

# Biobanks and Biomolecular Resources: Outreach and Linkages

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# *The Grand Challenges*

- **Global warming**
- **Supplies of energy, water and food**
- **Ageing societies**
- **Public health**
- **Pandemics and security**

# *The Grand Challenges*

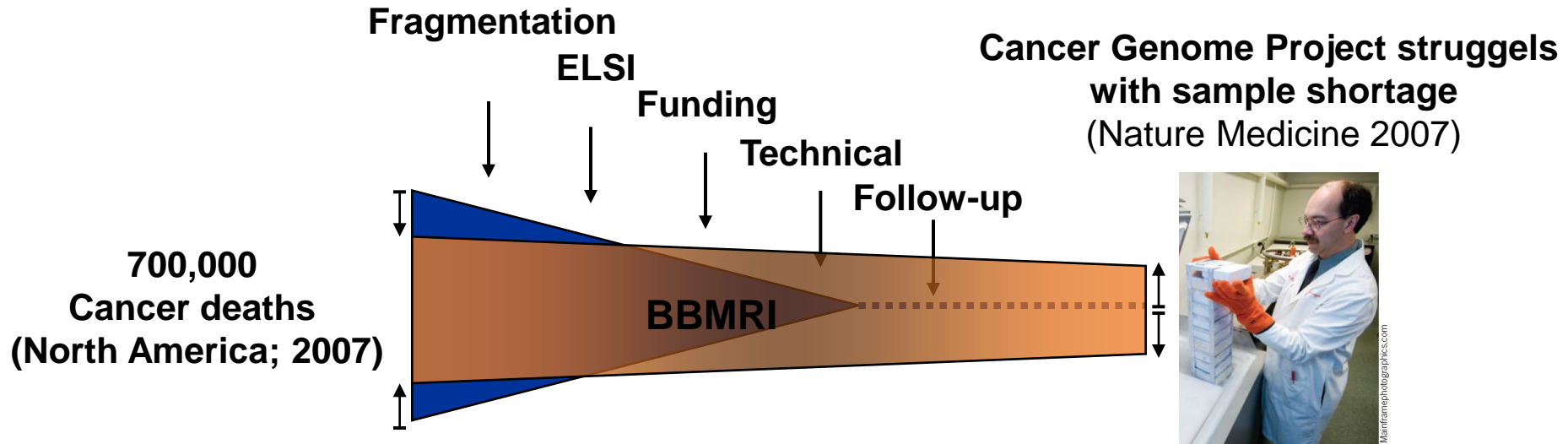
- **Global warming**
- **Supplies of energy, water and food**
- **Ageing societies**
- **Public health**
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} require access to  
human biological samples

**The „Grand Challenges“ are global and can only be efficiently addressed in a globally coordinated approach**



# Biobanks in Medical Research



**NCI:** Biological samples are #1 roadblock

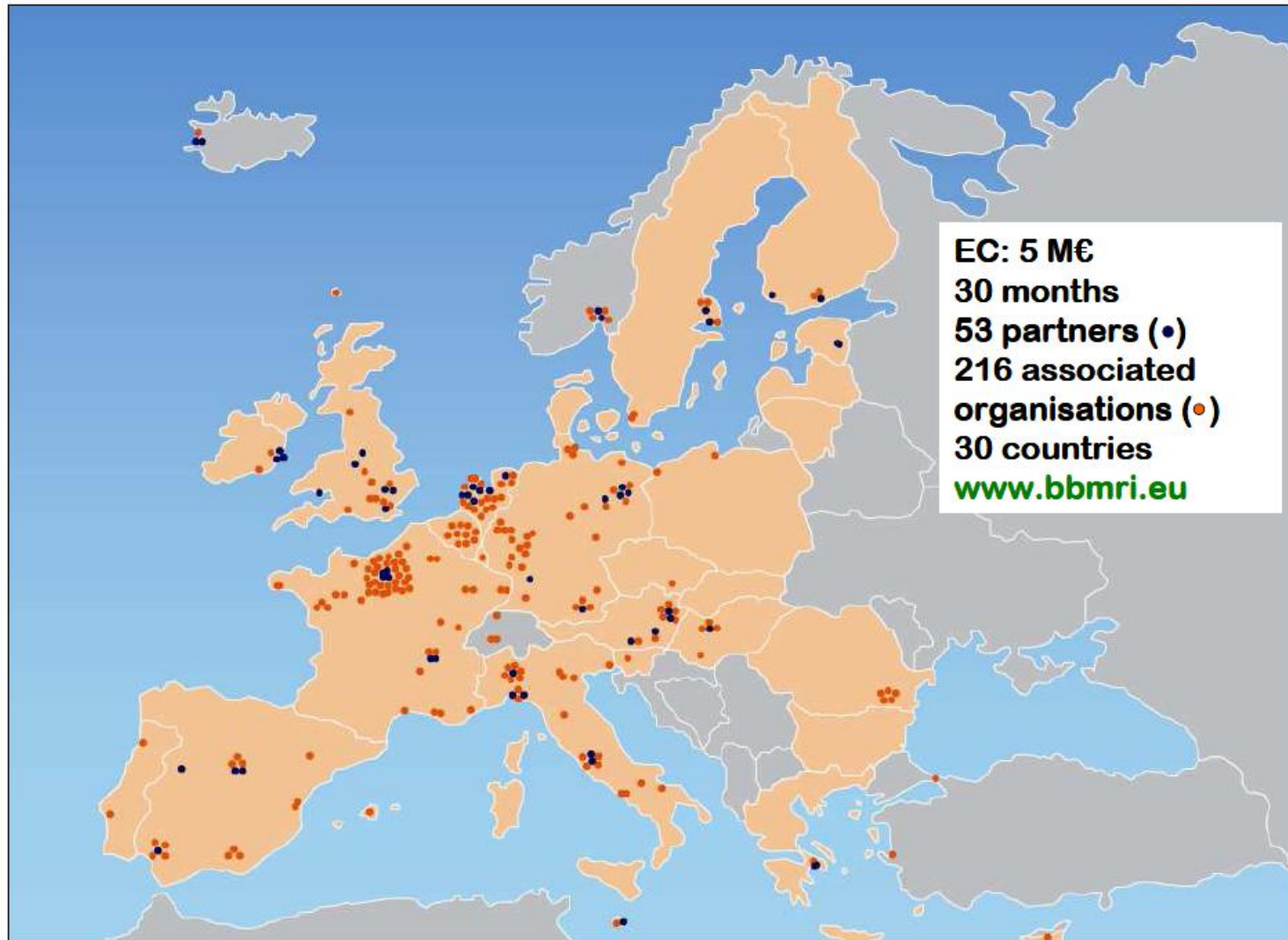
**OECD:** Global Biological Resource Centre Network

**WHO/IARC:** Standards for biological resource centres

**ESF:** Science Policy Briefing: Need for integration

**EU/ESFRI:** Research infrastructure for Biobanks and  
Biomolecular Resources (BBMRI)

# ***BBMRI: A pan-European Infrastructure***



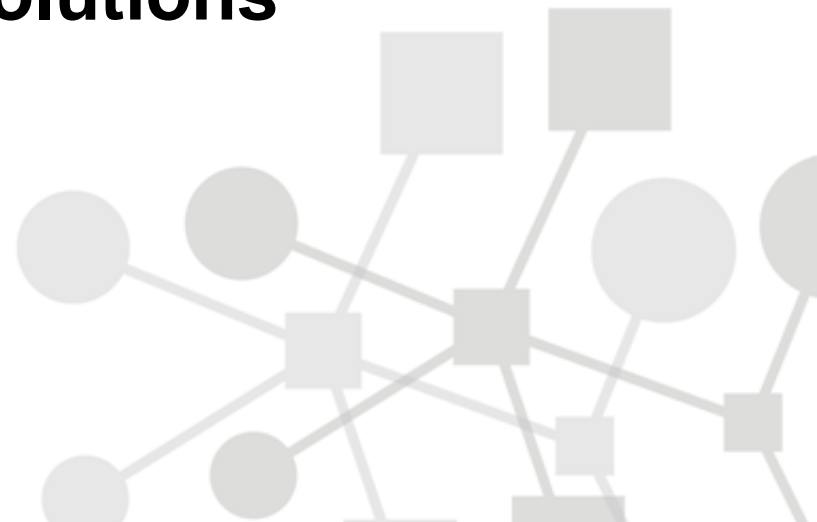
# The pan-European Research Infrastructure for Biobanking and Biomolecular resources as the European part of a human domain GBRCN



# *Different Levels of Interoperability*

- **Ethical and legal frameworks**
- **Data management**
- **Sample management**

 **Requires different solutions**





# The ERIC Legal Framework



Internationally recognized legal entity

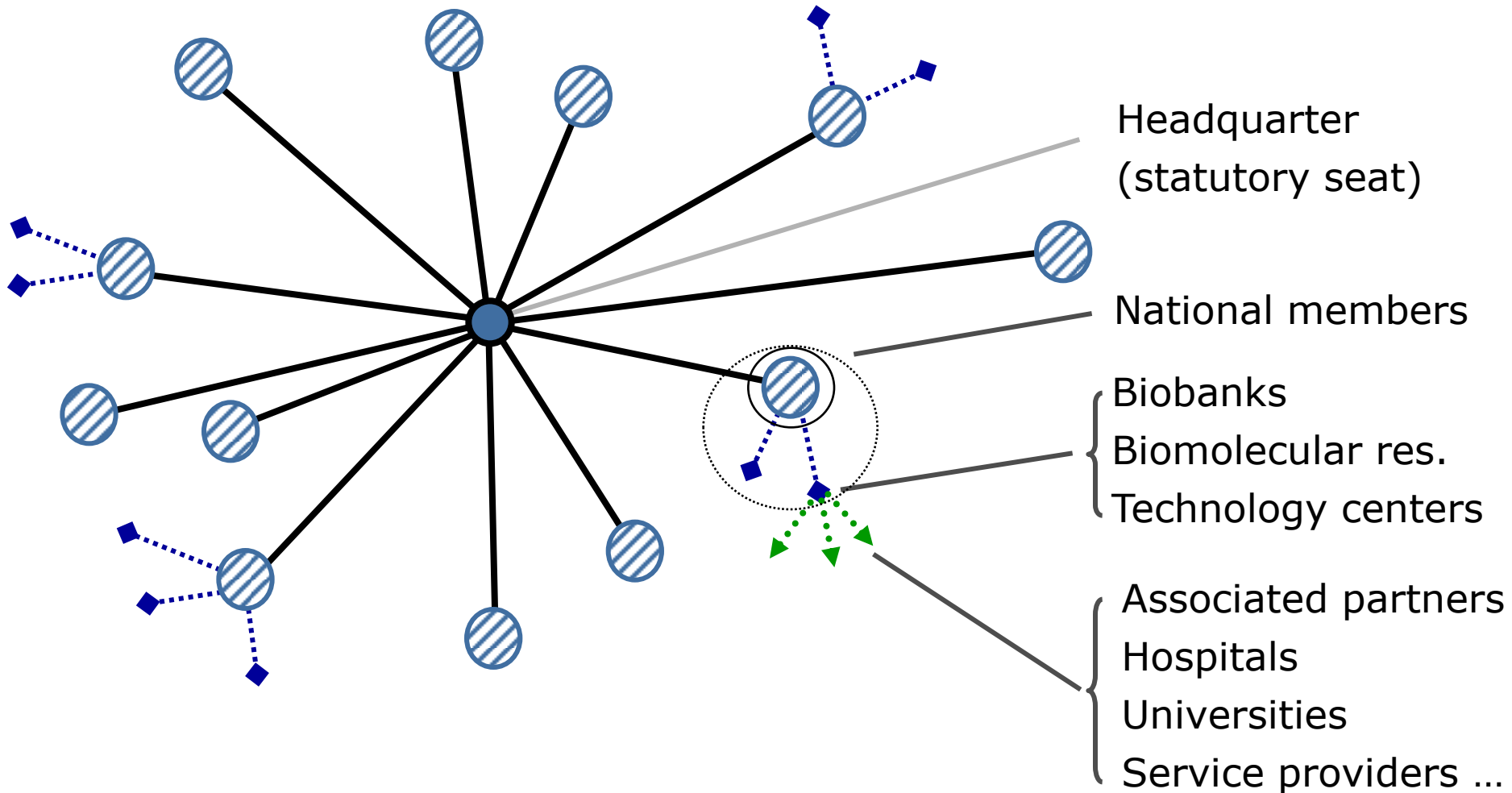
Establishment of operational sites in different Member States that operate under one legislation

VAT exemption

In force since 28.8.2009

# *ERIC as the Legal Structure of BBMRI*

## *Distributed hub and spoke structure*



# ***BBMRI Partner Charter (in brief)***

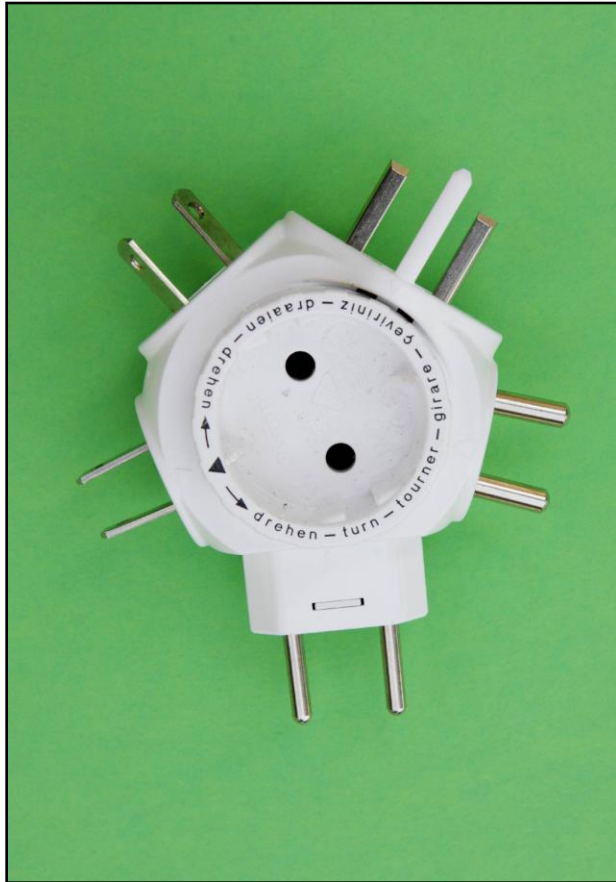
- **Primacy**  
Respect the primacy of national and European legislation and respect the jurisdiction of competent authorities
- **Data protection policy:**  
No data on individuals will be made publicly accessible
- **Access policy:**  
Fair access in context of specific research projects and after REC approval; biobanks do not lose control
- **Informed consent:**  
Implementation of the OECD guidelines for Human Biobanks and Genetic Research Databases
- **Infrastructure and management:**  
Implementation of the OECD best practice guidelines for Global Biological Resource Centres Networks.
- **Sample collection and processing:**  
SOPs for processes considering the WHO/IARC guidelines for biological resource centres for cancer research

# ***BBMRI and Publics***

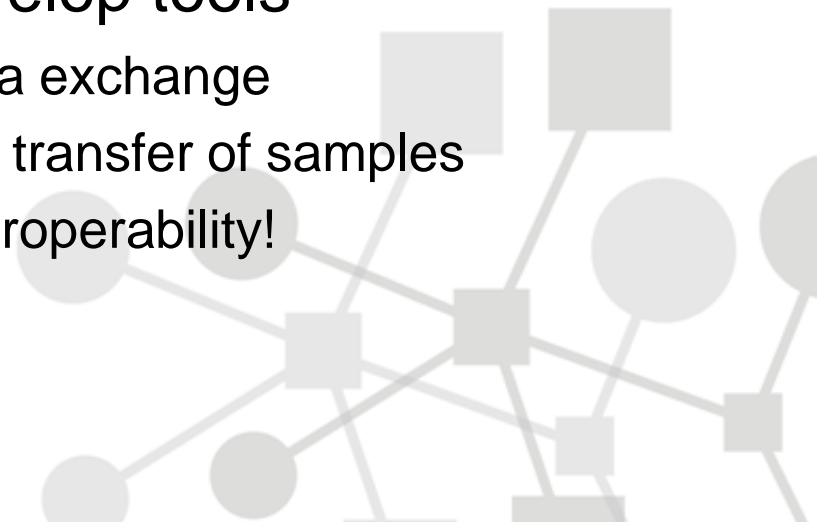
- Public perception (focus groups and Eurobarometer)
- Active participation of patient organizations
- Socio-economic impact study  
(impact on science, economy, health care)
- Political engagement process



# The Adaptor Approach of *BBMRI* to Achieve Interoperability



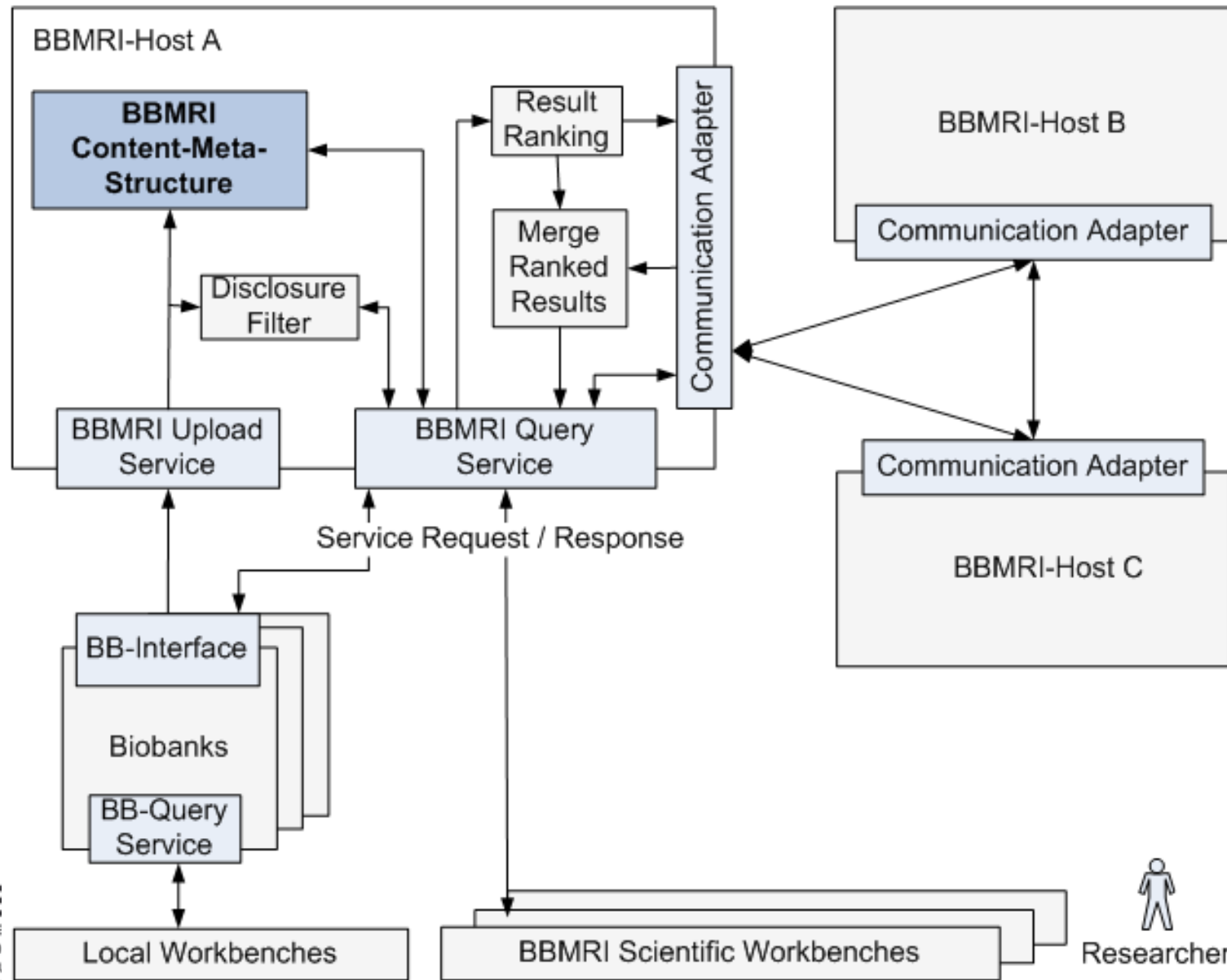
- Define criteria
  - Which samples and data can be combined?
  - Evidence-based quality indicators
- Develop tools
  - Data exchange
  - Intl. transfer of samples
  - Interoperability!



# *Inventory of Biobanks in Europe*

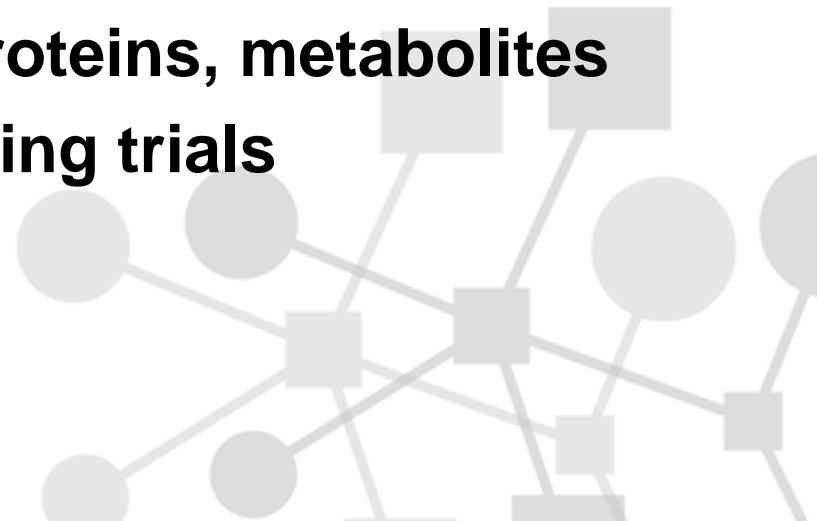
- **BBMRI questionnaires have been developed jointly with P<sup>3</sup>G**
- **Detailed information on samples, data, access, governance, costs and funding**
- **Questionnaires from >260 biobanks evaluated**
- **Stored in a relational database system**  
(<http://www.bbmri.eu/index.php/catalog-of-european-biobanks>)

# Integration of Data Management



# *European FP 7 Large Integrated Project*

- **Evidence-based quality parameters**
- **New stabilization procedures**
- **New sampling procedures**
- **Evaluation of morphology**
- **Evaluation of antigenicity**
- **Evaluation of DNA, RNA, proteins, metabolites**
- **Validation in international ring trials**
- **European Norm (CEN)**





**OECD BEST PRACTICE GUIDELINES FOR  
BIOLOGICAL RESOURCE CENTRES**



ORGANISATION FOR ECONOMIC CO-OPERATION  
AND DEVELOPMENT

Endorsed by CSTP in March 2007

## ***Human-Derived Material***

- Organisational requirements
- Staff-qualifications and training
- Premises
- Equipment
- Documentation
- Informatics
- Services
- Preparation of samples
- Accession of deposits
- Preservation
- Supply of biological material
- Quality audit and quality review

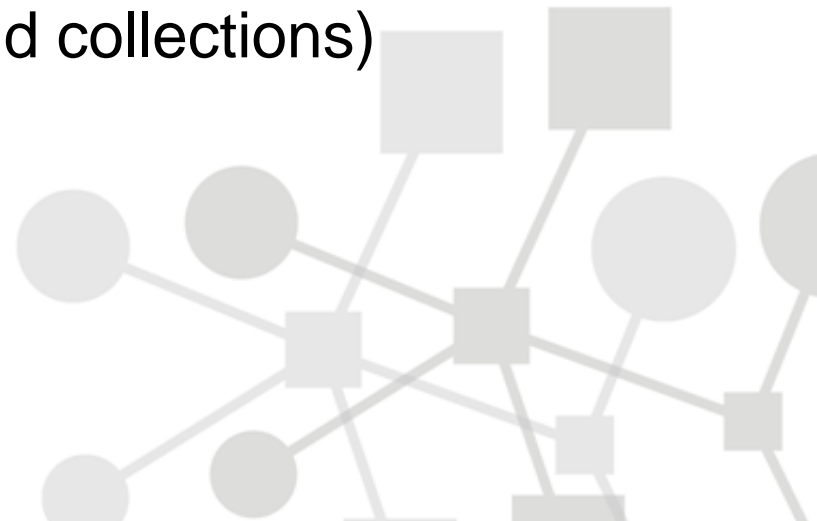
**OECD Guidelines  
on Human Biobanks  
and Genetic Research  
Databases**



***HBGRD***

- Informed consent
- Governance
- Stakeholder
- Involvement of donors
- Data protection
- Change of scope
- (Old collections)

Endorced by OECD Council November 2009



# Consensus SOPs

WORLD HEALTH ORGANIZATION

INTERNATIONAL AGENCY FOR RESEARCH ON CANCER



IARC

Working Group Reports

Volume 2

COMMON MINIMUM TECHNICAL  
STANDARDS AND PROTOCOLS  
FOR BIOLOGICAL RESOURCE  
CENTRES DEDICATED  
TO CANCER RESEARCH

# Biobanks need pharma

Which is why Europe's citizens need reassurance that their donations will be in the public interest.

Medical geneticist Thomas Meitinger remembers when biobanking was a simple craft. As a postdoc thirty years ago, he travelled from Oxford to Yugoslavia to track down a family afflicted with a rare disease causing blindness. The family listened enthusiastically as he explained his research over a fish dinner. He returned with blood samples and over the next decade used them to identify the single gene defect that caused the condition.

cal good". But the large majority of healthy donors will need more persuading that profit-making industry should get access to their voluntary tissue donations.

The concept of expert centres, unveiled by the BBMRI at the meeting, should help. These would do all the molecular analyses

aimed at linking the biobanks into one distributed infrastructure. Now Meitinger, who currently works at the Institute of Human Genetics in Neuherberg, Germany, and the rest of the scientific consortium driving the effort, called the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), must find stable funding for the project and arrange access for the scientific community.

That's a lot of tough challenges at a time when the general public is sensitive to any issue involving genes and biological material. Key concerns in biobanking are those of anonymity and whether true informed consent can be given by individual donors now too numerous to be educated over dinner.

Another, potentially incendiary, issue is whether the pharmaceutical industry should have the same access rights to biobanks as academic researchers. Europe's citizens could easily turn against biobanking if they start to feel exploited for financial gain. The BBMRI must accommodate industry while avoiding such a backlash.

Biobank resources may be fundamental to understanding the molecular bases of common complex diseases, but it is the pharmaceutical industry that will develop the treatments for such ailments. Companies generate their own biobanks, but these cannot reach the scale necessary to move forward. Industry wants access to large public biobanks, and the BBMRI recognizes its obligation to facilitate new medicines. The consortium hopes that relentless outreach and appropriate control of banked materials will achieve this without

infrastructure, and data would be stored for re-use in other studies, so industry could not gain exclusive rights.

Industry must also be prepared to give something back, in the form of access to its own biobanks and their richly financed expertise. Research departments across all companies believe that biobanks and the molecular information generated from them are outside the competitive realm, but their managers tend to be wedded to secrecy. So managers must be persuaded to follow their researchers' instincts, before the public gets the idea that industry is there only to exploit, gets deterred from donating, and the whole enterprise becomes tainted with distrust. ■

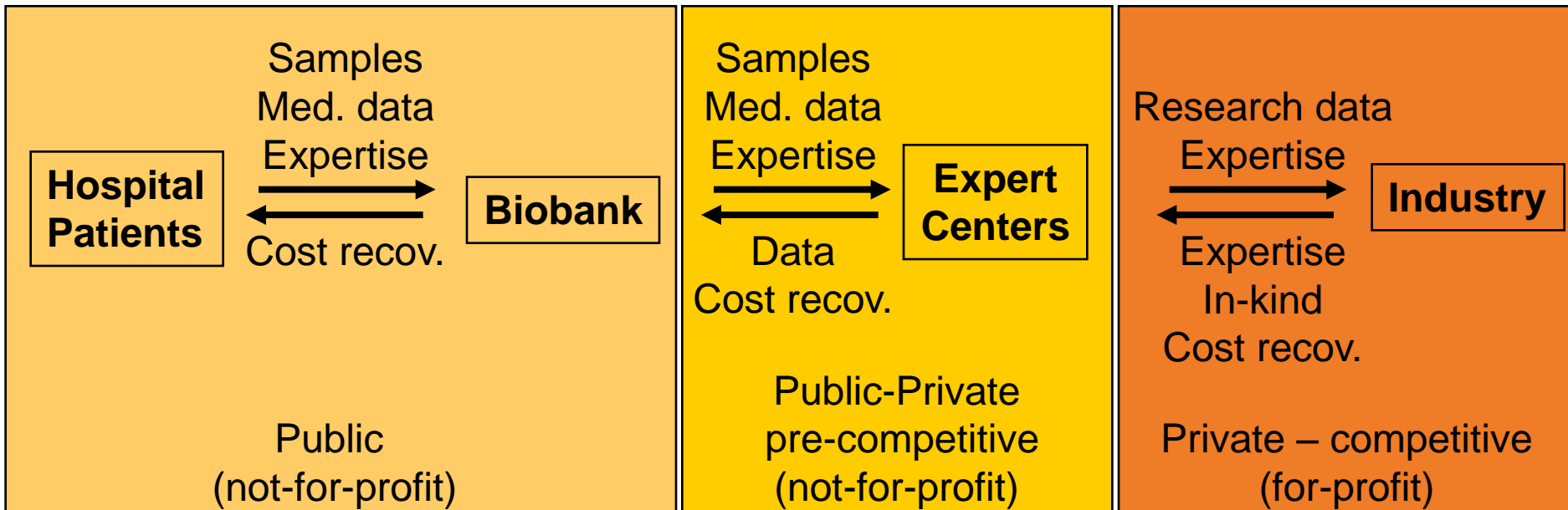


# *The Win – Win Situation*

- Industry needs access to samples, data **and** scientific/medical expertise
- Industry can provide important know how and in-kind contribution
- Biobanks require involvement of industry to contribute to improved health care
- Biobanks require additional funds for sustainability

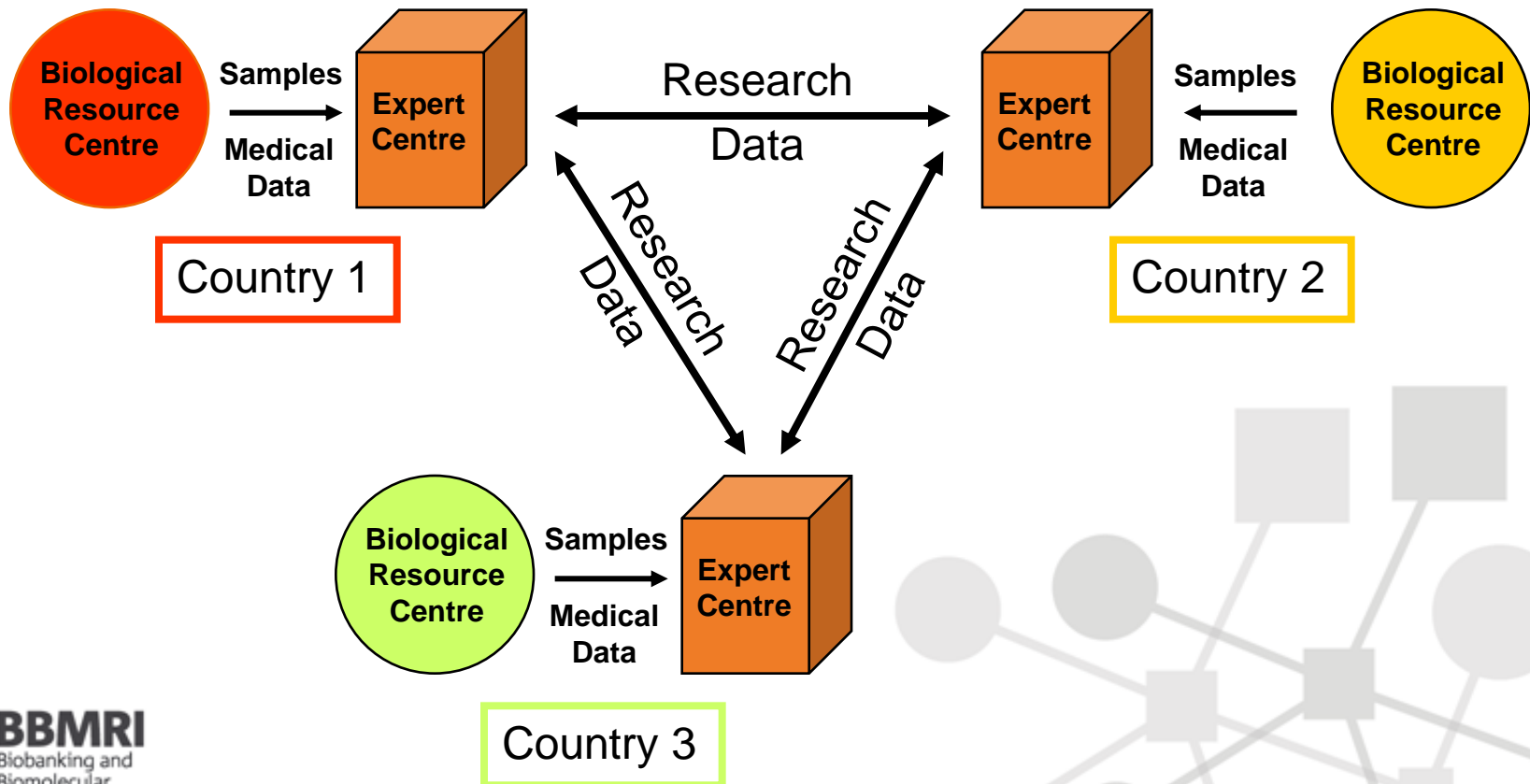


# Expert Centers



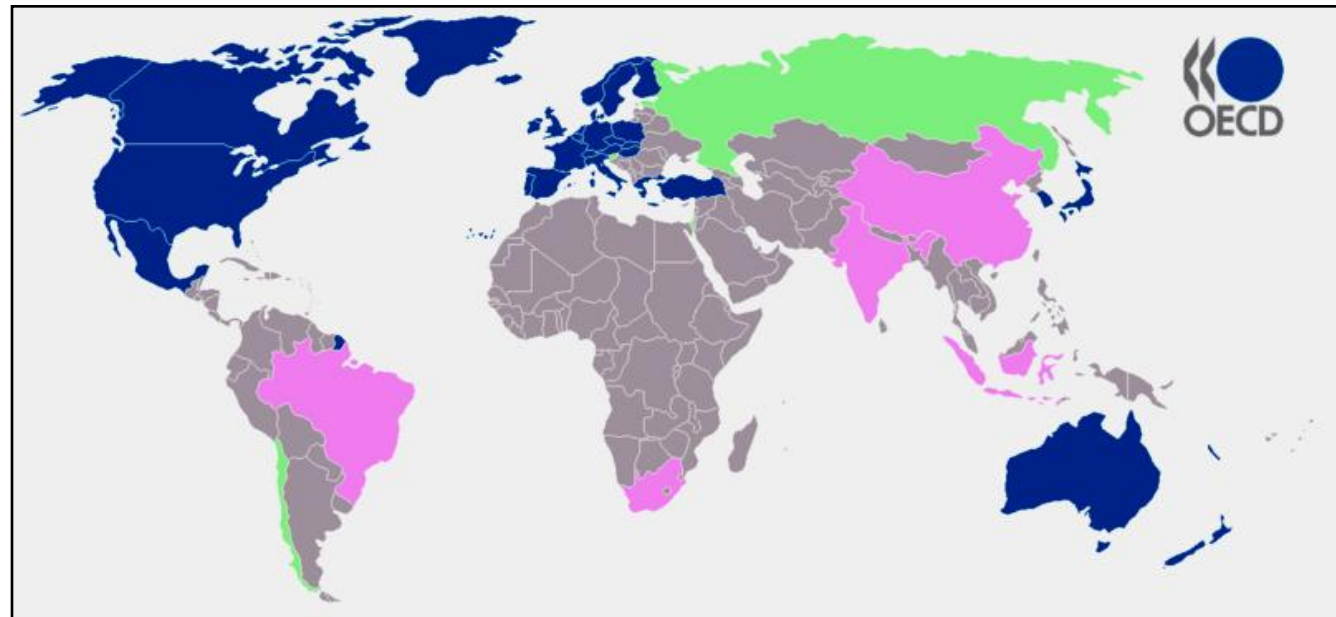
Provides efficient access to samples, data and expertise  
Mutual benefit from expertise and in-kind contributions  
Joint generation of pre-competitive data and knowledge  
Reduces requirements for sample shipment  
Gateway for global collaborations

# Expert Centres as Highways for Transnational Research Collaborations



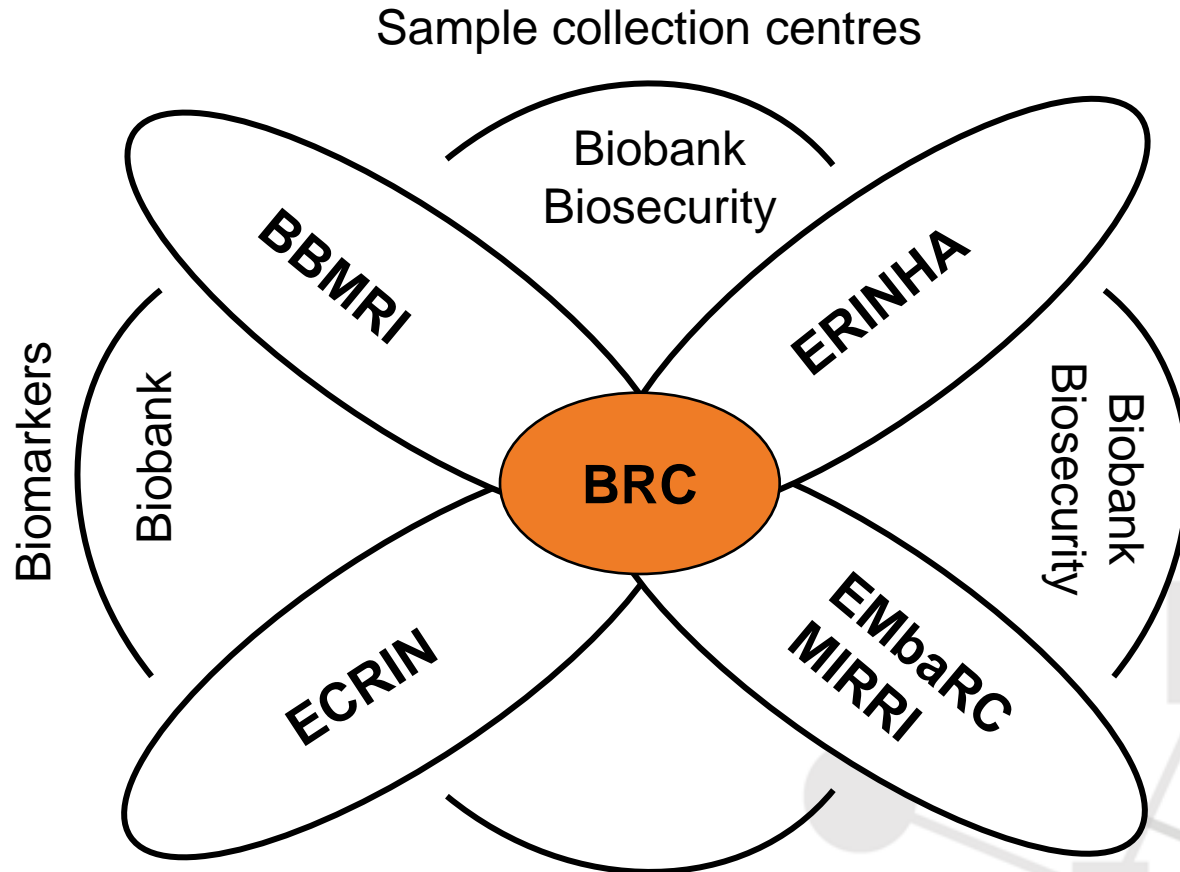
# *Secretariat for a human domain GBRCN pilot phase*

<b>Phase 1: Establishment of secretariat</b>	<b>2009</b>
<b>Phase 2: Identification of participants for pilot phase</b>	<b>2010</b>
<b>Phase 3: Pilot phase for implementation of OECD best practice guidelines</b>	<b>2011</b>
<b>Report to OECD WPB</b>	<b>2012</b>





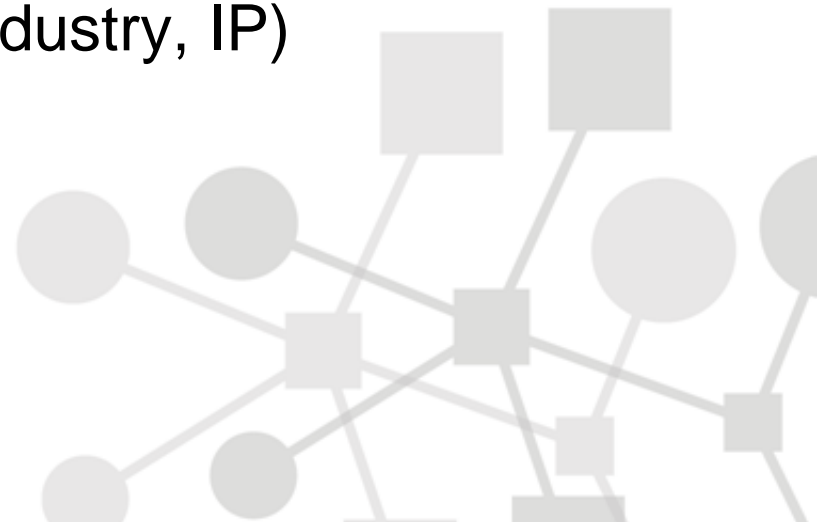
# Linkages between Human and Microbial Domains



# *Upcoming Events 1*

**European Parliament Hearing on  
“Health-related Research Infrastructures and their  
contribution to the EU’s policy priorities”  
*Brussels, Tuesday 26th October 2010***

- Research for sustainable health care
- Epidemics, biosecurity, bioterrorism
- Technology transfer (academia/industry, IP)
- ELSI
- International coordination



# Upcoming Events 2

## Joint human & microbial domain GBRCN pilot phase meeting

**DATE:** 29th – 30th November 2010

**VENUE:** Federal Ministry of Science and Research  
Freyung 3, 2nd Floor  
A-1010 Vienna

GLOBAL BIOLOGICAL  
RESOURCE CENTRE  
NETWORK



**GBRCN** human



# Thank you

