes), except pursuant to a court order.

**Informed consent**

BBMRI-ERIC and Partners will, at any time, honour commitments owed to donors. Partners shall aim at prospectively implementing the OECD Guidelines for Human Biobanks and Genetic Research Databases for issues related to informed consent, as appropriate and subject to the primacy of national and EU legislation.

**Infrastructure and management**

Partners will commit themselves to future implementation of the OECD best practice guidelines for Global Biological Resource Centres Networks. These guidelines define in particular requirements concerning the following issues:

- Infrastructure (building, facility)
- Management (responsibilities and qualifications)
- Traceability
- Biosecurity
- Data protection
- Minimal and recommended datasets
- Quality management and certification

**Quality management**

All Partners should commit themselves to implement quality management /assurance procedures compliant with OECD best practice guidelines for Global Biological Resource Centres Networks. SOPs should be established and made publicly available for all processes related to sample collection, processing, storage, retrieval and despatch. It is recommended that SOPs should follow the procedures as specified in the WHO/IARC guidelines for biological resource centres for cancer research whenever feasible. A unique BBMRI biobank (collection) identifier should be provided (see Kauffman, F & Cambon-Thomsen, A. Tracing biological collections: Between books and clinical trials. JAMA 2008, 299: 2316-2318). Criteria for the identifier will be provided by BBMRI-ERIC. Partners should allow external audits by BBMRI-ERIC.

**Reporting**

Partners will provide annual reports to the National Node Director on which research projects have been supported and information on the outcome that partners have received (e.g., publications, patents). Projects that have been supported by BBMRI-ERIC should acknowledge the contribution of BBMRI-ERIC in any publication according to the principles of good scientific practice. Partners will provide a yearly updated inventory to the National Node Director on the type, content and quality of collections and resources they are holding.

**Charges**

BBMRI-ERIC will pursue its principal task on a non-economic basis. However, it may carry out limited economic activities, provided that they are closely related to its principal task and that they do not jeopardise the achievement thereof. Biobanking-related services might be subject to cost recovery. Costs can be recovered for staffing, consumables, licensing, equipment servicing/maintenance. No patient samples or data are sold for profit. Supply of samples by or to external commercial organisations shall be conducted in accordance with the Community Framework for State Aid for Research and Development and Innovation (2006/C 323/01).

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The Director / Responsible / Curator of the Biobank / BRC:

\_\_\_\_\_ acronym: \_\_\_\_\_,

hereby agrees to adopt the above partner charter. The Biobank / BRC is aware that compliance with the partner charter is essential to foster scientific excellence, guarantee interoperability, and compliance with ethical and legal requirements, and is required in order to take part in the Italian Infrastructure of Biobanks and to join the Board of Directors of BBMRI.it

The Director / Responsible / Curator of the Biobank / BRC:

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Place: \_\_\_\_\_ Date: \_\_\_\_\_



BBMRI-IT is a research infrastructure involving biobanks and biological resource centers located throughout Italy. The Italian node BBMRI-IT includes 18 universities, 23 IRCCS, 40 hospitals, many associations of patients and about 80 bioresources among biobanks, collections and biological resource centers.

The main objectives of the node BBMRI-IT are:

- coordinating the activities of biobanks in order to promote their efficiency and interoperability;
- providing new services;
- improving access for users of the public and private sectors;
- contributing to the pan-European research infrastructure BBMRI-ERIC activities.

In particular, the activities of BBMRI-IT are aimed at harmonizing the standard operating procedures (SOPs) of biobanks, implementing the quality management system and encouraging public/private partnerships, with the ultimate aim to foster biobanks' economic sustainability.

[Join in the BBMRI.it network](#)

### NEWS

[Download Ongoing Calls](#)  
[Ongoing Fellowship Calls](#)



[BRIF - "Open Journal of Bioresources"](#)

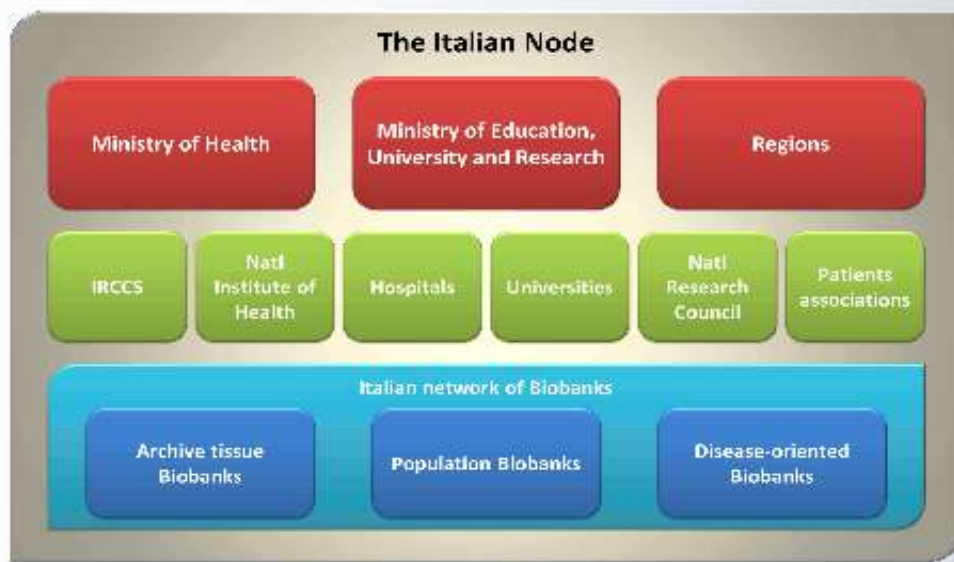
[Foglio dei Bandi per Fellowship in corso \[21 Luglio 2014\]](#)

### EVENTS



[ESBB Annual Meeting](#)

[BBMRI-LPC Practical Biobanking Workshop](#)





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HOME BBMRI ITALY BBMRI-ERIC PARTNERS BIOBANKS SAMPLES NEWS SERVICE DOCUMENTS



SEARCH BIOBANK INFORMATIONS SUBSCRIPTION FORM FOR BBMRI.IT BIOBANK DESCRIPTIONS FORM

Biobanca Selezionata: 1382686156197551

Salva ed Esci Salva Esci

Informazioni Generali Ubicazione Certificazioni/Partecipazioni Dettagli Conferma

INFORMAZIONI GENERALI		GENERAL INFORMATION	
Nome Biobanca *	Interlab Cell Line Collection	Biobank Name *	Interlab Cell Line Collection
Acronimo Biobanca *	ICLC	Biobank Acronym *	ICLC
Nome Responsabile *	Barbara Parodi	Curator Name *	Barbara Parodi
Qualifica Responsabile *	medico responsabile Banca biologica e cell fact	Curator Qualification *	MD, unit manager
Link Catalogo Online *	www.iclc.it	Online Catalogue Link *	www.iclc.it
Descrizione Biobanca *	La Banca cellule Interlab Cell Line Collection (ICLC) è operativa dal 1994 per raccolta, autenticazione, controllo di qualità, espansione, conservazione e distribuzione di linee cellulari umane e animali con l'obiettivo di fornire ai 35 Caratteri Rimanenti	Biobank Description *	Born in 1994, it became soon a point of reference for academical and industrial researchers, to whom it supplies: •human and animal cell lines, mainly of tumoral origin, of certified quality for 306 Characters remaining
Marker Paper DOI Link *	Romano P, Manniello A, Aresu O, Armento M, Cesaro M, Parodi B. Cell Line Data Base: structure and recent improvements towards molecular authentication of human cell lines. 727 Caratteri Rimanenti	Marker Paper DOI Link *	Romano P, Manniello A, Aresu O, Armento M, Cesaro M, Parodi B. Cell Line Data Base: structure and recent improvements towards molecular authentication of human cell lines. Nucleic Acids Res. 2009; Jan;37(Database 727 Characters remaining



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## GENERAL INFORMATION

Biobank Name *	Interlab Cell Line Collection
Biobank Acronym *	ICLC
Curator Name *	Barbara Parodi
Curator Qualification *	MD, unit manager
Online Catalogue Link *	www.iclc.it
Biobank Description *	<p>Born in 1994, it became soon a point of reference for academical and industrial researchers, to whom it supplies:</p> <ul style="list-style-type: none"> <li>•human and animal cell lines, mainly of tumoral origin, of certified quality (on-line catalogue);</li> <li>•quality control service, detection and eradication of mycoplasma;</li> <li>•identification service: authentication of human cell lines through STR profile</li> <li>•information and technical-scientific support on cell line availability at the international level, functional features, transport of biological samples;</li> <li>•safe deposit for tissue samples, cell lines and hybridomas</li> <li>• patent deposit of cell lines and hybridomas: International Deposit Authority (IDA) under the Budapest Treaty.</li> </ul>

## BIOBANK LOCATION

Institute *	IRCCS AOU San Martino - IST
Institution Typology *	IRCCS, oncology
Laboratory/Department *	s.s. Banca biologica e cell factory
Address *	Largo Rosanna Benzi, 10
Region *	Liguria
ZIP Code *	16132
City *	Genoa
<b>BIOBANK CONTACTS</b>	
Phone *	010 5558474
FAX *	010 5558293
E-Mail *	barbara.parodi@hsanmartino.it
Web Site *	www.iclc.it
Marker Paper DOI Link *	Romano P, Manniello A, Aresu O, Armento M, Cesaro M, Parodi B. Cell Line Data Base: structure and recent improvements towards molecular authentication of human cell lines. Nucleic Acids Res. 2009 Jan;37(Database issue):D925-32.

## CERTIFICATION/ACCREDITATION/RECOGNITION

Certification *	IRCCS Certified UNI EN ISO 9001:2008 BUREAU VERITAS 949 Characters remaining
Accreditation *	International Deposit Authority under Budapest treaty, WIPO 940 Characters remaining
Recognition *	Reference lab Int. J. Cancer for human cell lines authentication through STR profile 916 Characters remaining
<b>NETWORKING</b>	
Regional Networking *	Ligurian Biobank Network 976 Characters remaining
National Networking *	RIBBO, CRB-NET 986 Characters remaining
International Networking *	BBMRI, MIRRI, GBRCN, CABRI



**INFORMATION IN DETAIL**

Activities and Services \*

- collection and distribution of human and animal cell lines, mainly of tumoral origin, of certified quality (see on-line catalogue);
- quality control service, detection and eradication of mycoplasma;
- identification service: authentication of human cell lines through short tandem repeat (STR) profile
- information, technical and scientific support on cell line availability at the international level, functional features, transport of biological samples;
- safe deposit for tissue samples, cell lines and hybridomas
- patent deposit of cell lines and hybridomas: International Deposit Authority (IDA) under the Budapest Treaty.

Biobank typology \*

- Oncological
- Genetic
- Population
- Tissues
- Pathology
- Cytology
- Gynecology
- Obstetric
- Transfusion
- Transplant
- Clinical
- IVF
- Bacteriology
- Virology
- Other

List of diseases \*

Human and animal tumors

977 Characters remaining

Sample typology \*

- Nucleic Acid
- Full blood
- Cellular blood fraction
- Serum/Plasma
- FTPE tissue
- Cryo-preserved tissue
- Cell Line
- Marrow
- Urine
- Saliva
- CSF
- DNA
- RNA
- Other

Sample typology details \*

Human and animal continuous cell lines, mainly of tumor origin

438 Characters remaining

Informed consent form link \*

ok

Recorded data \*

- Personal data
- Ethical
- Clinical/Phenotype/Instrumental
- Environmental
- Genetic
- Biological sample data
- Follow-up data

Evaluation of Requests \*

Biobank curator. The established cell lines can be grown for several passages. Therefore there is no need for project prioritization.

867 Characters remaining

Sample Distribution \*

- Free
- Total Cost-recovery
- Partial Cost-recovery (distribution service)
- Other



**Ricerca:**

1

Nome	Responsabile	Tipologia	Regione	Tipologia Campioni
da Vinci European BioBank	Giordana Marcon	<ul style="list-style-type: none"> <li>• Altro</li> </ul>	Toscana	<ul style="list-style-type: none"> <li>• Acidi Nucleici</li> <li>• Frazioni Cellulari del Sangue</li> <li>• Linee Cellulari</li> <li>• Urine</li> <li>• Siero/Plasma</li> <li>• Tessuti crio preservati</li> </ul>
Biogene	Francesca Torricelli	<ul style="list-style-type: none"> <li>• Genetica</li> <li>• Oncologica</li> <li>• Popolazione</li> <li>• Tessuti</li> <li>• Altro</li> </ul>	Toscana	<ul style="list-style-type: none"> <li>• Acidi Nucleici</li> <li>• Frazioni Cellulari del Sangue</li> <li>• Linee Cellulari</li> <li>• Urine</li> <li>• Sangue Intero</li> <li>• Siero/Plasma</li> <li>• Midollo osseo</li> <li>• Saliva</li> <li>• Tessuti crio preservati</li> </ul>
Genetic Biobank of Siena	Alessandra Renieri	<ul style="list-style-type: none"> <li>• Genetica</li> <li>• Oncologica</li> </ul>	Toscana	<ul style="list-style-type: none"> <li>• Acidi Nucleici</li> <li>• Frazioni Cellulari del Sangue</li> <li>• Linee Cellulari</li> <li>• Sangue Intero</li> <li>• Siero/Plasma</li> <li>• Urine</li> </ul>

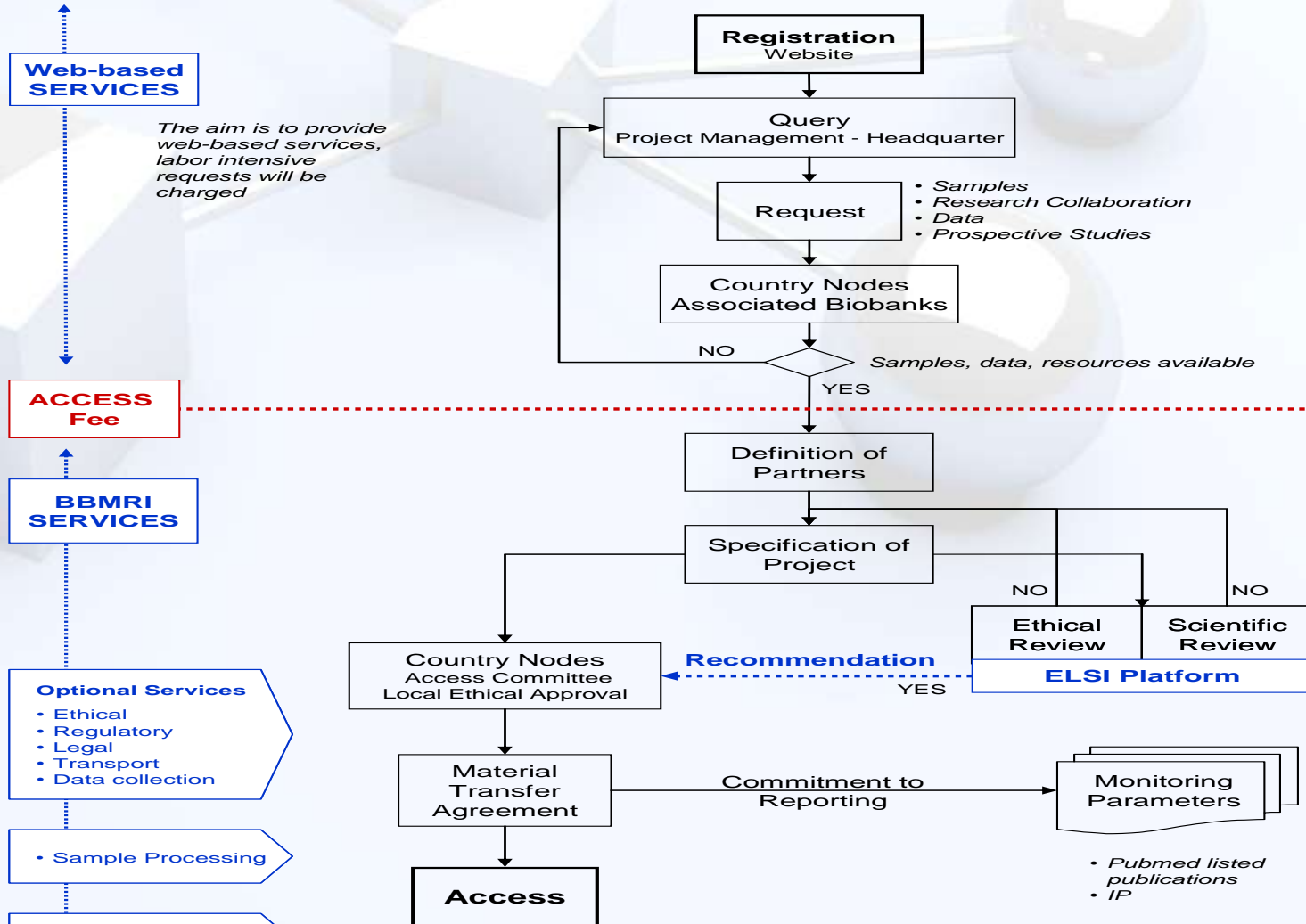
# Strumenti Web

BBMRI Italia mette a disposizione delle [biobanche](#) e dei ricercatori un elenco ragionato di strumenti web utili per le attività di ricerca che prevedono l'uso di campioni biologici. Alcuni di questi sono stati prodotti durante la fase preparatoria di BBMRI o di altre infrastrutture europee. Le descrizioni sono in inglese perché tratte dai siti web. Segnalateci ([italy@bbmri.it](mailto:italy@bbmri.it)) altri strumenti utili e li aggiungeremo alla lista.



<a href="#">MIAPAR</a>	MIAPAR is intended to be used as a guideline for experimentalists who wish to unambiguously describe <b>protein affinity reagents</b> and their protein targets (including but not limited to Ab/Ag interactions). It specifies the minimum amount of information which should be present, or directly traceable, in any publication, database entry or commercial catalogue describing either the production or use of affinity reagents such as antibodies, <a href="#">aptamers</a> , protein scaffolds etc.
<a href="#">MOLMETH</a>	<a href="#">Molmeth</a> , the <b>Molecular Methods Database</b> , is a free and powerful tool. It has unique collaborative features for researchers to publish and improve methods or lab protocols online.
<a href="#">CLIMA</a>	The <b>Cell Line Integrated Molecular Authentication database (CLIMA)</b> links available authentication data to actual cell lines distributed by cell banks. It was designed in the frame of the Cell Line Data Base, a well-known reference information source on human and animal cell lines. CLIMA includes STR profiling obtained by using different platforms; the end users can retrieve data on cell line authentications performed by different cell banks.
<a href="#">BioSharing</a>	<a href="#">BioSharing</a> works to map the landscape of <b>community developed standards in the life sciences</b> , broadly covering biological, natural and biomedical sciences.
<a href="#">Legalpathways</a>	The objective of this platform is to serve as a dynamic, online, grass roots platform for sharing, discussing, validating and issuing <b>authoritative and reliable legal forms and standards</b> to aid the BBMRI community in navigating the legal pathways that govern its pan European, cross border, multi-jurisdictional infrastructure and operations. The platform is to unearth any existing knowledge, expertise and templates currently in use by (prospective) BBMRI Members and Partners.
<a href="#">hSERN</a>	<b>Human sample exchange</b> regulation navigator, a web based information tool on legal requirements for exchanging biological samples
<a href="#">MIABIS</a>	Minimum Information About <a href="#">Biobank data Sharing</a>
<a href="#">CoBiBa</a>	<b>Connecting BioBanks</b>

# Come si accede ai servizi di BBMRI





**BBMRI.it**Biobanking and BioMolecular Resources Research Infrastructure  
of Italy[HOME](#) [BBMRI ITALY](#) [BBMRI-ERIC](#) [PARTNERS](#) [BIOBANKS](#) [SAMPLES](#) [NEWS](#) [SERVICE](#) [DOCUMENTS](#)**COMMON SERVICE QUALITY**[COMMON SERVICE ELSI](#)[WEB SERVICES](#)[HELP DESK](#)[COMITATO BBMRI.IT](#)[DOC](#) [PDF](#) [Print](#)

## COMMON SERVICE QUALITY

The Common Service Quality of BBMRI Italy is operational and it aims to:

- Map and monitor biobanks, repositories and biomolecular resources
- Harmonize and standardize SOPs
- Develop criteria for accreditation and certification
- Implement quality management criteria
- Improve interoperability
- Set up training in quality control
- Standardize and set up proficiency testing
- Promote a certification program

Send an email to BBMRI Italy ([italy@bbmri.it](mailto:italy@bbmri.it)), we will reply as soon as possible. If you want to be contacted by phone, please send us your contact.

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# Common Service

## Common Technology and Reagent Services

- Establish a National catalogue of facilities and services for the biobank network
- Identify Expert Centres

Giorgio Stanta

## Catalogue of services offered by BBs to the network

- DNA and RNA extraction
- supply of genetic material for method validation
- cell line production
- molecular characterization of biological samples
- cell line authentication
- validated mycoplasma QC
- cryopreservation biological samples
- preparation and storage pathogens
- consultancy biological samples transport (IATA)
- statistical analysis
- counseling SOPs preparation
- counseling ethical issues
- data analysis
- data mining
- training of operators for cryobiology
- training of operators for biobanking



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## IT Services

- Sustain the matrix architecture of the network (links among BBs into Regional and thematic networks)
- Offer common services to the network
- Promote collaborative studies at the National and International levels
- Guarantee safe transfer of information
- Provide visibility to Italian BBs
- Adopt BBMRI standards and create the interface to National BBs
- Maintain the Lexicon BBMRI portal for multi-lingual BBs terminology definition

Luciano Milanese



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## Ethical, Legal and Societal Issues

- Define the status of bioresources
- Define the status of BBs
- Promote public consultation
- Establish the informed consent form
- Define the access to bioresources
- Regulate patentability
- Set up and monitor good practices in biobanking
- Provide in-formation and permanent training
- Biobanking 2.0

Marialuisa Lavitrano



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# Analisi dei costi e sostenibilità

<p><b>Pre-banking data</b></p>	<p>Clinical data from GP Questionnaire and survey Imaging Histopathology and cytology Serological tests Communication, information to donors and informed consent Recording, processing and data management (e.g. LIMS) Storage and updating clinical data Data release Monitoring, audit Others</p>
<p><b>Collection of biological specimens</b></p>	<p>Collect Accrual Processing of samples Storage Distribution and transport Despatch management Quality control Monitoring/Audit Others</p>
<p><b>Collection of data related to biological specimens</b></p>	<p>Recording, storage and data management Data analysis and linking Quality control and computer system engineering Despatch management Monitoring, audit Others</p>
<p><b>Expertise</b></p>	<p>Project management, advisory, study design Recruitment Data generation Data analysis and statistics SOPs and support Processing Storage Quality management, certification and accreditation, audit Education and training Communication and public engagement Others</p>
<p><b>Administration and management</b></p>	<p>Financial and administrative management Scientific management and strategy Loads and running charges Maintenance of equipment and consumables Internal R&amp;D Investments Ethics and regulatory issues Partnership development, business development, contracts, networking Others</p>

# Milan – a city in the heart of Europe



**The HandsOn: Biobanks 2015 will be hosted by BBMRI.it and be a part of Expo 2015 in Milan, Italy**

