



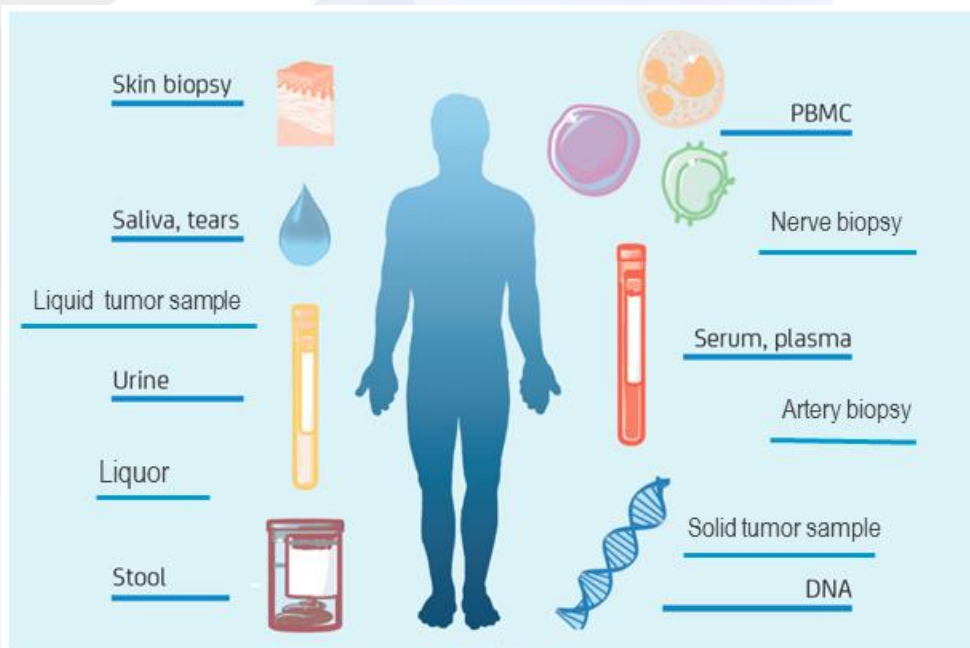
**BBMRI.it**

**Italian node of the European Biobanking and Biomolecular  
Resources Research Infrastructure (BBMRI-ERIC)**

**Barbara Parodi**

**Project manager BBMRI.it, Responsible Common Service Quality,  
Executive manager Centro Risorse Biologiche IRCCS Ospedale Policlinico San Martino, Genoa**

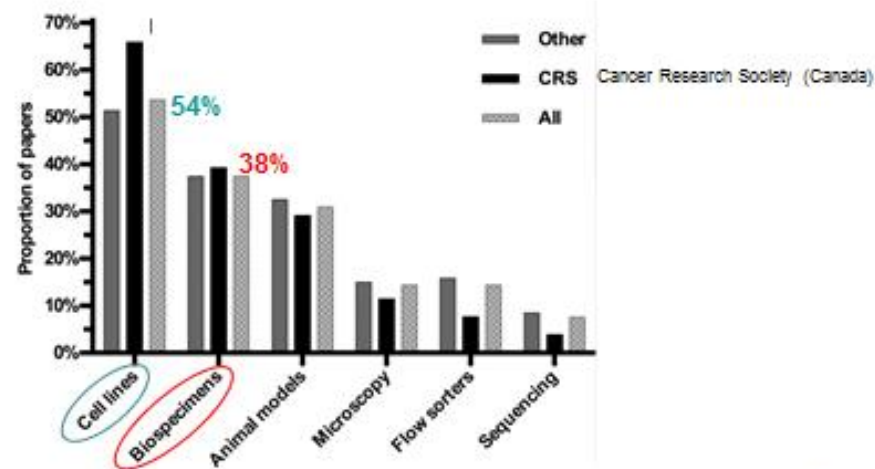
# Most of our current knowledge on diseases as well as available diagnostic assays and drugs are based on investigation of biological samples and data



BIOPRESERVATION AND BIOBANKING  
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## The Importance of Biobanking in Cancer Research

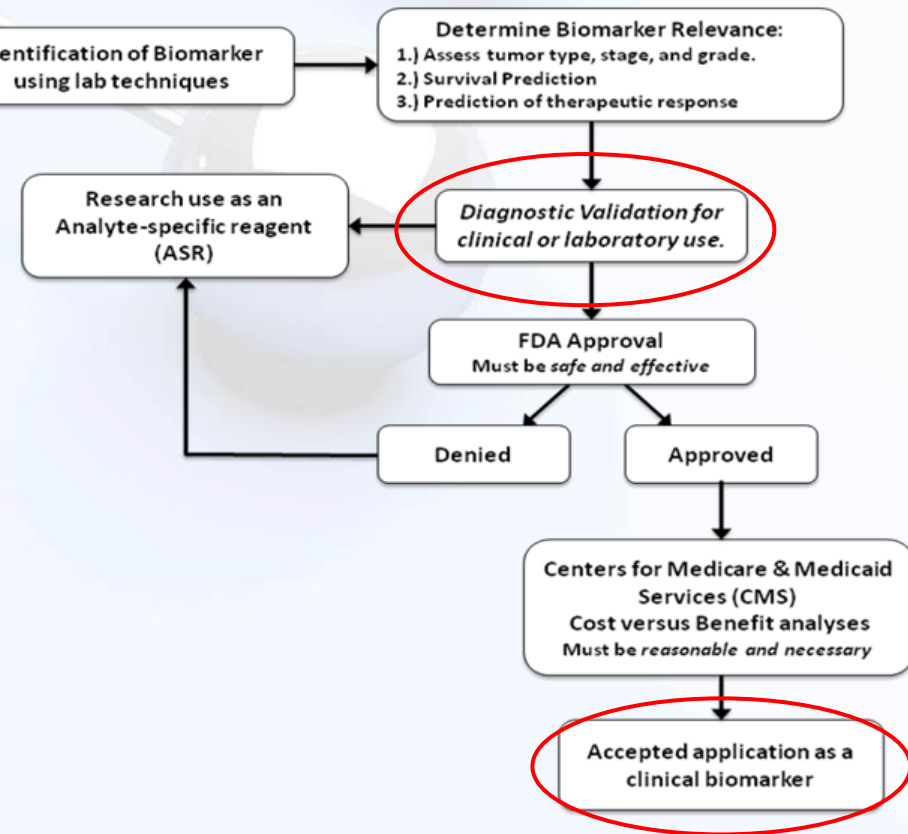
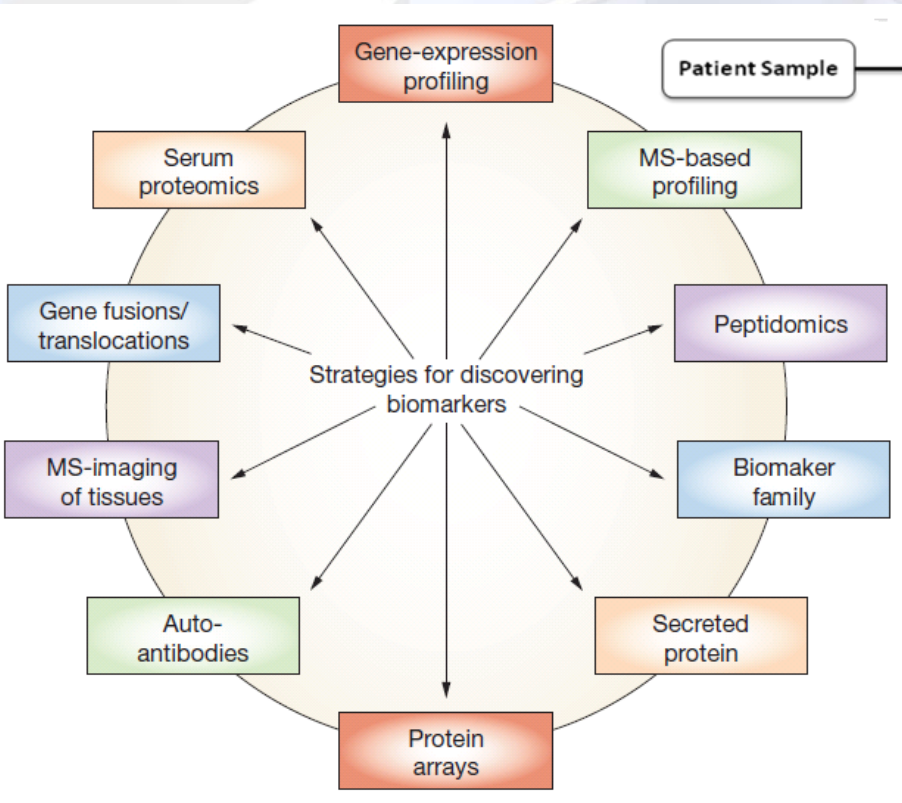
Tania Castillo-Pelayo,<sup>1</sup> Sindy Babinszky,<sup>1</sup> Jodi LeBlanc,<sup>1</sup> and Peter H Watson<sup>1,2</sup>



# Biomarkers

In the last 20 years from -omics studies >200 potential Biomarkers

**Only a few validated through clinical trials on biological samples**





## The OECD initiative on BRCs

2001

OECD BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES



ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

2007

*"Biological resources – living organisms, cells, tissues, genes, and related information – are the essential raw material for the advancement of biotechnology, human health, and research and development in life sciences"*

2009

OECD Guidelines on Human Biobanks and Genetic Research Databases

European Strategy Forum on Research Infrastructures

ESFRI

EUROPEAN ROADMAP FOR RESEARCH INFRASTRUCTURES  
Report 2006

## 1<sup>st</sup> ESFRI Roadmap

- This roadmap proposes research facilities of pan-European interest
- Among them: BBMRI

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.

## The BBMRI Preparatory Phase

**BBMRI**  
Biobanking and Biomolecular Resources Research Infrastructure

Preparatory Phase: 2008-2011

Funding € 5 million

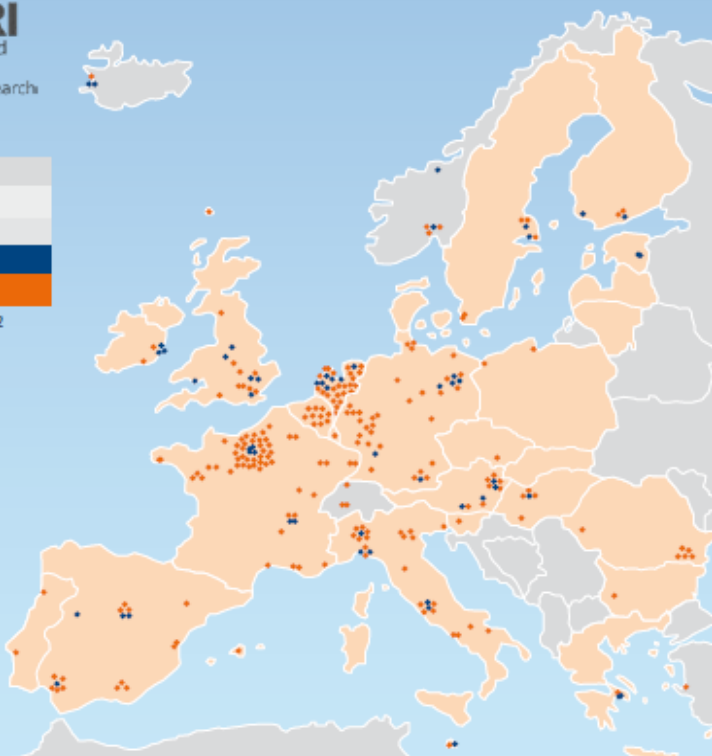
33 Countries

53 Participants

222 Associated Organizations

Construction/Operation Phase: 2012

www.bbMRI.eu





## BBMRI-ERIC

An ERIC has legal personality based on EU law (Article 171 of the EC Treaty). Its main task is to establish and operate a research infrastructure



### NATIONAL NODES & CONTACT FOR LOCAL BIOBANKS

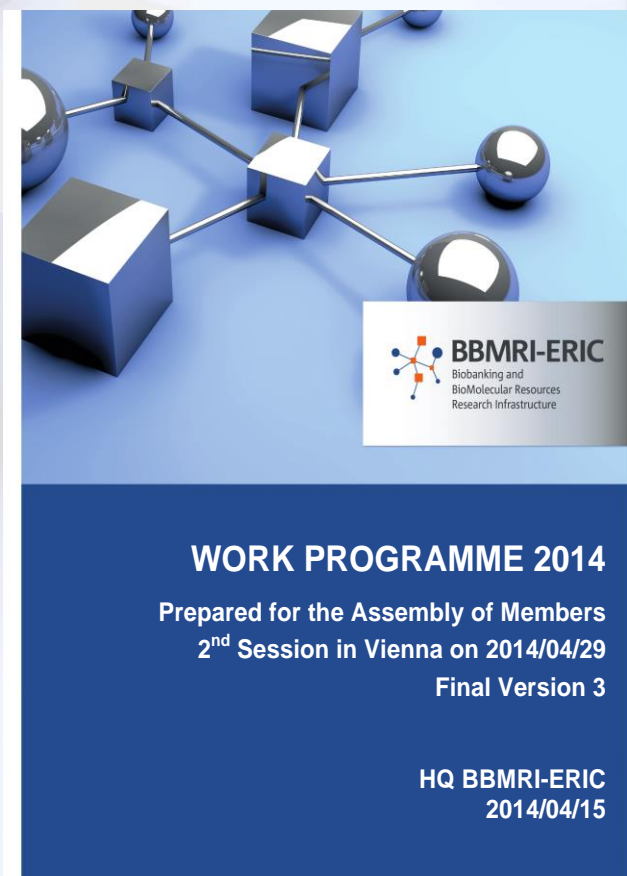


BBMRI was awarded ERIC status December 3<sup>rd</sup> 2013



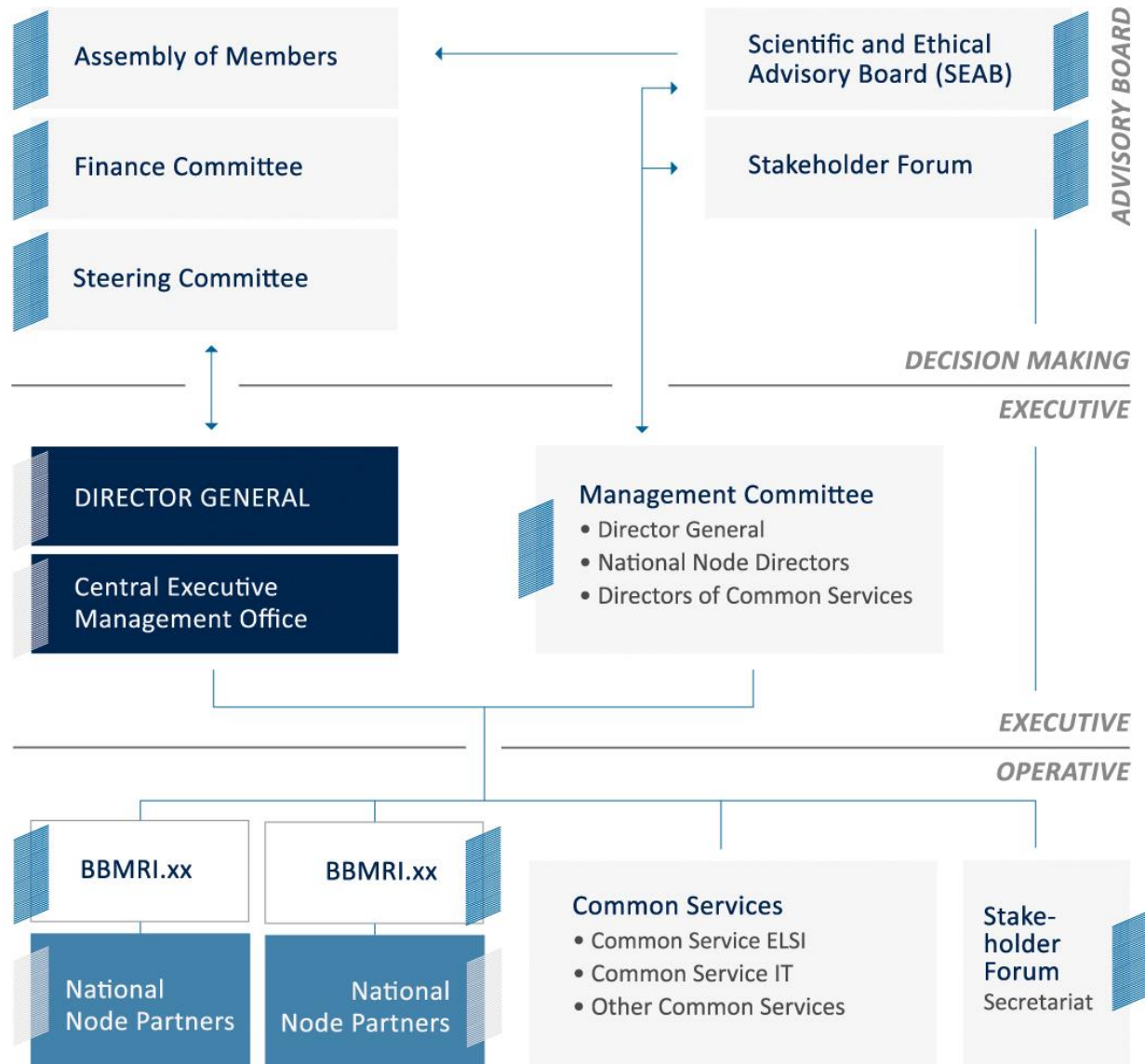
20 Member States  
1 International Organization

# Seven Pillars of BBMRI-ERIC



- Scientific excellence
- One single infrastructure for Europe
- Access to high quality human biological samples and associated data
- Access to high quality Biomolecular resources
- Ethical and legal compliance
- Long-term sustainability
- International integration

# Governance structure






# Sample quality

“Pre-analytical errors still account for nearly 60%-70% of all problems occurring in laboratory diagnostics, most of them attributable to mishandling procedures during collection, handling, preparing or storing the specimens”.

Lippi G. *et al.*. Preanalytical quality improvement: from dream to reality. Clin Chem Lab Med. 2011 Jul; 49(7):1113-26. Epub 2011 Apr 25.




**Self Assessment**

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for snap frozen tissue - Part 1: Isolated RNA

The integrity of molecules can change during primary sample collection, transport, storage and processing thus influencing the research results. Standardisation of the entire process from collecting sample to applicable analysis techniques is key.

The European Committee for Standardisation (CEN) published Technical Specifications to determine influencing factors and provide recommendations for the handling, documentation and processing of frozen tissue specimens intended for RNA analysis.

CEN/TS 16826-1:2015 E Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for snap frozen tissue - Part 1: Isolated RNA

For further details, please visit [the CEN website](#).

This Self-Assessment-Survey will help you to assess and improve your sample processing.

The colour coding of the following questions asked in this survey indicated by orange that you shall meet given criterion respectively by blue that you should meet the given criterion.

True and accurate responses will give you genuine feedback on your sample collection procedures and will help you to improve certain processes in future.

**Main Contact**

1)	Biobank	<input type="text"/>
2)	Name of contact person	<input type="text"/>
3)	E-Mail of contact person	<input type="text"/>
4)	Address	<input type="text"/>
5)	ZIP	<input type="text"/>
6)	City	<input type="text"/>
7)	Country	<input type="text"/>
8)	Phone	<input type="text"/> e.g. +43 316 34 99 17

**Overview**

9)	Biobank type	<input type="text"/>
10)	ICD-10	<input type="text"/>



# Molecular in vitro diagnostic examinations

## Specifications for pre-examination processes

### for ...

Norm	Date	Title
EN ISO 20166-1:2018	2018-12-19	... formalin-fixed and paraffin-embedded (FFPE) tissue - Part 1: Isolated RNA (ISO 20166-1:2018)
EN ISO 20166-2:2018	2018-12-19	... formalin-fixed and paraffin-embedded (FFPE) tissue - Part 2: Isolated proteins (ISO 20166-2:2018)
EN ISO 20166-3:2019	2019-01-23	... formalin-fixed and paraffin-embedded (FFPE) tissue - Part 3: Isolated DNA (ISO 20166-3:2018)
EN ISO 20184-1:2018	2018-12-19	... frozen tissue - Part 1: Isolated RNA (ISO 20184-1:2018)
EN ISO 20184-2:2018	2018-12-12	... frozen tissue - Part 2: Isolated proteins (ISO 20184-2:2018)
CEN/TS 16945:2016	2016-05-18	... metabolomics in urine, venous blood serum and plasma
CEN/TS 17305:2019	2019-04-03	... saliva - Isolated human DNA
CEN/TS 16826-3:2018	2018-07-18	... snap frozen tissue - Part 3: Isolated DNA
EN ISO 20186-1:2019	2019-03-27	... venous whole blood - Part 1: Isolated cellular RNA (ISO 20186-1:2019)
EN ISO 20186-2:2019	2019-03-27	... venous whole blood - Part 2: Isolated genomic DNA (ISO 20186-2:2019)
CEN/TS 16835-3:2015	2015-10-14	... venous whole blood - Part 3: Isolated circulating cell free DNA from plasma

# The national nodes

*"To obtain the power of many we have to be able to combine the resources we have"*

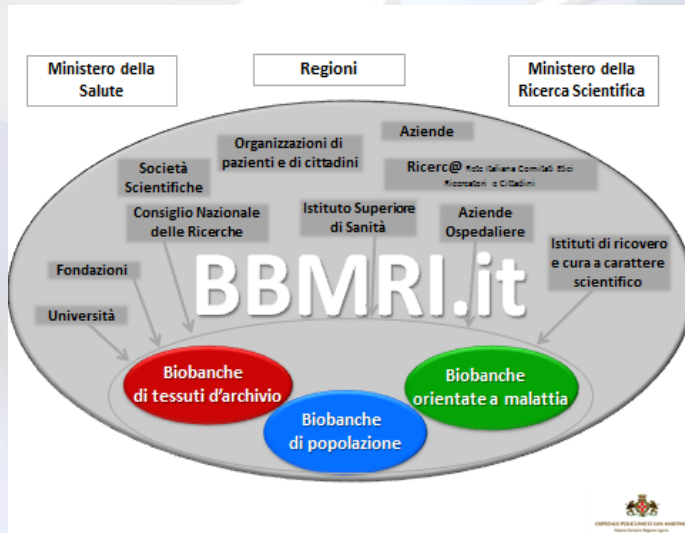
**(Eero Vuorio, BBMRI Stakeholder's Forum 2009)**

*'National Node' means an entity, not necessarily with legal capacity, designated by a Member State, that coordinates the national biobanks and biomolecular resources, and links its activities with the pan-European activities of BBMRI-ERIC.*

**(Statutes, Article 1.6)**

The BBMRI-ERIC Italian node was established in October 2013 thanks to the joint commitment of the Ministry of Health and the Ministry of University and Research.

The National Institute of Health, the CNR, 33 IRCCS, 19 Universities, 45 Hospitals and a network of stakeholders, including 14 patient associations including UNIAMO (Italian Federation of Rare Diseases) and FAVO (Italian Federation of voluntary associations) participate in the infrastructure. in oncology), biomedical and biotechnological companies and scientific societies (AIOM, SIAPEC, SiBIOC).



BBMRI.it includes over 90 biobanks, biological resource centers and collections located in different Italian regions and three Common Services (Quality, CS Information Technology, CS ELSI ethical, legal and social issues).



# BBMRI.it aims

- Survey of biobanks, in collaboration with Regional Authorities
- promote a continuous self-assessment process
- Promote institutional recognition
- guarantee quality standards and compliance with ethical and legal requirements
- coordinate and harmonize the activities of biobanks, in order to promote their efficiency and interoperability
- develop good practices
- guarantee and facilitate access to biological samples and associated data
- offer services and training



# BBMRI.it achievements

- Strategies of involvement and path of adhesion of biobanks to BBMRI.it, self-assessment questionnaire
- support services (Common service IT, ELSI, quality), Information Desk (about 200 requests / year processed), Help Desk (over 250 requests / year processed)
- portal BBMRI.it, support to update biobank webpages, contribution to the European Directory
- contribution to public consultations
- community building & engagement: digital tools, social media, newsletters (about 900 subscribers), European Biotech Week 2017 and 2018

# BBMRI.it achievements

- Working groups: 140 participants in 2017 and 170 in 2019, representing 73 institutions
- Quality handbook (guidelines, management, operational)
- Measures for sustainability and national tariffs for biobank services
- Matrix for the informed consent to research biobanking and for the ethical evaluation of the research biobank
- Good practice of research based on biobanking
- Training (20 courses, 33 meetings & workshops, Master in management of IRs)
- Interaction and coordination with other IRs in biomedicine

# SELF ASSESSMENT ON LINE QUESTIONNAIRE

## Aim 1

Identifying Biobanks who do not act as simple collections of biological samples but give assurance of:

- ❖ Service to the scientific community
- ❖ Interoperability
- ❖ Compliance with ethical and legal standards
- ❖ Compliance with National and Intl best practices

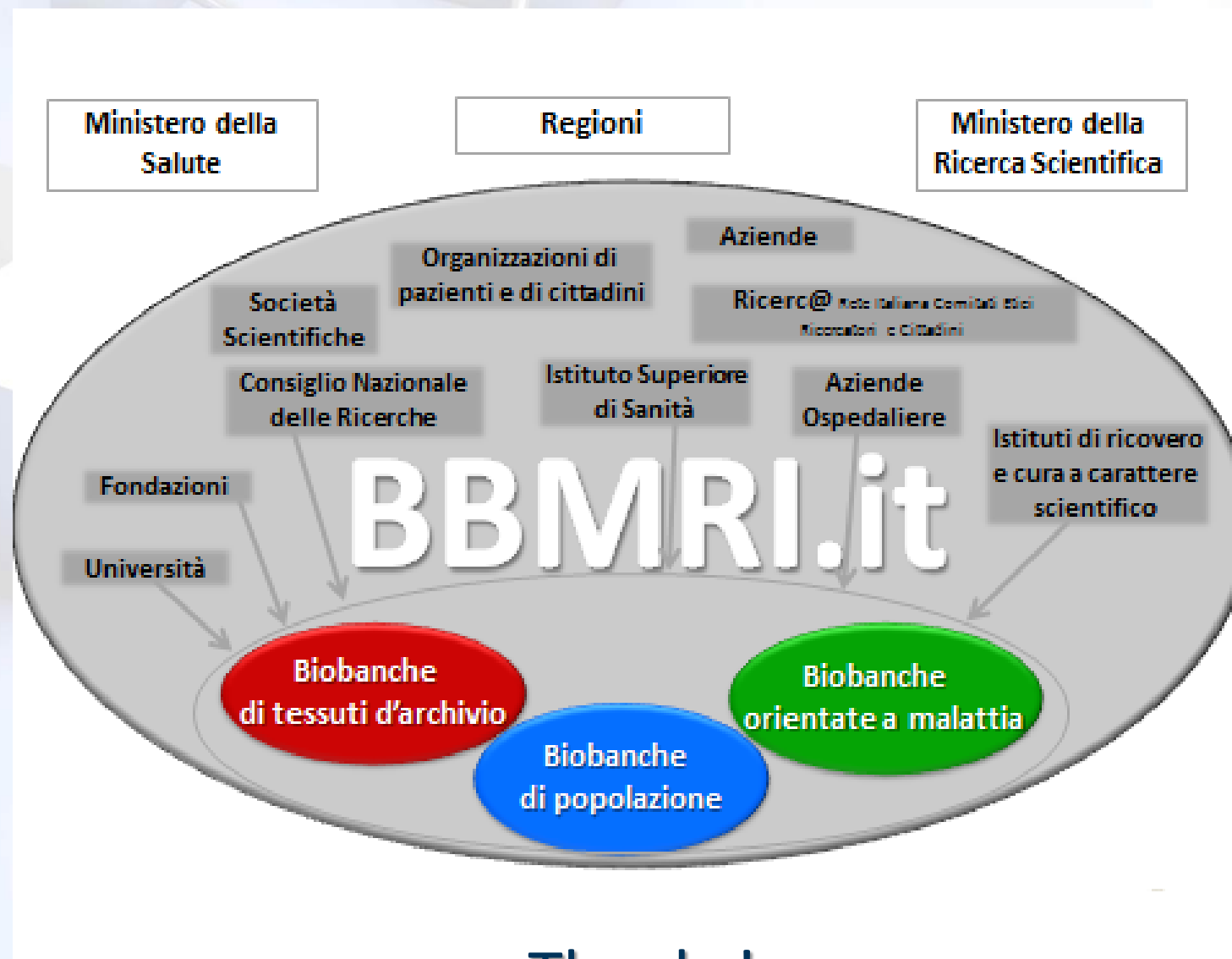
## Aim 2

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

## PATH OF MEMBERSHIP

- 1 The Biobank (BB) willing to enter the network fills out the online form.
- 2 Only after the formal approval by the Legal Representative (or the Scientific Director) of the host Institution the Biobank submits the completed form to BBMRI-IT.
- 3 The Evaluation Committee checks if the requirements for the inclusion of the BB in the National infrastructure are met, and arranges to visit the site
- 4 The Informatics Italian Node Team implement in the BBMRI.IT Web Portal the procedure to manage all the Biobanks data questionnaire workflow
- 5 The Biobank signs the BBMRI-ERIC partner charter
- 6 The Biobank on the website:
  - integrates and updates its data (in Italian and in English), to be shared with the National infrastructure
  - indicates its willingness to provide technical support to the National infrastructure
  - selects the key words that best describe its activities and samples





Thanks!