
# BBMRI-ERIC-Associated

# Expert Centres / Trusted Partners

# V2.0

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# 2 OBJECTIVE

“BBMRI-ERIC associated Expert Centres trusted partners” are building the bridge between academic and applied research in a public-private partnership model; by integrating pre- competitive research and development endeavours by providing not only access to biological samples and medical data but access also to the broad spectrum of medical and scientific expertise related to the samples, data, and their analysis.

BBMRI-ERIC Expert Centres are closely linked to the Vision and Mission strategy of BBMRI-ERIC.

This document describes the BBMRI-ERIC Expert Centre public-private-partnership model, the application criteria, the assessment and vote process

Adopted by Assembly of Members 27 October 2015.

# 3 TERMS AND DEFINITION

| Terms | Definition |
|---|---|
| Expert Centres | Expert Centres are key intermediaries between public and private sectors performing the analysis of biological samples under internationally standardized conditions. |
| DG | Director General of BBMRI-ERIC |
| BBMRI-ERIC -HQ | BBMRI-ERIC Headquarter (DG and Central Executive Management Office), Neue Stiftingtalstrasse 2/B/6, 8010 Graz |
| MC | Management Committee (Statutes of BBMRI-ERIC, Official Journal of the EU 30 November 2013, L320/63-80, Article 14) |
| AoM | Assembly of Members (Statutes of BBMRI-ERIC, Official Journal of the EU 30 November 2013, L320/63-80, Article 10) |

# 4 RATIONALE

Cutting-edge research as well as further innovations in life-science industry will strongly depend on efficient and secure transnational access to high-quality human biological samples and associated medical information for both academia and industry. Human biological samples are a finite key resource subject to a series of ethical and legal restrictions, which means that innovative solutions for their efficient utilization are needed. By performing the primary analysis of biological samples under internationally standardized conditions in a pre-competitive environment, two major goals are addressed:

1) Providing access to primary data that can easily be shared in contrast to biological samples and

2) Providing high-quality information from biological samples to industry for further product development.

This is intended to be achieved by so called 'BBMRI-ERIC Expert Centres' that are associated with BBMRI-ERIC (Fig.1).

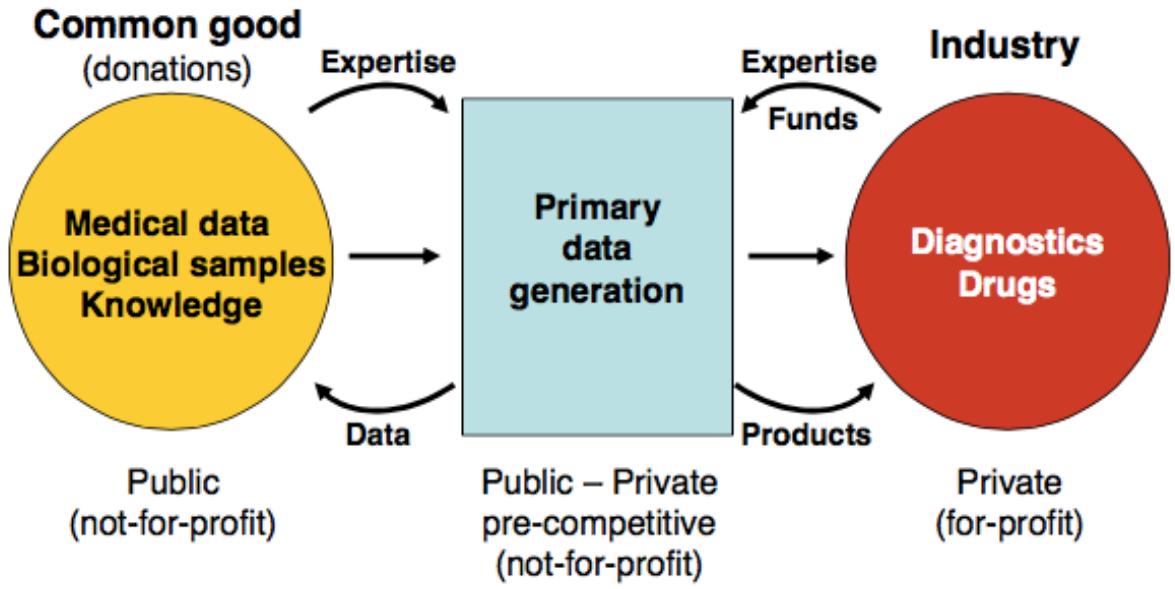


Fig. 1 Expert Centres: collaborative research of public and private sectors

BBMRI-ERIC Expert Centres are non-profit organisations that represent a novel public-private partnership model. They are responsible for the analysis of samples in the country of origin under internationally standardized conditions and for the generation of primary data. BBMRI-ERIC Expert Centres integrate pre- competitive public and private research and development activities by providing

access not only to biological samples and medical data but also to the broad spectrum of medical and scientific expertise related to the samples, data, and their analysis.

Thus a win-win situation is created for both parties by

- enhancing collaborative research;
- using limited resources efficiently;
- sharing data, technology, knowledge and expertise;
- facilitating innovation;
- and thus: increasing competitiveness in academic science as well as on the marketplace through product innovation and increased R&D efficacy.

## Medical expertise

It is becoming important to take into account the whole spectrum of medical, scientific and technological issues related to a certain disease. Important issues include the quality of biomolecules extracted from a sample and which features of a disease are actually represented in a biological sample – but also the whole medical context. To properly interpret the results of an analysis of biological samples, full knowledge of the disease and information on the individual patient are needed.

## Technological / analytical expertise and efficacy

The tremendous progress in the development of new analytical technologies has resulted in specific sample quality requirements in order to enable these technologies to be applied. Specific know-how on sample quality features is needed to guarantee proper interpretation of analytical data. This is even more important because evidence-based studies are not available to demonstrate the effects of variations in sample quality on the data generated by various analytical platforms. Another consequence of the rapid technological advances is that technology platforms are becoming more and more specialized and major upgrades have to be implemented approximately every 6 months. This situation and the fact that capacities of these new technologies exceed the requirements of most research groups or even whole universities or companies, particularly SMEs, make the case for specialized genome centres that provide research services. There is a need to develop new technologies and statistical tools to integrate and interpret the enormous amount of data generated.

## Expert Centres address ethical and legal restrictions

BBMRI-ERIC Expert Centres function as a focal point of contact between the public and the private sectors. The private industry sector needs access to biospecimens and data to develop innovative products to keep or gain market leadership. Since commercialization of human bodily materials is forbidden according to the European Oviedo Convention (ETS 164) and by national legislation in most member states, and because public opinion generally does not approve of financial compensation even on a cost-recovery basis, only research collaboration provides a sound basis for accessing human biological samples and associated medical data. This situation is a source of conflict that makes access for industry difficult or even impossible in many cases. Expert Centres that operate on a not-for–profit basis offer an efficient solution for this problem.

## Expert Centres as the future 'highways' for transnational research collaborations

Some countries like China, Russia, Brazil, and India have legal restrictions on export of biological samples that make transnational research collaboration difficult. The establishment of partner Expert Centres in Europe and non-European countries that operate under same standards and quality management schemes could generate novel 'highways' for future transnational research collaborations, because samples will be analysed in the country of origin and only research data are shared (Fig 2).

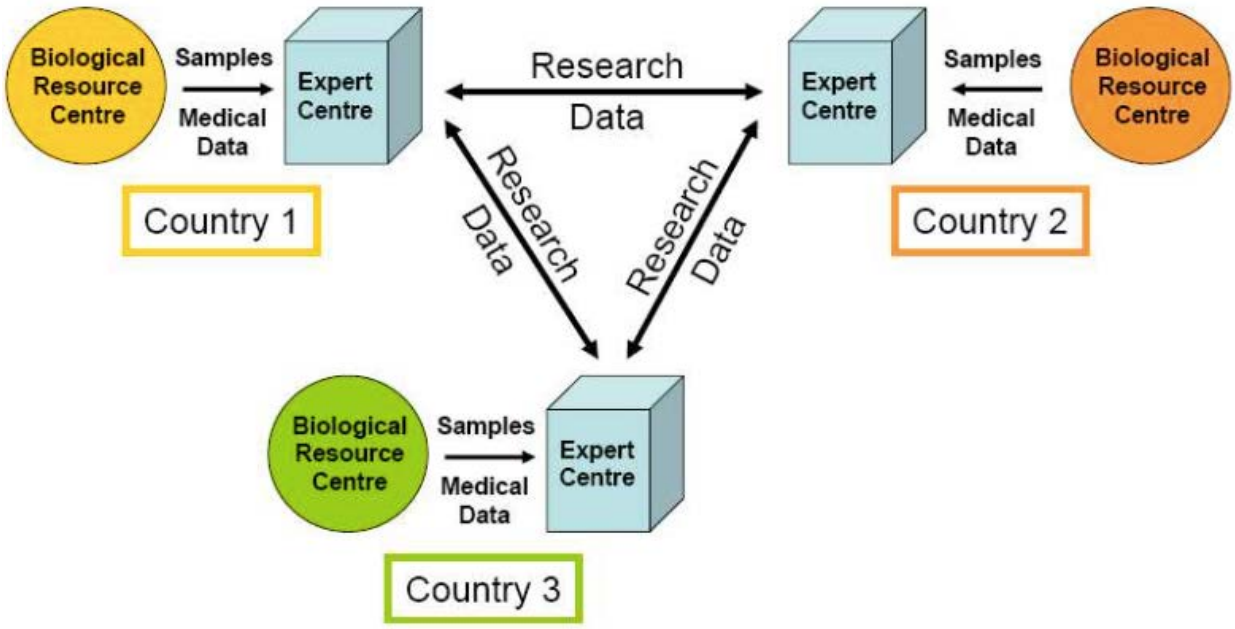


Fig. 2 Expert centres as new 'highways' for transnational research collaborations

## Key features of Expert Centres

Expert Centres are characterised by the latest technology, adequate IT solutions, cost efficacy, a high level of standardisation, professional quality management, confidentiality, flexible solutions for generation of intellectual property, and ethical and legal compliance.

## Latest technologies

For optimal biospecimen analysis a wide spectrum of '-omics' analysis platforms needs to be established. Being up to date with the latest developments is increasingly becoming a technical and financial challenge. Furthermore the tremendous growth of analytical data volume and the necessity to correlate them with clinical and scientific information requires the development of new IT solutions and statistical tools that will be provided by Expert Centres.

## Cost efficacy

The enormous advances in analysis technologies create the need for specialised centres because smaller institutions/non-specialised institutions are not able to keep up to date with this development. These developments are in line with the general tendency of outsourcing specific tasks to specialised service providers. Also, these new technologies, particularly Next-Generation Sequencing, have enormous analytical capacity that cannot be utilized properly by individual institutions. Therefore Expert Centres should operate at lower costs than classical research laboratories in academia and industry.

## High level of standardisation

A major limitation in multi-centre studies is that most of the latest "-omics" analysis platforms and the related pre-analytical processes are not sufficiently standardised to allow proper data integration of analysis performed in different centres. This can be improved by implementing harmonized SOPs, common certification and accreditation procedures, use of common reference materials and regular participation in ring trials. Data generated by such internationally harmonised and standardised analysis platforms are expected to be efficiently combined and integrated to investigate a variety of biological and medical questions. This will result in a more efficient use of the biological materials analysed and will generate important added value for the scientific community.

## Professional quality management

Quality management is essential for any industrial research and development, and is becoming increasingly important for academic research as well. Quality management within Expert Centres should build on experience established within the industrial field. Representatives of industry can contribute guidance or supervision to support the establishment of appropriate quality management in Expert Centres.

## Confidentiality

Any project performed for industry will underlie strict confidentiality regulations, guaranteeing that no confidential information is disclosed to any other industrial partner or distributed within the academic community. Confidentiality principles will follow the principles established by Clinical Research Organisations (CRO).

## Intellectual property

Providing biological samples or performing analysis on established platforms by itself is not considered an inventive step and, therefore, does in principle not justify claims to intellectual property by the Expert Centre. However in the context of scientific collaborations, joint intellectual property between industrial partners and Expert Centres might be generated. The exploitation of the intellectual property should be as flexible as possible and could be negotiated between the partners on a case-by-case basis. The general policy should be that industrial partners have optimal freedom to generate value out of intellectual property (e.g., industry as holder/owner of the patents). In case of joint inventions the academic partners should benefit in the form of royalties or other benefit-sharing models that properly reflect and reward the contribution of public resources, expertise and work.

## Ethical and regulatory issues

Ethical and regulatory issues are often major roadblocks to access to samples and related data. Expert Centres will provide the institutional framework as well as appropriate counselling and services to facilitate ethically and legally compliant access to biological resources for academia and industry within Europe and globally. BBMRI-ERIC has also launched a Common Service ELSI in all of its member states.

## Implementation

BBMRI-ERIC Expert Centres will be established outside of BBMRI-ERIC in the member countries and have to comply in general with the following key criteria:

- Involvement of leaders in the field
- Implementation of latest technologies
- Implementation of common quality management systems together with other Expert Centres with similar focus
- Use of common standards & reference samples
- Participation in proficiency testing/ring trials
- Publication of general SOPs for sample pre-analytics, analysis and data generation
- Establishment of confidentiality and IP rules
- Compliance with ethical and legal rules
- Commitment to efficient handling of contracts and projects
- Certification (e.g., ISO)
- Evaluation by BBMRI-ERIC
- Periodic external audits by BBMRI-ERIC management
- Cooperation agreement between BBMRI-ERIC and Expert centres that refers to the above mentioned criteria

Expert Centres, with the primary objective of operating analytical technologies, will actively contribute to validation of examination procedures beginning from non-standard methods, laboratory-designed or developed standards, standard methods used outside their intended scope and validated methods subsequently modified and will provide the definition and provision of common reference samples and proficiency testing to the BBMRI-ERIC community.

# 5 INCLUSION CRITERIA FOR A BBMRI-ERIC EXPERT CENTRE

In order to guarantee the excellence of transnational research collaborations, the aim of BBMRI-ERIC is to evaluate the abovementioned high-quality Expert Centres. For evaluation purposes, it is necessary to define certain criteria in a transparent manner and to ensure that all candidates for the status of Expert Centre/Trusted Partner are only approved if they meet these criteria.

The applicant will provide a summary of statements and documentation in an official application document to the following points:

1. **General**

   The Expert Centre will demonstrate its purpose in the appropriate field of expertise.

2. **Terms and definitions**

   The Expert Centre will declare certain terms and definitions regarding the appropriate field of expertise in order to maintain a common language for common understanding among the stakeholders.

3. **Management**

   The Expert Centre will declare the responsibilities of parties and the governance structure in order to safeguard legal responsibilities.

   The Expert Centre will provide a summary of the business model.

   Management commitment: The Management of the Expert Centre will declare compliance with law and ethics (regional, national, international).

   Responsibility, communication, dissemination, publication, and access rights: The Expert Centre will provide general information on these aspects

   Customer focus: The Expert Centres will provide key aspects of the business plan that shapes the customer relationship.

4. **Resource management**

   The Expert Centre will provide key aspects of financial provisions and ownership.

   Human resources, competence, and training: Expert Centre will show a HR plan for key highly trained employees.

   Infrastructure, work environment: Expert Centre will provide information about its infrastructure and work environment (local, national, international).

5. **Technical Requirements**

   The Expert Centre will declare its cutting-edge research and technology capabilities.

6. **Customer property, IPR, Non-disclosure of information**

   The Expert Centre will show key aspects of the customer property, IPR and policy on non-disclosure of information.

7. **Quality management system (QMS)**

   The Expert Centre needs to declare that an appropriate quality management system is implemented furthermore aligned with quality management system of Partners and Expert Centres with similar focus.

   The Expert Centre declares the use of common standards & reference samples, in order to safeguard comparability of methods and results.

   The Expert Centre will participate in proficiency testing/ring trials.

   The Expert Centre shall publish general SOPs for sample pre-analytics, analysis and data generation.

   The Expert Centre needs to declare that an applicable QMS is implemented for monitoring, auditing, certification or accreditation processes, to assure high-quality research and product development.

   The Expert Centre needs to declare the appropriate management of data & information technologies practice (data documentation, processing, security, access).

   Continual improvement (PDCA), Corrective action, preventive action, risk-analysis, control of non-conforming product, and analysis of data: The Expert Centre is asked to implement processes to assure the quality of the product provided.

   The BBMRI-ERIC associated Expert Centre/Trusted Partner agrees on periodical review (audit) to prove ongoing compliance and continuous improvement of the centre.

## Assessment

Director General ensures a transparent assessment of the application document. An agreed audit procedure with the Expert Centre will assure that the Expert Centre fulfils the criteria for being a high-quality Expert Centre and Trusted Partner. Director General will, if applicable, invite an ad hoc expert review committee, with technical capabilities to evaluate the validity of the criteria.

Director General will bring forward a recommendation for a simple majority consensus-based approval of the Expert Centre to the Management Committee.

## Vote

The approval or rejection of the submitted recommendation is the decision of DG and the Management Committee.

The DG and the MC may ask the applicants to amend their submission documents to enable a positive vote, such that failure to make the changes requested will result in rejection of the application.

DG will take action to publish and disseminate the new brand of 'BBMRI-ERIC Expert Centre/Trusted Partner' within the BBMRI-ERIC family and to appropriate stakeholders.

# 6 PUBLICATIONS

1. Van Ommen G-JB, Törnwall O, Bréchot C, Dagher G, Galli J, Hveem K, et al. BBMRI-ERIC as a resource for pharmaceutical and life science industries: the development of biobank-based Expert Centres. Eur J Hum Genet-. 2015;23(7):893–900. Available from: http://www.nature.com/doifinder/10.1038/ejhg.2014.235

# 7 ANNEXES

| No. | |
|---|---|
| 1 | Work Programme 2015, 7. Work Plan Expert Centres page 45-46 |
| 2 | Business Plan v21.1 03.12.2012 |