



**BBMRI-ERIC**<sup>®</sup>

Biobanking and  
BioMolecular resources  
Research Infrastructure

# 2016 ANNUAL AND FINANCIAL REPORT

[www.bbmri-eric.eu](http://www.bbmri-eric.eu)





'Biobanks (and Biomolecular Resources Centres)' means collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and micro-organisms that might contribute to the understanding of the physiology and diseases of humans.

**BBMRI-ERIC Statutes, Article 1(1)**

## Words by the Director General

I am pleased to introduce my last BBMRI-ERIC Annual and Financial Report, which describes the achievements of the distributed research infrastructure BBMRI-ERIC according to the Work Streams outlined in the Work Programme 2016 and approved by the Assembly of Members at the 6<sup>th</sup> session on 28<sup>th</sup> April 2016.

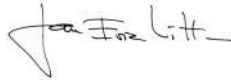
It's all about the sample: Human biological material stored in biobanks, including both samples and data, is the most critical resource that is required to translate progress in molecular biology and technology into patient benefit. That is how we move closer to personalised medicine. According to the OECD, biobanks have the potential to substantially impact economic growth and improve health-care. Consequently, one of the key challenges for BBMRI-ERIC is facilitating access to biological samples and data that represent the diversity of European populations and diseases. We have taken important steps to create new tools and services for our Member States, such as the BBMRI-ERIC Negotiator 1.0 that was designed to facilitate access to samples and data by simplifying communication between requesters and biobankers. Furthermore, ensuring the reproducibility and reliability of scientific work is an issue of great concern for BBMRI-ERIC and resulted in activities facilitating better quality of and accessibility to biological samples and data. By introducing the CEN/ISO Technical Specifications, we have taken important steps towards building a BBMRI quality community together with biobanking experts.

The rapid developments in analysing technologies make it difficult to foresee whether the current sample handling procedures are adequate for future analysis purposes. The key is thus to ensure complete documentation of the entire process. In 2016, we also took the first step with regard to the second B in BBMRI-ERIC, referring to biomolecular resources. In the coming years, there will be dramatic changes in the way biobank samples are used, which means that providing efficient support to users of the relevant procedures will be necessary.

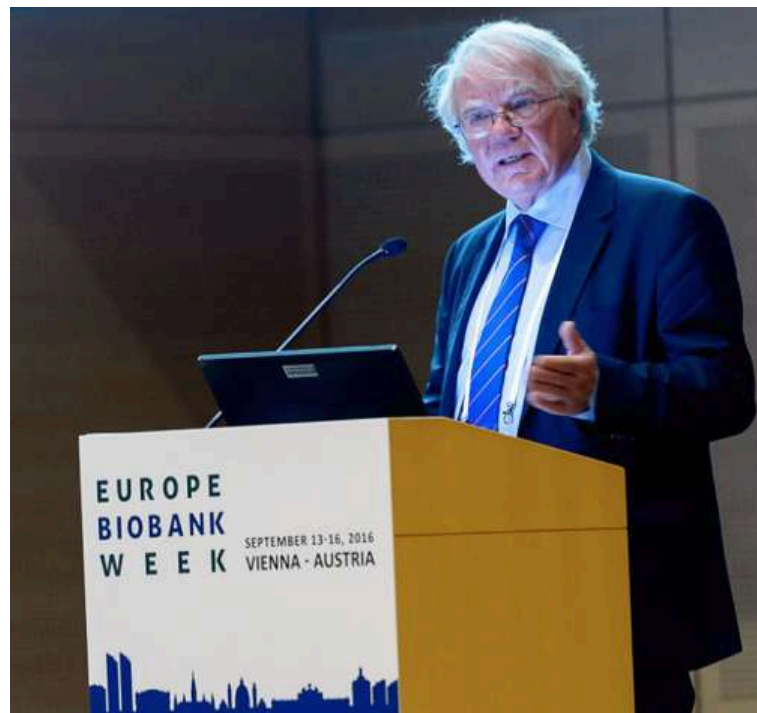
BBMRI-ERIC is making continuous efforts to ensure additional funding for its core activities. Between January and October 2016, BBMRI-ERIC participated in 18 proposals. Between 2014 and 2016, BBMRI-ERIC was involved in a total of 42 H2020 calls. 11 of the proposals submitted were accepted. This equals an overall success rate of 26%, in contrast to the average success rate of 14%.

In 2016, we welcomed Latvia as a new Member and Cyprus as an Observer, while Norway and Poland upgraded their membership from Observer to Member. Additionally, the Stakeholder Forum was re-conceptualised. This year, our two first BBMRI-ERIC Associated Expert Centres have been launched.

I would like to thank the National Node Directors and the Member States for their contributions to this pan-European effort. Also, I would like to express my thanks to the staff at the Headquarters and the Common Service and quality experts for their excellent work during 2016.



*Prof. Jan-Eric Litton, PhD*  
Director General BBMRI-ERIC  
29<sup>th</sup> April 2017



At the opening ceremony during the 2016 *Europe Biobank Week* in Vienna.

## Words from the SEAB

The activities of BBMRI-ERIC shall be periodically evaluated by an independent Scientific and Ethical Advisory Board (SEAB), the SEAB shall also advice the Assembly of Members with regard to proposals of the Director General on the implementation of the Work Programme. The SEAB shall compose of distinguished scientist or experts in their own right, not as representatives of their respective background organisations or of Members. The Assembly of Members shall appoint the SEAB members and decide on their rotation and on the terms of reference of SEAB.

### BBMRI-ERIC Statutes, Article 16(1–3)

**The following statements were shared at the 8<sup>th</sup> session of the Assembly of Members:**

*'I am extremely impressed with where you've come. There are many advantages to the structure of BBMRI, having the National Nodes gives scalability and flexibility, there may never be a substitute for real human cell tissue in translational research, science that will benefit human life. The challenges were addressed in the work plan. The number one challenge is knowing exactly what the specimens are in terms of common language, definitions, and quality indicators to know if they are fit for purpose. You have to have an eye towards the future to make sure you collect the types of spec needed by the scientific community. Suggestions going forward: coordinating collection design to overcome collection bias that might compromise the quality of the collections. Focusing on quality will help this organisation make a huge impact in the future. Interoperability, working together, having the suitable ELSI frame are important, can't be efficient without it. You're on the right track but have the same challenge of parts coming from competitive backgrounds that start working together. You need to define the common goals. I would like to coordinate US efforts with BBMRI efforts. There is an optimistic outlook on the future of BBMRI and what it can achieve.'*



**SEAB Member Prof. Carolyn Compton**  
Arizona State University, Mayo Clinic  
College of Medicine, National Biomarker  
Alliance, USA



**SEAB Member David Byrne**

Chair of European Alliance for Personalised  
Medicine and Senior Counsel, Ireland

*'BBMRI-ERIC is a fascinating opportunity, looking forward to it. I agree on the importance of quality to ensure good outcomes. We came a long way in a short space of time and what you're doing is vastly beyond what the EC was envisaging in 2002. I hope to contribute to the ELSI initiative. There is a strong desire and deep demand to ensure the full compliance with legislation.'*

*'It's important to recognise the enthusiasm of individuals to contribute samples. It's a reflection of their individual hopes for improvement, but it will be a benefit to future generations. They expect that they play a part in delivering change so we have a responsibility to maximise the potential. We need to respect that altruism and make sure that we create a system that is as efficient and effective as possible in delivering that. BBMRI is responsible for harmonising and standardising, making sure we have a common understanding. The initiatives set up by BBMRI (ELSI, IT, and Stakeholder Forum) are essential to securing the long term sustainability, public confidence in the venture and also in maintaining the opportunities to move forward. Of course there are going to be tensions, different priorities, legal possibilities, codes of practice, etc. It's not an easy road, but the willingness to work together is obvious, so we need to commit strongly in supporting this joint enterprise. It is a very promising start in a very challenging area. Looking forward to working with you in the coming years to make sure that this exciting opportunity is turned into a real health gain for the citizens, for future generations.'*



**SEAB Chair Alastair Kent**

Genetic Alliance, United Kingdom

## Words from the National Nodes

*'Over the last years, there has been a prolonged and difficult discussion around the new Data Protection Act, which has temporarily landed with an acceptable solution for the research community. I will give credit to the BBMRI-ERIC secretariat for their significant involvement in the final face of this process. We have, however, two challenging years ahead of us to make sure the new act is properly implemented. Building a successful European biobank network requires both diplomatic skills and a strong commitment amongst the member states to collaborate. I sincerely hope we will succeed in following up on these positive achievements.'*

**Kristian Hveem, National Node Director [BBMRI.no](http://BBMRI.no)**

**Biobanks Europe, Issue No. 4/2016**

*'BBMRI-ERIC as the only European research infrastructure for biobanking, which is owned by European Member States, has achieved an important stakeholder role in science policy in Europe. This enables BBMRI-ERIC to contribute to the development of a research environment that improves competitiveness of European biomedical research as well as public understanding and acceptance. Such impact cannot be generated by any national or local initiative. Examples of successful execution of this role are BBMRI-ERIC's contribution to the general data protection regulation, contributions to the development of ISO standards, and BBMRI-ERIC's recognition as a key research infrastructure for ELSI issues in biomedical research.'*

**Kurt Zatloukal, National Node Director [BBMRI.at](http://BBMRI.at)**

**Biobanks Europe, Issue No. 5/2016**

*'Work Package 2 [of the H2020 project ADOPT BBMRI-ERIC ] is mapping the well-established European biobanks with the aim of establishing the first BBMRI-ERIC-wide disease cohort for colon cancer, which will become a unique resource for future research in precision medicine. This joint effort is the first step towards the interoperability of European biobanks.'*

**Marialuisa Lavitrano, National Node Director [BBMRI.it](http://BBMRI.it) / Co-Director Common Service ELSI**

**Biobanks Europe, Issue No. 5/2016**



*'Finland aims to establish an official biobank consortium and implementation of common quality standards as an essential part of the national joint operations. It will be of great help to the Finnish biobanks that BBMRI-ERIC has taken up the excellent activity in establishing working groups of quality and aims to survey biobanks for CEN compliance as well as to develop an audit programme.'*

**Anu Jalanko, National Node Director BBMRI.fi**

**Biobanks Europe, Issue No. 6/2017**

*'At BBMRI.mt, we believe that harmonisation of pre-analytical procedures in human biobanking is key to progress in the search of reliable biomarkers. This is why we are joining our many collaborating partners in the BBMRI-ERIC network to develop a common quality management system that meets the requirements of the recently published CEN/Technical Specifications for pre-examination processes. As a small biobank, the Malta Biobank can act as a prototype for biobanking quality practices.'*

**Alex Felice, National Node Director BBMRI.mt**

**Biobanks Europe, Issue No. 6/2017**

*'The German Biobank Node (GBN) started in 2013, set up as a central platform for national biobanks that simultaneously acts as the national hub for the European initiative, BBMRI (Biobanking and Biomolecular Resources Research Infrastructure). Funded by the Federal Ministry of Education and Research, GBN has worked hard to foster networking and to harmonize the activities of all national biobanks. Our initiative dovetails perfectly to current developments of the national and international biobanking community...'*

**Michael Hummel, National Node Director German Biobank Node / BBMRI.de**

**German Biobank Node Newsletter, Q3/2016**

## Words from the Stakeholders

*'EURORDIS, as a one of EuroBioBank project founders and former coordinator, spurred dynamics in rare diseases biobanking, developing relevant best practices that remain in today's biobanking through its collaboration with BBMRI-ERIC. Preserving biological material and samples from rare disease patients is crucial to fostering research on rare diseases. EURORDIS represents a major actor in the field of rare diseases through its advocacy activities. Therefore, being a member of the Stakeholder Forum will enable EURORDIS to be the link between the patient and research communities, facilitating communication by using both a bottom up approach—considering the patient perspective regarding data and bio samples protection—and a top down approach—balancing the needs and constraints of researchers.'*

**Virginie Bros-Facer, EURORDIS – The Voice of Rare Disease Patients in Europe**

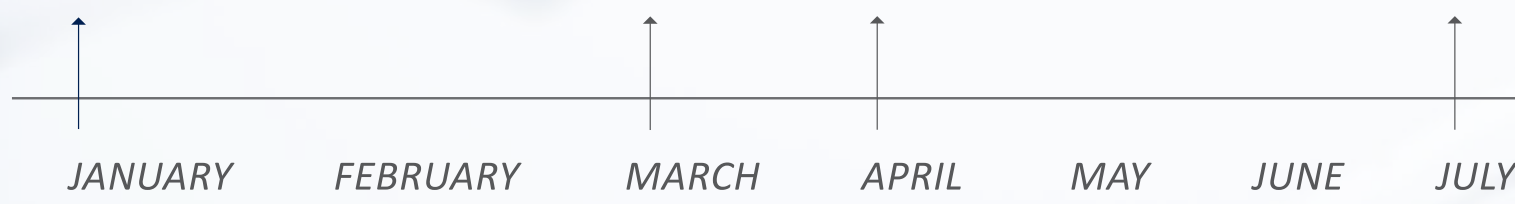
*'BBMRI-ERIC has achieved a lot in a short time. Most useful to us is the ongoing exchange on Data Protection and research, the Stakeholder Forum and IMI. We look forward to deepen the collaboration.'*

**Brendan Barnes, EFPIA**



# Key Achievements

- Common Service IT Kick-off meeting, Vienna
- Work Programme 2016 disseminated
- MIABIS 2.0 core published
- MC #13 Valletta
- Proposals submitted: AARC<sub>2</sub>, EMBRACE BRASS, eBIONET, ENTRANCE, EuHFORIC
- ELSI Experts Database launched
- FAQs GDPR published
- Biobanks Europe Magazine #4 published
- AoM #6 Vienna
- AoM #7 Vienna
- Biomolecular Resources Workshop, Uppsala
- Stakeholder Forum Patient Chapter Kick-off meeting, Brussels
- Working Groups established for disease-oriented biobanks, liquid biopsies and immortalised cell lines



- MIABIS-Imaging WG instantiated
- Participation in ISO/TC 276 plenary meetings, Washington
- Scientific Retreat #3 Athens
- Colorectal cancer data set 1.0 defined
- CBmed certified as BBMRI-ERIC Associated Expert Centre/Trusted Partner

- Website featuring new design and structure relaunched
- Rare Disease Helpdesk conceptualised
- MC #15 Prague
- ATMA-EC certified as BBMRI-ERIC Associated Expert Centre/Trusted Partner
- Directory 3.0 delivered
- Negotiator 1.0 delivered
- BIBBOX 1.0 delivered
- 9 Self-Assessment Surveys developed

AUGUST

SEPTEMBER

OCTOBER

NOVEMBER

DECEMBER

- Europe Biobank Week and satellite events by Common Service ELSI and Quality, Vienna
- BBMRI-LPC Forum Vienna
- Annual Report 2015 and Biobanks Europe Magazine #5 published
- Imaging component of MIABIS defined
- Set of performance indicators developed
- AoM #8 17-18 November
- Participation in ISO/TC 276 plenary meetings, Dublin

## Finance Facts & Figures: H2020 Projects

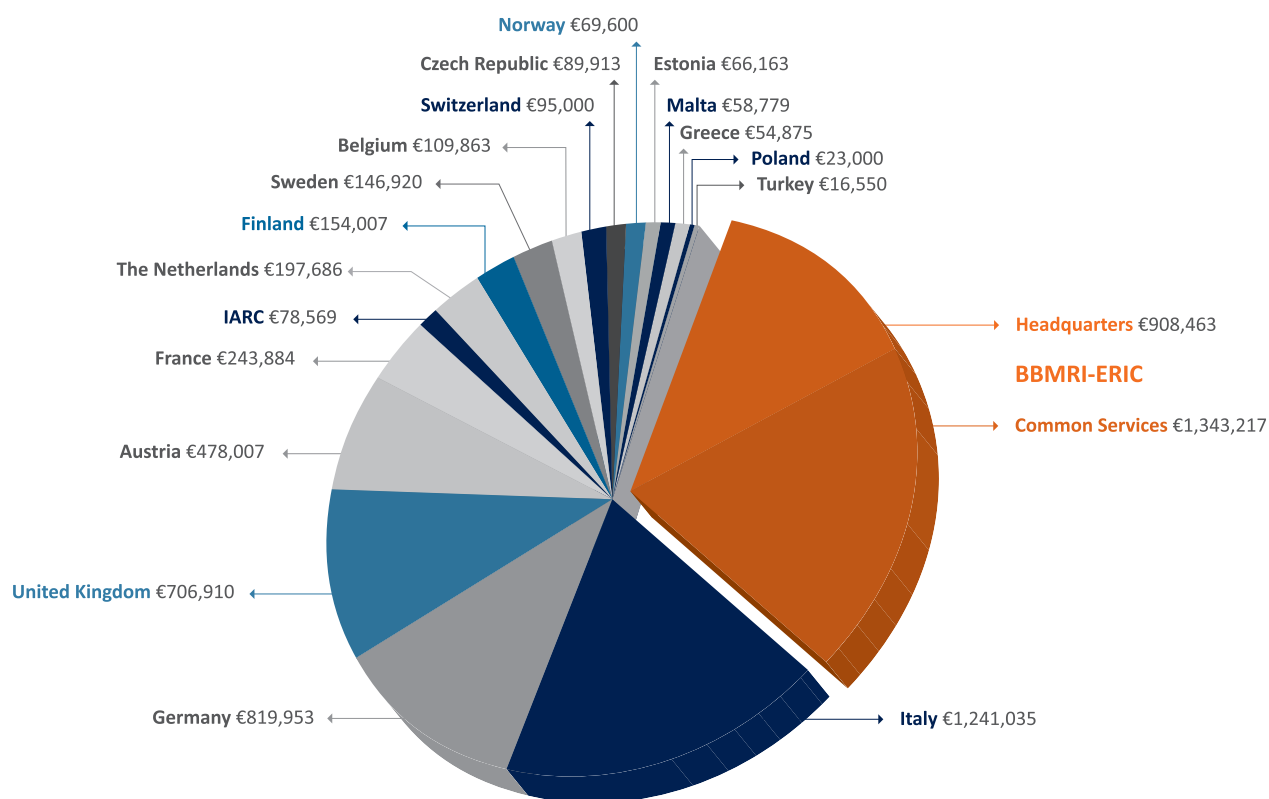


Figure 1.: Distribution of project grants where BBMRI-ERIC is coordinator

This pie chart includes all H2020 projects where BBMRI-ERIC is coordinator, namely ADOPT BBMRI-ERIC (page 130) and RItrain (page 139). It indicates the distribution of funds to the BBMRI-ERIC Headquarters, the Common Services, and to BBMRI-ERIC Members and Observers. Latvia and Malta are not included in the chart as they are not beneficiaries of the projects. Note that the amount of €1,241,035 allocated to Italy contains €450,000 that are reserved for European biobanks participating the colorectal cancer collection (financial support per number of cancer cases collected).

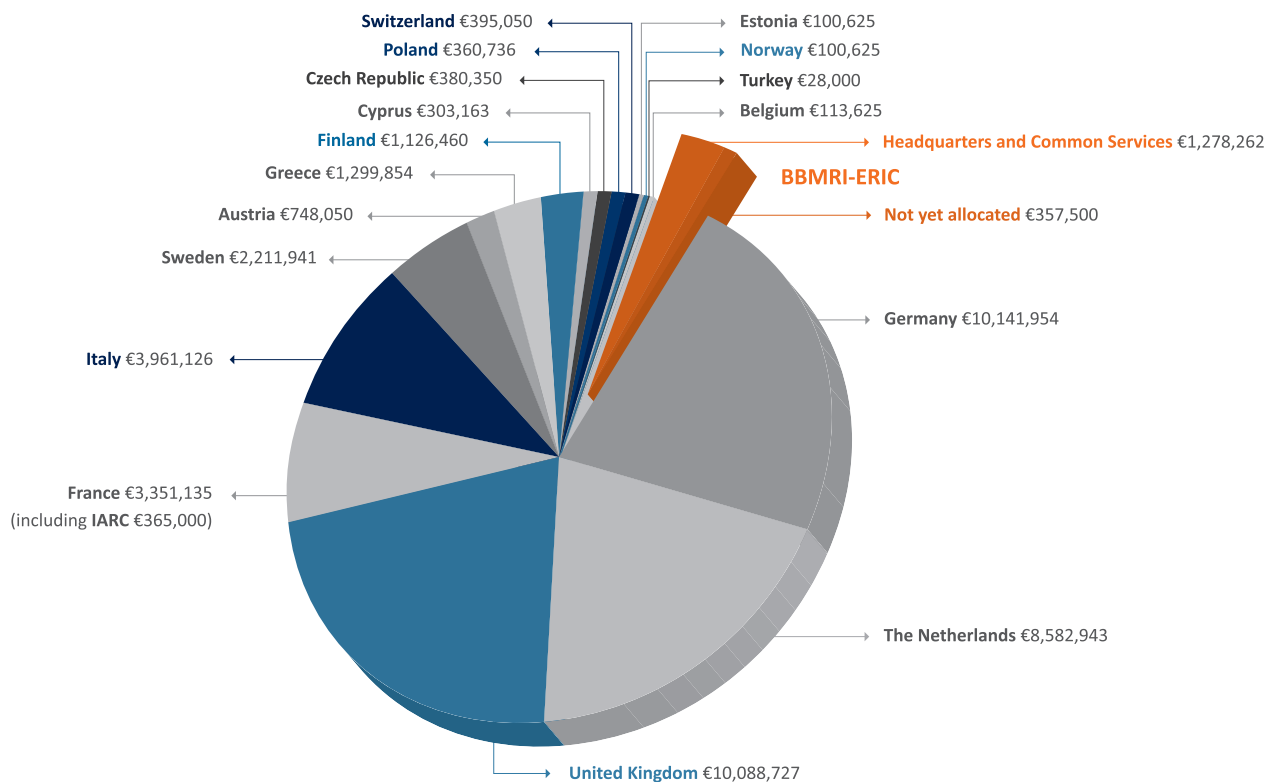


Figure 2.: Distribution of project grants where BBMRI-ERIC is partner

This pie chart includes all H2020 projects in which BBMRI-ERIC is involved as partner. It indicates the distribution of funds to the BBMRI-ERIC Headquarters including Common Services, not allocated funds (such as for new partners) as well as to BBMRI-ERIC Members and Observers. Note that the amount of €357,500 (listed as 'not yet allocated') is reserved for additional participants in COR-BEL (page 134) where expansion of sample providers and user base is foreseen. Cyprus and Latvia are not included in the chart as they are not beneficiaries of these H2020 projects.

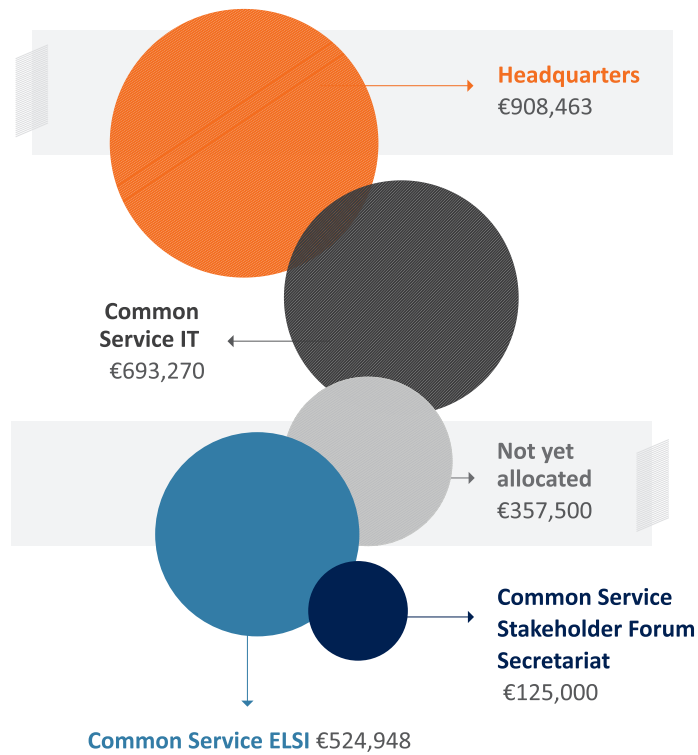


Figure 3.: BBMRI-ERIC's share of H2020 project grants

This figure specifies the H2020 project grant share of BBMRI-ERIC by differentiating between Headquarters, Common Service IT, Common Service ELSI and not yet allocated funds.



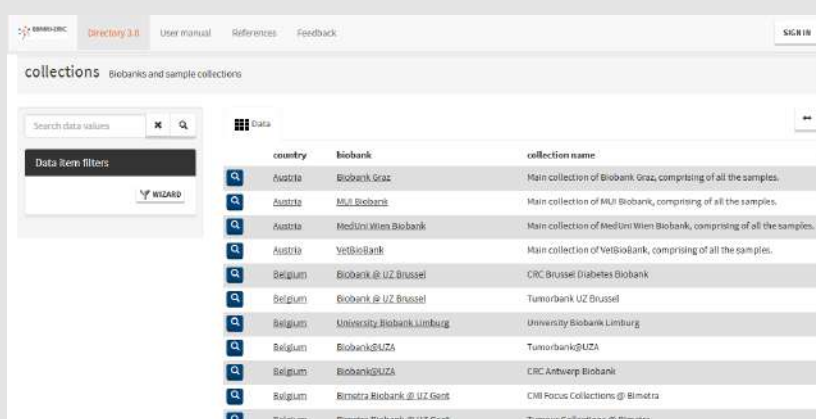
## Key Services at a Glance

### BBMRI-ERIC Directory 3.0

**Name of the service:** BBMRI-ERIC Directory 3.0

**Availability since:** version 1.0 from 2015, version 3.0 from beginning of 2017.

**Available at:** <https://directory.bbmri-eric.eu/>



The screenshot shows the BBMRI-ERIC Directory 3.0 interface. At the top, there are navigation links: "Directory 3.0", "User manual", "References", and "Feedback". A "SIGN IN" button is in the top right. The main heading is "collections" with the subtitle "Biobanks and sample collections". Below this is a search bar labeled "Search data values" and a "Data Item filters" section with a "WIZARD" button. The main content is a table with columns for "country", "biobank", and "collection name".

country	biobank	collection name
Austria	Biobank Graz	Main collection of Biobank Graz, comprising of all the samples.
Austria	MUW Biobank	Main collection of MUW Biobank, comprising of all the samples.
Austria	MedUni Wien Biobank	Main collection of MedUni Wien Biobank, comprising of all the samples.
Austria	VetBioBank	Main collection of VetBioBank, comprising of all the samples.
Belgium	Biobank @ UZ Brussel	CRC Brussel Diabetes Biobank
Belgium	Biobank @ UZ Brussel	Tumorbank UZ Brussel
Belgium	University Biobank Limburg	University Biobank Limburg
Belgium	Biobank@UZL	Tumorbank@UZL
Belgium	Biobank@UZL	CRC Antwerp Biobank
Belgium	Bimetra Biobank @ UZ Gent	CMI Focus Collections @ Bimetra
Belgium	Bimetra Biobank @ UZ Gent	Tumor Collections @ Bimetra

#### What does it do?

Provides highly aggregated metadata on biobanks and their sample/data collections and related biobank networks.

#### What is new in version 3.0?

- Support for metadata describing capabilities of biobanks (e.g., sample/data hosting services, analytical services).
- Support for metadata describing quality management procedures implemented in sample/data collections.
- Support for metadata describing compliance of sample/data collections to standards.
- Service ported to MOLGENS framework to enable advanced functionality in the future.

#### For whom is it intended?

- Academic and industrial researchers looking for candidate biobanks to collaborate with and/or get samples/data for their research.
- Biobankers promoting visibility of their biobank.
- Funding organisations to have oversight of nationally funded bioresources.
- Any other users interested in overview of bioanking resources.

## Quality: Self-Assessment Survey

**Name of the service:** BBMRI-ERIC Self-Assessment Survey

**Available:** Q1 2017

**Available at:** <http://www.bbmri-eric.eu/BBMRI-ERIC/quality-management/>



### **What does it do?**

The Self-Assessment Survey (SAS) is a quality assessment tool that is complementary to the CEN Technical Specifications (CEN/TS). It can be used by biobanks to evaluate the quality of their samples and collections. SAS supports biobankers in their efforts to 1) improve sample handling processes 2) implement quality requirements and 3) assess their performance. Furthermore, SAS helps biobanks to gain visibility and prestige once positive evaluation results are marked in the Directory 3.0.

### **For whom is it intended?**

It is primarily intended for biobankers and academic users located in BBMRI-ERIC Member and Observer countries.

## ELSI Helpdesk

**Name of the service:** ELSI Helpdesk

**Availability since:** version 1.0 from 2016.

**Available at:** <http://www.bbmri-eric.eu/services/elsihelpdesk>



**What does it do?** The vision and aim of the ELSI Helpdesk is to make it available, feasible, practical, usable, reliable, verifiable and sustainable. It will provide general information on topics that are crucial for biobanking, regarding for example informed consent, data protection and support on ethical questions. It will also offer customised help and build on the achievements of the Common Service ELSI Task Forces.

**What is the challenge?** The field covers many questions intimately connected to fundamental legal rights, and involves ethical and societal issues that often are politically controversial. Different countries have different regulations, professionals bring different perspectives and different expertise, and the knowledge of genetics and genomics is uncertain. Researchers will always have to reflect upon, and be responsible for, their practice themselves: both legally and ethically. But the BBMRI-ERIC Common Service ELSI provides tools and expertise to navigate within this landscape of reflection.

**For whom is it intended?** The Helpdesk offers support on ethical, legal and societal issues related to biobanking activities. It is primarily intended for users who are Members of BBMRI-ERIC.

### **What has been achieved recently**

- Putting request tracking system in place
- Updating FAQs on the General Data Protection Regulation to version 2.0
- Preparing joint positions and opinions on public consultations launched by European and or international bodies such as the Council of Europe's Recommendation (2006)<sup>4</sup> on research on biological materials of human origin
- Providing an overview of binding and non-binding ethical/legal instruments
- Vacancy opened for ELSI Helpdesk Coordinator

## **Part I.**

# **2016 Activities and Achievements BBMRI-ERIC Core Work Programme**

# 1. Work Plan: e-Infrastructure

## 1.1. Workstream: Development of IT Gateway to European Biobanks

**Aim:** The goal of this workstream is to implement the core IT infrastructure of BBMRI-ERIC. The main focus in 2016 was on improving the findability and accessibility of resources in European biobanks associated with BBMRI-ERIC, in compliance with the FAIR<sup>1</sup> and FAIR-Health principles.<sup>2</sup>

### Achievements:

- **BBMRI-ERIC Negotiator 1.0** designed to facilitate access to the samples and data in BBMRI-ERIC associated biobanks by simplifying communication among the requesters and biobankers (see Figure 5).

BBMRI-ERIC Negotiator is available at <http://negotiator.bbmri-eric.eu/>, undergoing piloting since beginning of 2017.

- **BBMRI-ERIC Directory 3.0** as the updated main findability service was delivered in December 2016. The updates include the transition to the MOLGENIS 1.x/2.x platform and substantial extensions of the data model with support for imaging in collections (in collaboration with the MIABIS-Imaging Working Group), quality management, and additional capabilities/services of biobanks.

BBMRI-ERIC Directory 3.0 is now available at <http://directory.bbmri-eric.eu/>.

A paper on the *BBMRI-ERIC Directory 2.0*<sup>3</sup> was published, accompanied by Deliverable D3.1<sup>4</sup> of ADOPT BBMRI-ERIC (page 130).

- The **BBMRI-ERIC Sample/Data Locator architecture** was delivered as ADOPT BBMRI-ERIC Deliverable D3.4.<sup>5</sup>
- **Tools for National Nodes and biobanks** were released as BIBBOX 1.0,<sup>6</sup> in collaboration with B3Africa (page 131).

<sup>1</sup> Wilkinson, MD, Dumontier, M, Aalbersberg, IJ *et al.*: The FAIR Guiding Principles for scientific data management and stewardship. *Scientific Data* **3** (2016).

<sup>2</sup> Holub, P, Kohlmayer, F, Prasser, F *et al.*: Boosting Reuse of Data and Biological Material in Medical Research: From FAIR to FAIR-Health. *PLOS Medicine*. Submitted. (2016).

<sup>3</sup> Holub, P, Swertz, M, Reihs, R, van Enckevort, D, Müller, H & Litton, JE: BBMRI-ERIC Directory: 515 Biobanks with Over 60 Million Biological Samples. *Biopreservation and Biobanking* **14**, 559–562 (2016).

<sup>4</sup> Holub, P, van Enckevort, D, Reihs, R *et al.*: *Consolidated Registry of BBMRI-ERIC Biobanks* 2016. doi:10.5281/zenodo.273550.

<sup>5</sup> Alexandre, D, Lablans, M, Ückert, F *et al.*: *Implementation of the BBMRI-ERIC architecture and database* 2016. doi:10.5281/zenodo.273766.

<sup>6</sup> <http://bibbox.org>

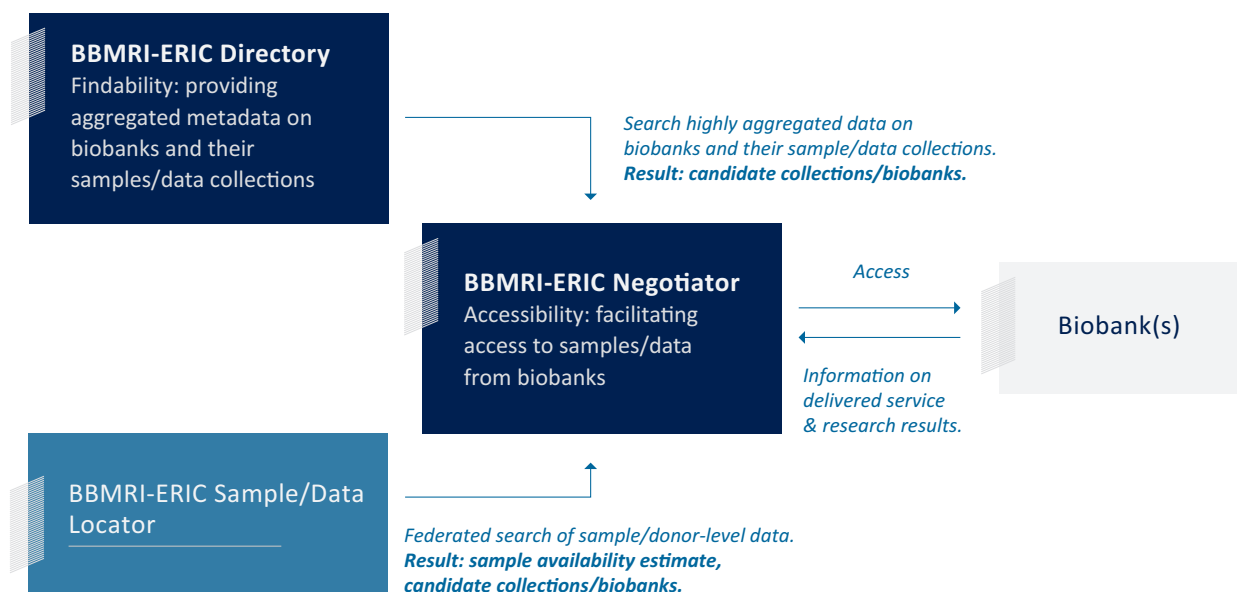


Figure 4.: Use of main BBMRI-ERIC findability and accessibility tools: BBMRI-ERIC Directory, BBMRI-ERIC Negotiator and upcoming BBMRI-ERIC Sample/Data Locator.

- **Publishing data models and ontologies** resulted in publishing a paper describing the MIABIS 2.0 Core<sup>7</sup> and setting up the MIABIS-Imaging Working Group. The MIABIS-Imaging Working Group delivered the data model for representing imaging data collections in biobanks—see also Workstream 7.1 – Biobanks Meet Imaging (page 45). The MIABIS governance has been reconstructed in order to improve delivery speed. BBMRI-ERIC started to participate in BioSchemas<sup>8</sup> activities together with BBMRI.uk.
- The **BBMRI-ERIC User Forum** was set up to evaluate the BBMRI-ERIC Directory 2.0 in order to improve the usability of the BBMRI-ERIC Directory service. Resulting feedback was incorporated into the development of the BBMRI-ERIC Directory 3.x.
- As part of the development of **tools for the semi-automated collection of 7,000 colorectal cancer cases**, a *data model* was designed to collect the data about the cases and an international workshop was organised to survey state-of-the-art of focusing on tools for data mining of medical records and natural language processing.
- A data collection application called *CCDC*<sup>9</sup> was developed for the manual collection of data from 3,000 colorectal cancer cases in compliance with the plan of the ADOPT BBMRI-ERIC project.

<sup>7</sup> Merino-Martinez, R, Loreana Norlin, DvE, Anton, G *et al.*: Towards Global Biobank Integration by Implementation of the Minimum Information About Biobank data Sharing (MIABIS 2.0 Core). *Biopreservation and Biobanking* **14** (4 2016).

<sup>8</sup> <http://bioschemas.org/>

<sup>9</sup> <https://bbmri-ccdc.mitro.dkfz.de/>

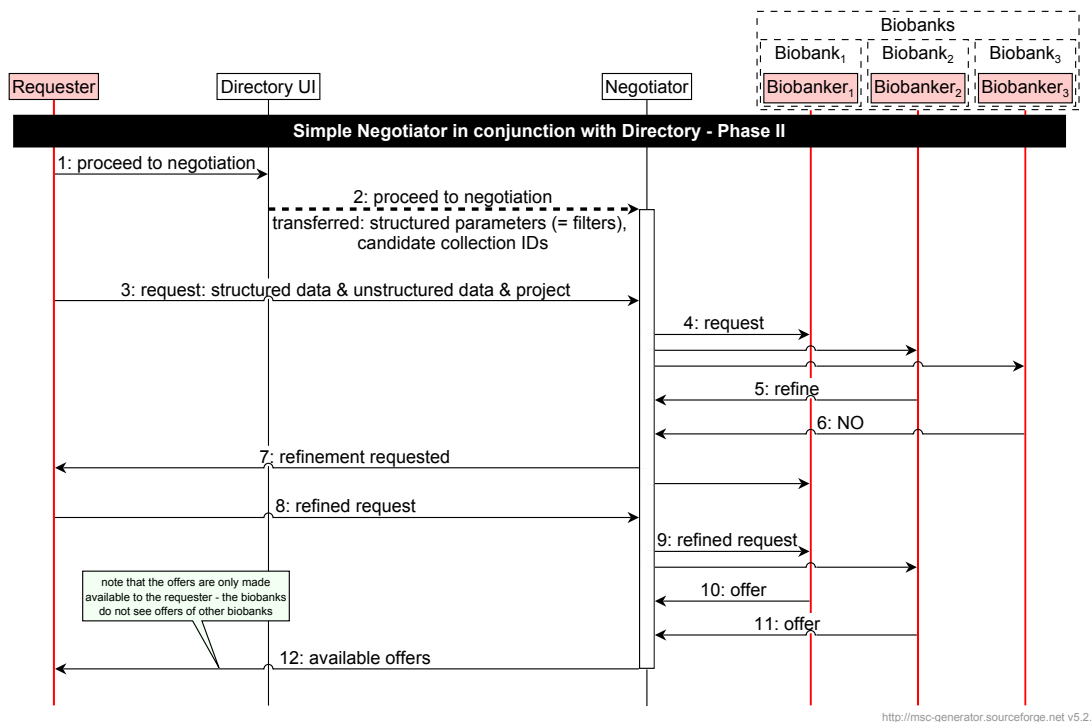


Figure 5.: Overview of communication between sample/data requesters and biobankers as implemented by BBMRI-ERIC Negotiator (available at <http://negotiator.bbmri-eric.eu/>). The requester pre-filters candidate biobanks in the Directory using simple structured parameters such as material type and disease, and proceeds to the Negotiator. Additional free text description and information on the project is added, allowing the collection representatives to assess sample/data availability. If the request is not specific enough, they can request a refinement of the query and all the biobankers from other candidate biobanks see this refinement, which means that the efficiency of the process is improved. Finally, the biobanks provide sample/data availability information to the requester confidentially.

- The **development of ontology translation services** resulted in the specification of requirements for data harmonisation and terminology mapping tools<sup>10</sup> and an overview of existing data harmonisation tools.<sup>11</sup>
- The **BBMRI-ERIC Authentication and Authorisation Infrastructure (AAI)** was delivered<sup>12</sup> in collaboration with BBMRI.cz as its in-kind contribution. **BBMRI-ERIC services have also been integrated with eduGAIN<sup>13</sup>** in collaboration with CESNET, in order to allow researchers from the whole of Europe (and even beyond) to access the services requiring authentication.

<sup>10</sup> Eklund, N, Mate, S, Schüttler, C et al.: *D8.1 Requirements specification for data harmonisation and terminology mapping tools* 2016. doi:10.5281/zenodo.164398.

<sup>11</sup> Mate, S, Leb, I, Schüttler, C et al.: *D8.2 Overview Document on Already Existing Data Harmonisation Tools* 2016. doi:10.5281/zenodo.165775.

<sup>12</sup> <https://perun.bbmri-eric.eu/>

<sup>13</sup> <http://www.edugain.org>

**Outlook:** Ongoing development and deployment of BBMRI-ERIC IT services, including bringing BBMRI-ERIC Negotiator into production; specification of Connector API for Sample/Data Locator and development of a reference implementation of it; implementation of data harmonisation services; development of BBMRI-ERIC Directory 4.0 with support for semantic search; and development of BIB-BOX 2.0.

## 1.2. Workstream: Operations of BBMRI-ERIC IT Infrastructure

**Aim:** This workstream targets the operation of the BBMRI-ERIC IT infrastructure for both production and development purposes, as well as for use outside of the BBMRI-ERIC IT services (e.g., for the Common Service ELSI and rare diseases).

### **Achievements:**

- Virtualisation of the infrastructure hosting BBMRI-ERIC production information technology services hosted by BBMRI.it as the implementation of **operation of the common BBMRI-ERIC IT infrastructure**. Setup of smaller-scale backup infrastructure hosted by the commercial provider Nessus (Austria), with development and initial deployment of failover switching from the primary site.
- **Operation of the BBMRI-ERIC Directory and the BBMRI-ERIC Negotiator** according to plan.
- **User support and training** delivered initial version of user's and implementor's training materials for BBMRI-ERIC Directory.
- **Deployment of** the request-tracker-based **Helpdesk** for the Common Service IT, the Common Service ELSI and for rare diseases (ADOPT BBMRI-ERIC Work Package 7).

**Outlook:** Operations, support and training of all the delivered BBMRI-ERIC services delivered as a part of Common Service IT.



### 1.3. Workstream: Interfaces to Other e-Infrastructures and IT-related Projects

**Aim:** This workstream aims at coordinating BBMRI-ERIC IT development with the development of European eInfrastructures<sup>14</sup> and other relevant IT projects, in order to develop synergies and avoid duplication of effort.

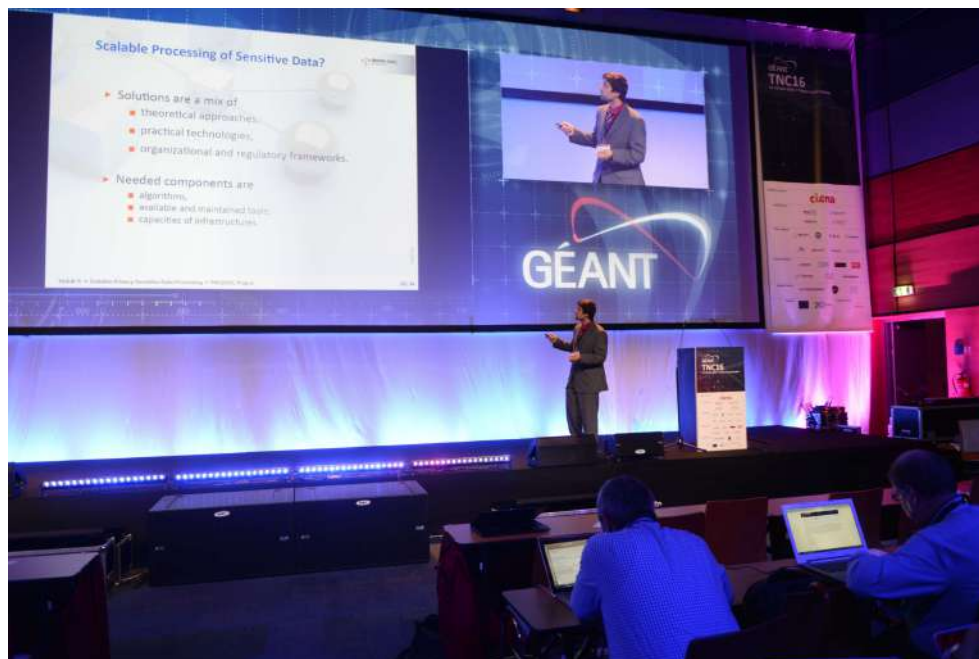


Figure 6.: Petr Holub, Senior IT/Data Protection Manager of BBMRI-ERIC and CIO of Common Service IT, presenting a plenary keynote at TNC16 Conference for over 650 participants.

#### Achievements:

- As a part of the **BBMRI Competence Centre within the EGI-Engage** project, BBMRI-ERIC and its partners have delivered Security & privacy requirements document,<sup>15</sup> released Security toolset<sup>16</sup> for BBMRI-ERIC, and delivered a document titled Analysis of requirements on biobank and study workflows.<sup>17</sup>
- The **Participation in the CORBEL** project resulted in a joint work group between the projects CORBEL (page 134) and Authentication and Authorisation for Research and Collaboration (AARC) on the AAI and organisation of a CORBEL Joint Compute Workshop on Data Storage and Integration<sup>18</sup> adjoint to the CORBEL (page 134) Annual General Meeting 2016.

<sup>14</sup> <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/e-infrastructures>

<sup>15</sup> Holub, P, Dowling, J, Muhammad, S, Niazi, K, Hakimzadeh, K & Parák, B: *Security and privacy requirements and secure storage architecture* Delivered as Milestone M6.2 document of EGI- Engage. 2016. doi:10.5281/zenodo.161551.

<sup>16</sup> Dowling, J & Hakimzadeh, K: *Security toolset release for BBMRI-ERIC* 2016. doi:10.5281/zenodo.273860.

<sup>17</sup> Swertz, M, Neerincx, P, Vojtíšek, O & Holub, P: *Analysis of requirements on biobank and study workflows* 2016. doi:10.5281/zenodo.273901.

<sup>18</sup> <http://www.bbMRI-eric.eu/news-events/corbel-1st-annual-general-meeting-agm/>

- The **Collaboration with Research Data Alliance (RDA) and EUDAT** led to BBMRI-ERIC participating in the Group of European Data Experts (GEDE) and a proposal for the use of EUDAT components for BBMRI-ERIC services within EGI-Engage (page 135).
- BBMRI-ERIC became part of the EOSCpilot project, set to launch in 2017 to **pilot the European Open Science Cloud**, with BBMRI-ERIC focusing on policies for sharing and processing sensitive data.
- Plenary keynote at TNC16 Conference,<sup>19</sup> the largest and most prestigious European research networking conference, with more than 650 participants attending this annual event (Figure 6).

**Outlook:** Further development of BBMRI-ERIC AAI and work withing H2020 AARC2 project (page 129) and CORBEL projects to propagate the experiences into the production AAI services provided by European eInfrastructures. Work toward standardisation of provenance information for the biomedical material/data domain through ISO Technical Committee (ISO/TC) 276.

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<sup>19</sup><https://tnc16.geant.org/>

## 2. Work Plan: Quality

### 2.1. Workstream: Molecular In-vitro Diagnostic Examination Standards of CEN/TC 140

**Aim:** First and foremost, the aim was to establish a BBMRI-ERIC quality community involving biobanking experts to initiate standardisation and harmonisation measures in order to improve sample quality at biobanks and, subsequently, lay the base for reproducible research conducted with human samples from biobanks. Over 90 experts from 18 Member and Observer countries have succeeded in establishing one of the largest connected networks in Europe, which deals with quality management in biobanks.

The current European standards were introduced to the network of biobankers and associated experts mentioned above. To this end, the CEN Technical Specifications (CEN/TS) published in 2016 were presented as a basis for standardised sample processing in the BBMRI-ERIC community to improve sample handling processes. Nine Self-Assessment Surveys (BBMRI-ERIC SAS) were developed with the BBMRI-ERIC quality community, making it possible to assess the biobanks' internal sample handling processes by comparing them to the respective standards and the requirements of the CEN/TS for pre-analytical sample handling.

As a result, biobanks can now check the quality of human samples with respect to the applicable standards through self-evaluation. A positive evaluation of the sample quality can be reported to BBMRI-ERIC. After reviewing these biobanks or biobank samples and collections, BBMRI-ERIC can take steps to increase the visibility of these biobanks in the BBMRI-ERIC Directory by awarding them a quality label.

#### Achievements:

- **Establishing five expert working groups for pre-examination processes** *Expert Working Group 1: Snap frozen tissue (35 participants/18 countries); Expert Working Group 2: FFPE tissue (36 participants/18 countries); Expert Working Group 3: Venous whole blood (39 participants/18 countries); Expert Working Group 4: urin/serum/plasma metabolomics (28 participants/18 countries); Expert Working Group 5: QMS for biobanks (37 participant/18 countries).* First work process achievements of the expert working groups were discussed in a closed working session during the 2016 *Europe Biobank Week* conference as well as in the open session titled *E1: Improved Output Quality of Human Biological Material Across European Biobanks*.
- **Initiating an intra- and inter-biobank benchmark process** As a basis for sample handling, standards relevant to biobanks and CEN/TS were analysed by the individual expert groups and compared with the respective work processes at biobanks. The applicable standards and valuable working documents provided by BBMRI.at, BBMRI.uk and BBMRI.de supported these benchmark processes. Deviations could thus be made visible and subsequent improvements

were initiated by the respective biobanks. The continuation of these supporting activities by BBMRI-ERIC is planned for 2017, providing the basis for the development of standardisation and harmonisation measures.

- **Integrating the evaluation of nine CEN/TS by BBMRI-ERIC Experts into ISO/TC 212** The specifications for pre-analytical sample handling, published as European Technical Specifications (CEN/TS), are currently being revised by the ISO/TC 212 as an international standard.

The practical implementation and applicability of the CEN/TS was reviewed by the BBMRI-ERIC quality community in numerous web conferences. As a result, all observed errors were directly integrated into the current development of the International Organization for Standardization (ISO) standards as proposals for changes and corrections.

**Outlook:** Established expert working groups will be continued consistently in 2017.

## **2.2. Workstream: Self-Assessment Tool for Biobanks (formerly known as Self-Evaluation)**

**Aim:** Actively supporting biobanks with regard to building and improving their quality management systems with a special focus on the pre-examination of sample processing.

*Self-Assessment Tool (SAT)* was the working title used during development in 2016. Adapted as a survey relating to quality criteria, the tool was renamed *BBMRI-ERIC Self-Assessment Survey (SAS)*.

### **Achievements:**

- **Developing nine BBMRI-ERIC Self-Assessment Surveys:** The BBMRI-ERIC community adapted existing technical specifications and standards to develop nine complementary Self-Assessment Surveys that can be used to assess a biobank's internal pre-examination process. This way, biobanks can find out whether their sample processing is in compliance with applicable requirements.

**Outlook:** By Q2 2017, access authorisation and on-line access for the Self-Assessment Surveys will be developed and the integration to the BBMRI-ERIC Directory prepared.



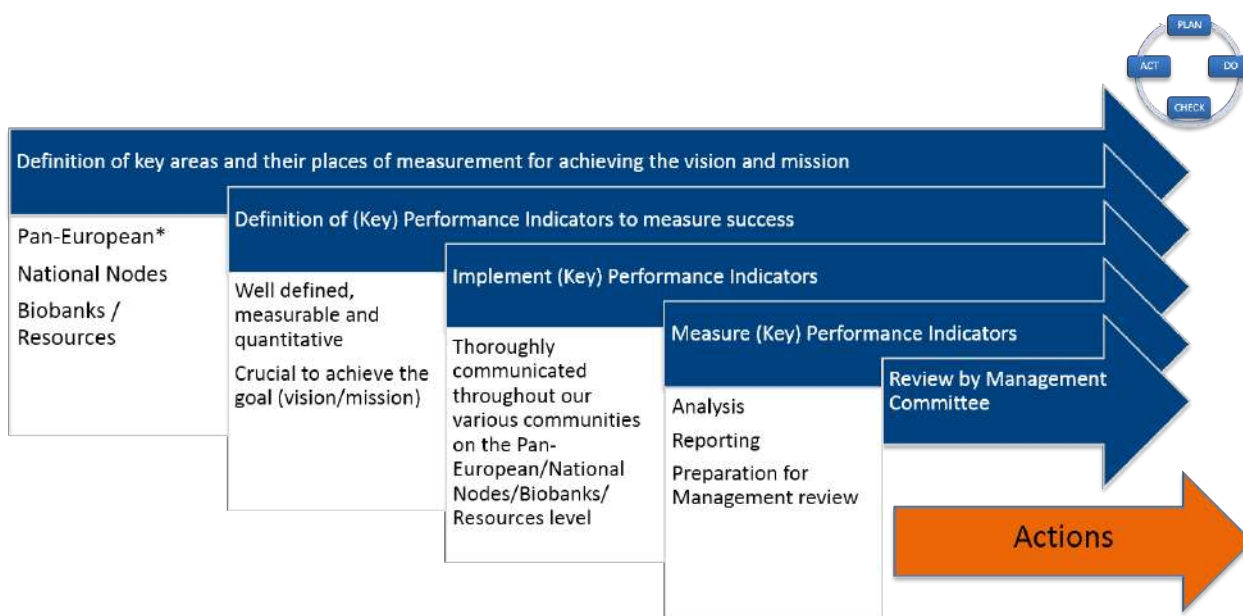
Figure 7.: Outlook on the process of accessing and using of Self-Assessment Survey for 2017

## 2.3. Workstream: Implementation of Performance Indicators

**Aim:** Introducing ‘performance indicators’ to BBMRI-ERIC with the objective of evaluating the organisation’s, its programmes and its projects success. Performance indicators, specified in the H2020 ADOPT BBMRI-ERIC project (page 130) project, will contribute to the overall assessment of the research infrastructure.

- **Development of Performance Indicators for BBMRI-ERIC:** A vast set of Performance Indicators was established<sup>20</sup> together with the Management Committee of BBMRI-ERIC. The process started in 2015, but most of the work was completed in between May and September 2016 during which discussions and two reviews of the document describing the Performance Indicators took place. In September 2016, the Performance Indicators for BBMRI-ERIC were submitted to the Commission as a deliverable of ADOPT BBMRI-ERIC.

**Outlook:** A subset of Performance Indicators have been proposed as future BBMRI-ERIC Key Performance Indicators, but the consensus on the subset is still to be reached in 2017.



\* Pan-European: Common Service IT, Common Service ELSI, Quality Management Service, Management Committee, Stakeholder Forum, Headquarters BBMRI-ERIC

Figure 8.: Process of designing and implementing of Performance Indicators

<sup>20</sup> Holub, P, Litton, JE, Wutte, A, Törnwall, O, Mayrhofer, MT & Management Committee of BBMRI-ERIC: *Performance Indicators for BBMRI-ERIC* 2016. doi:10.5281/zenodo.159416.

## 3. Work Plan: Healthcare Integrated Biobanking

### 3.1. Workstream: Disease-oriented Biobanks

**Aim:** Setting up a working group to tackle all issues common to all workstreams, especially in relation to the H2020 ADOPT BBMRI-ERIC (page 130) project.

**Achievements:**

- **Composition of the working group** Each National/Organisational Node was asked to designate its expert(s) to joining the working group, which aims to establish the first BBMRI-ERIC-wide disease cohort on colon cancer as set up in the context of the ADOPT BBMRI-ERIC (page 130) project. The working group consists of 39 representatives.<sup>21</sup>

Simultaneously, an additional interdisciplinary group consisting of biobankers, clinicians, disease registry experts, researchers and IT experts has identified the colon cancer data set that will be required to establish the BBMRI-ERIC-wide disease cohort.

**Outlook:** Ensuring liaising with and between the H2020 ADOPT BBMRI-ERIC (page 130) project's work packages.

### 3.2. Workstream: Archived Tissues

**Aim:** Developing the first European Network of Clinical Archived Tissues.

**Achievements:**

- **Define rules and activities:** The application of the Archive Tissue Molecular Analysis (ATMA) as a BBMRI-ERIC Associated Expert Centres/Trusted Partners was discussed in the BBMRI-ERIC Management Committee meeting in Prague in 2016 and shortly after later approved (see Workstream 10.8). AMTMA-EC has been set up in the campus of Aviano (CRO Aviano) specifically for archiving tissues for molecular analysis BBMRI.it has started the organisation of the Network of Italian Pathology Archive Biobanks (NIPAB). This experience should be informative for other European countries.

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<sup>21</sup> M. Lavitrano, K. Zatloukal, K. Haustermans, A. Metspalu, D. Valik, A. Jalanko, A. Carter, G. Dagher, M. Hummel, D. Thanos, A. Felice, G. van Ommen, K. Hveem, Ł. Kozera, J. Dillner, N. Atabey, M. Mendy, S. Wyss, B. Parodi, R. Reihls, A. Diez-Fraile, A. Debucquoy, B. Martharoo, M.R. Justo, P. Jonesa, A. Gander, P. Quinlan, M. Leego, O. Carpen, I. Hamalainen, S. Kolyva, E. Ortega, J. Ekström, M. Hortlund, S. Sarioglu, E. Carbox, M. Jenam, L. Chapatte and R. Warth

- **Biomarker verification and validation:** The H2020 HERCULES project<sup>22</sup> (2016–2021) provides comprehensive characterisation and effective combinatorial targeting of high-grade serous ovarian cancer via single-cell analysis. It brings together the basic research and biomarker validation processes. In 2016, the preparation of clinical population of high grade serous ovary carcinoma was started, which is now characterised on the clinical and molecular level.

**Outlook:** Continuing networking activities with the European Network of Archived Tissues and working towards developing accreditation and clinical research methods on archived tissues.

### 3.3. Workstream: Liquid Biopsies

**Aim:** Fostering the interoperability of liquid biopsy biobanks in order to characterise liquid biopsies through robust assay development, technical validation and standardisation.

**Achievements:**

- **Setting up a working group:** Each National/Organisational Node was asked to designate their expert(s) joining the working group. The group currently consists of representatives from BBMRI.it and BBMRI.be.
- **Producing Standard Operating Procedures (SOP's)** BBMRI.it produced SOP's and Best Practices for:
  - *Blood collection*
  - *Blood processing for different molecular analyses: genomic DNA circulating cell-free DNA, microRNAs, circulating tumor cells using different biomarker-based and unbiased procedures for the isolation of circulating tumor cells*
  - *Storage and banking*
  - *Pre-analytical measurement of factors affecting the evaluation of circulating biomarkers (hemolysis, etc.)*

**Outlook:** The quality SOP's will be circulated among the National/Organisational Nodes for comments, and a national survey on pre-analytical and analytical procedures for liquid biopsies will be analysed and evaluated in 2017.

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<sup>22</sup><http://www.project-hercules.eu/>



### 3.4. Workstream: Immortalised Cell Lines

**Aim:** Increasing awareness within the BBMRI-ERIC community concerning the authentication of established as well as primary cell lines and human tissues.

**Achievements:**

- **Setting up a working group:** Each National/Organisational Node was asked to designate their expert(s) to join the working group. The group currently consists of representatives from BBMRI.it and BBMRI.mt.
- **Producing SOP's:** BBMRI.it defined quality SOP relating to:
  - *Development of a new cell line*
  - *Acquisition of a cell line from another laboratory*
  - *Storage and banking*
  - *Shipment of cell cultures*
  - *Cell line misidentification*

**Outlook:** In 2017, the quality SOP's will be circulated among the National/Organisational Nodes for comments.

### 3.5. Workstream: Microbiome

**Aim:** Bringing together the microbiome and the BBMRI-ERIC community in relation to human health.

**Achievements:**

- **Exploring opportunities related to the BBMRI-ERIC Directory:** The inclusion of microbiome biobanks into the BBMRI-ERIC Directory was explored during a meeting with the *Interactive Microbiome* research group from the Medical University of Graz in October 2016. The BBMRI-ERIC Directory and other work done by BBMRI-ERIC were presented during the Theodor Escherich Symposium on Medical Microbiome Research in November 2016, in order to further establish contact and exchange information. The symposium brought together international experts and helped to promote medical perspectives on microbiome research.
- **Setting up a working group:** A discussion on the MIABIS Working Group with the *Interactive Microbiome* research group was initiated. However, more work is needed to identify additional members and subsequently include them.

**Outlook:** Further steps to include the microbiome biobanks into the BBMRI-ERIC Directory will be taken by the MIABIS Working Group in 2017.

### **3.6. Workstream: Biomarker Verification and Validation Models**

**Aim:** Verifying new biomarkers in large multiple retrospective case studies directly developing a preliminary kit in collaboration with the industry, after which the kit can be validated in three OECl-accredited cancer centres.

**Achievements:**

- Biomarker verification and validation models: The first steps regarding biomarker verification and validation were taken within the H2020 HERCULES project (2016–2021) that focuses on finding solutions to drug resistance in high-grade ovarian cancer.

**Outlook:** This work is linked to Workstream 10.8 on BBMRI-ERIC Associated Expert Centres/Trusted Partners were certified: CBmed (Austria) and ATMA-EC (Italy).

## 4. Work Plan: Population-Based Cohorts

### 4.1. Workstream: BBMRI-LPC

**Aim:** Facilitating networking, harmonisation and access to large prospective cohort samples and data available in Europe. BBMRI-ERIC aims to implement concepts and solutions provided by BBMRI-LPC (page 132).

**Achievements:**

- **Communicating BBMRI-LPC results:**<sup>23</sup> Participation in the Annual Meeting (8<sup>th</sup> – 9<sup>th</sup> September 2016) and regular project teleconferences (Steering Committee, coordination and access). Publishing developments and achievements related to BBMRI-LPC in the Biobanks Europe Magazine No. 5/2016.
- **BBMRI-LPC Forum for Biobank initiatives (esp. Eastern Europe):**<sup>24</sup> BBMRI-ERIC joint activity with the FP7 BBMRI-LPC project during the 2016 *Europe Biobank Week* in Vienna (15<sup>th</sup> – 16<sup>th</sup> September 2016): BBMRI Biobank Forum presented sessions on *Infrastructure Policies in Widening Countries* and *How can BBMRI-ERIC support Emerging Biobanks*.
- **Preventing activities from overlapping:** The FP7 BBMRI-LPC project's concepts and solutions were further implemented and developed under several other workstreams, such as 5.3. Biomolecular Resources, 9.1. Biobanking Conference and 10.8. Expert Centres.

**Outlook:** In the Work Programme 2017, the FP7 BBMRI-LPC's project work is partitioned over several workstreams including 4.1. Biomolecular Resources Service, 4.2. Technology Watch, 5.1. Catalogues, 5.2. A Biobank Cost Calculator, 7.3. Global Biobank Week (The *BBMRI-LPC Forum* will be titled henceforth *BBMRI Biobank Forum*.) and 8.1. Expert Centres. This ensures a sustainable continuation of the project's achievements within BBMRI-ERIC.

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<sup>23</sup> [http://www.bbmri-eric.eu/wp-content/uploads/2016/07/2016\\_Newsletter5\\_WEB.pdf](http://www.bbmri-eric.eu/wp-content/uploads/2016/07/2016_Newsletter5_WEB.pdf)

<sup>24</sup> Report on the fourth BBMRI-LPC Forum meeting. Available at members area: <http://www.bbmri-lpc.org>



Figure 9.: The final Annual Meeting of BBMRI-LPC in Levi, Finland, September 2016

## 5. Work Plan: Common Services

### 5.1. Workstream: Common Service ELSI

**Aim:** Giving appropriate consideration to ethical, legal, and societal issues (ELSI) related to biobanking and research infrastructure activities by providing relevant expertise, tools, policies and services. Additionally, task forces were formed to refine specific topics along the overall objectives of BBMRI-ERIC and its National Nodes:

- *Task Force International Organisations' Policy Assessment and Monitoring*<sup>25</sup>
- *Task Force GDPR*<sup>26</sup>
- *Task Force Code of Conduct*<sup>27</sup>
- *Task Force Rule Making US*<sup>28</sup>
- *Task Force Sharing and Access to Data and Human Biospecimens*<sup>29</sup>
- *Task Force Societal Issues*<sup>30</sup>

#### Achievements:

- **Launching an expert register ('ethical, legal, and societal issues (ELSI) Expert Database')**<sup>31</sup> launched in April 2016, inviting ELSI experts to contribute to the Common Service ELSI (e.g., as reviewers for the ethics check) and specifying their field of expertise (free online sign up).
- The **ELSI Helpdesk**<sup>32</sup> was set up to provide practical and general information/guidance on ELSI issues as well as advice on a case-by-case basis (Request Tracking System in testing phase). An ELSI Helpdesk Coordinator part-time position was created, funded through the ADOPT BBMRI-ERIC (page 130) project and the vacancy note published (open until February 2017).
- The **Ethics Check** criteria and procedures were further specified (incl. work-flow diagram). The Ethics Check is currently being assessed in the context of the ADOPT BBMRI-ERIC (page 130) colon cancer case study.

<sup>25</sup> Monitored and commented on relevant recommendations during public consultation phase and promoted published recommendations such as the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks, October 2016, see <http://www.wma.net/en/30publications/10policies/d1/>

<sup>26</sup> Developed FAQs for biobankers on the General Data Protection Regulation, see [http://www.bbMRI-ERIC.eu/wp-content/uploads/2016/08/BBMRI-ERIC\\_FAQs\\_on\\_the\\_GDPR\\_V1.0\\_for\\_print.pdf\(updateforthcoming1Q/2017](http://www.bbMRI-ERIC.eu/wp-content/uploads/2016/08/BBMRI-ERIC_FAQs_on_the_GDPR_V1.0_for_print.pdf(updateforthcoming1Q/2017)

<sup>27</sup> Prepared a working meeting and started a stakeholder engagement to arrive at a basis for a health and life sciences data protection code of conduct, see <http://www.nature.com/news/we-must-urgently-clarify-data-sharing-rules-1.21350>

<sup>28</sup> formed to follow the US proposal on governing the ethical conduct of research involving humans (operational 1Q/2017)

<sup>29</sup> Contributed to the access procedure as developed in ADOPT BBMRI-ERIC (page 130) and a draft access policy for BBMRI-ERIC to be discussed in the joint Common Service ELSI/Common Service IT meeting in January 2017

<sup>30</sup> Exchanged on engagement activities and the lessons-learned of the National Nodes and objectives 2017)

<sup>31</sup> <https://cs-elsi.biobankhub.fr/redcap/surveys/?s=JEXPEPRMC>

<sup>32</sup> <http://www.bbMRI-ERIC.eu/services/elsihelpdesk/>



Figure 10.: Anne Cambon-Thomsen (Director of the Common Service ELSI)

- A workshop titled ***Ethics Review of European Biobank Research: Towards Mutual RECOgnition?*** brought together research ethics committee representatives and stakeholders to discuss standards for a European-wide ethics review of data/sample access requests for cross border research projects (Vienna, 12<sup>th</sup> September 2016, see report<sup>33</sup>). The workshop was jointly organised with the BBMRI-LPC and B3Africa projects.
- Existing cooperation related to ***ELSI was further solidified*** in the form of Memoranda of Understandings (e.g., P<sup>3</sup>G), specific collaborations with societies (e.g., inviting the Global Alliance for Genomics and Health to partake in the Code of Conduct initiative) and European or international organisations (e.g., seeking observership at the Council of Europe). Furthermore, project related co-operations were established: A joint workshop with the RD-CONNECT project (BBMRI-ERIC is partner) and the COST Action CHIP ME<sup>34</sup> project on principles for collaboration between public and private partners; A joint survey on informed consent in collaboration with the projects RD-CONNECT, CHIP ME, Do-IT and others; Collaborating with the ELSI 2.0 working group (sharing announcements on meetings, webinars and vacancies).
- Having appropriate ***tools and methodologies for public debate and engagement with society*** is important for biobankers and several activities are ongoing in the National Nodes, which were presented to a wider audience during the 2016 *Europe Biobank Week*. Broader engagement activities are desired and require further resources. Among other things, a work

<sup>33</sup> [http://www.bbMRI-eric.eu/wp-content/uploads/2016/07/BBMRI\\_LPC\\_B3Africa\\_RECMeetingVienna2016report.pdf](http://www.bbMRI-eric.eu/wp-content/uploads/2016/07/BBMRI_LPC_B3Africa_RECMeetingVienna2016report.pdf)

<sup>34</sup> <http://chipme.eu/eng/about-us.aspx>

plan was developed focusing on comparative survey templates and how-to-guides for societal engagement, which became part of the Work Programme 2017 (page 27).

- Instead of organising one single **Common Service ELSI annual workshop**, several task force working meetings and one ELSI team meeting as well as eight dedicated ELSI sessions<sup>35</sup> (e.g., B1 Participation of Patients and Public in Biobanking; B2 ELSI Issues Practical) were held in the context of the 2016 *Europe Biobank Week*.
- An outline for a **Summer School ELSI outline** was developed. It builds on the five-day programme for a summer school organised by BBMRI-NL and the University of Groningen taking place from 19<sup>th</sup> – 23<sup>rd</sup> June 2017<sup>36</sup> and addresses fundamental concepts in biobanking research.

Deferred:

- **ELSI tools (orientation, access and use procedure)**, such as hSERN and LAT, are key elements<sup>37</sup> of the ELSI Helpdesk, providing a first orientation on ELSI issues. In 2016, first steps were taken towards integrating them into one user-friendly tool for biobankers, taking into account the results of a user need survey (executed in the context of CORBEL (page 134)). As regards access, a workshop report *Sharing and access to data and human biospecimens for the benefit of patients – Towards a BBMRI-ERIC Policy*<sup>38</sup> was published in spring 2016. The completion of the access policy itself has been deferred.

**Outlook:** Activities started in 2016 will continue with a special focus on the General Data Protection Regulation (GDPR) Code of Conduct (under the leadership of the Director General) and societal issues (under the leadership of the Task Force Societal Issues) as specified in the Work Programme 2017, p.24. In the context of ADOPT BBMRI-ERIC (page 130), a BBMRI-ERIC access policy and access procedure will be finalised in collaboration with the Common Service IT, expectantly spring 2017.

## 5.2. Workstream: Rare Diseases

**Aim:** Providing support for rare disease biobanks and/or registries to enable them to participate in BBMRI-ERIC and coordinating efforts within the rare disease community.

**Achievements:**

- **Reports from meetings related to coordination efforts:** the report compiled by the Istituto Ortopedico Rizzoli (Luca Sangiorgi, Work Package 7 Lead in ADOPT BBMRI-ERIC (page 130)) specifies links to the European Reference Networks, future call for projects (H2020), patient involvement and lists the participated networking meetings in 2016.
- **Registry/biobank support service/Helpdesk:**<sup>39</sup> As part of its collaboration with the ADOPT BBMRI-ERIC (page 130) project (Workpackages 3 and 7), the Common Service IT has installed the Request Tracking System as a Rare Disease Helpdesk application. This system allows users

<sup>35</sup> <http://europebiobankweek.eu/programme-3/final-programme/>

<sup>36</sup> <http://www.rug.nl/research/gradschool-medical-sciences/summerschools/biobanking/>

<sup>37</sup> <http://www.bbmri-eric.eu/services/other-services/>

<sup>38</sup> <http://www.bbmri-eric.eu/wp-content/uploads/2016/08/FINAL-BBMRI-Paris-2015-WORKSHOP-REPORT.pdf>

<sup>39</sup> Registry/ biobank support service/ Helpdesk facility – ADOPT BBMRI-ERIC deliverable D7.2 report. Available at intranet: [www.bbmri-eric.org](http://www.bbmri-eric.org)

from both inside and outside of BBMRI-ERIC to submit their requests and directs them towards the people responsible and monitors progress of their completion. A dedicated queue for rare diseases was set up within the Helpdesk together with introductory training provided to several selected people. Further, Work Package 7 delivered a background document describing the Helpdesk models to facilitate its implementation.

Deferred:

- **Developing training materials and holding training workshops:** The first training webinar on the Request Tracking System is planned to take place in 1Q 2017.
- **Defining and implementing quality standards for rare disease biobanks:** BBMRI-ERIC compiled a list of recommended, applicable Quality Management Systems (OECD and WHO/IARC), International Standards (ISO), Best Practices (ISBER) and Technical Specifications for pre-examination processes (CEN/TS) that can be implemented by rare disease biobanks.

**Outlook:** In 2017–2018, a rare disease biobank section in the BBMRI-ERIC Directory will be provided. Further work regarding the Helpdesk, quality standard implementation and coordination of activities is foreseen in 2017.

### 5.3. Workstream: Biomolecular Resources

**Aim:** Providing an open platform to support the development and dissemination of methods relevant to biomolecular resources.

- **Workshop:** A strategic workshop positioning biomolecular resources on the BBMRI-ERIC roadmap was held in Uppsala (12<sup>th</sup> – 13<sup>th</sup> April 2016). It involved 30 experts and key contributors within academia and industry. The meeting resulted in a roadmap document that is now incorporated in the Work Programme 2017<sup>40</sup> featuring:
  - *Biomolecular Resources Service*
  - *Technology Watch*
  - *Biomolecular Resources Officer*
- **Liasing with the B3Africa project:** The Common Service IT released BIBBOX 1.0 in collaboration with B3Africa (see also 2.1). The software is expected to be deployed as a complete biobanking toolbox in selected African biobanks in 2017.
- **Building up (non)-commercial cooperation:** A service enabling cooperation with commercial/non-commercial operators is part of Workstream 10.8 Expert Centres. In 2016, BBMRI-ERIC certified two Expert Centres: CBmed GmbH (Austria) and ATMA-EC (Italy).
- **Implementing BBMRI-LPC SOP's:** The BBMRI-LPC (page 132) collected and mapped processes, instrumentation, quality control measures and results from BBMRI-LPC collaborating biobanking facilities. This data was used to launch and test evidence based protocols for joint use.

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<sup>40</sup>Work Programme 2017: Workstreams 4.1 Biomolecular Resources Service and 4.2 Technology Watch



- **Accommodating new standards and protocols:** The BBMRI-LPC (page 132) project developed a recommended standardisation for sample handling of body fluids (whole blood, serum, plasma, RNA, DNA and urine) and the BRISQ-report was included into the Molecular Methods database (MolMet) in order to enable regular updates.

Deferred:

- **Liaising with Workstream 2.1. Molecular In-vitro Diagnostic Examination Standards of CEN/TC 140:** The Biomolecular Resources Service will work closely with quality experts when evaluating new biomolecular processes and protocols starting in 2017.
- **Creating a case model:** A case model designed to simplify methods reporting with links to scientific publications is part of the Technology Watch. The work will be initiated in 2017.

**Outlook:** In 2017, the Biomolecular Resources Service including yearly Technology Watches will be established to assist preparation for, and early adoption of, emerging technologies that are of relevance, and to identify best practices and support harmonisation of methods.



Figure 11.: Roadmap drafting group for the 'Second B' of BBMRI-ERIC in Uppsala, April 2016

## 6. Work Plan: International Standard Development

### 6.1. Workstream: WG1: Terminology

**Aim:** The ISO/TC 276 Working Group 1 Terminology uses national and international standards, guidelines and terms and definitions related to ISO/TC 276 Biotechnology. BBMRI-ERIC keeps track of the developments and acts as an information hub within the BBMRI-ERIC community.

**Achievements:**

- **Presentation of MIABIS 2.0** The Director General Jan-Eric Litton presented BBMRI-ERIC and MIABIS 2.0 at the 4<sup>th</sup> ISO/TC 276 Plenary meeting, held on 9<sup>th</sup> – 13<sup>th</sup> May 2016 in Washington DC.
- **Participation in ISO/TC 276 Plenary meetings** The 4<sup>th</sup> meeting was held from 9<sup>th</sup> – 13<sup>th</sup> May 2016 in Washington DC and the 5<sup>th</sup> from 24<sup>th</sup> – 28<sup>th</sup> October 2016 in Dublin.

**Outlook:** In 2017, there will be further contribution to international standard development.

### 6.2. Workstream: WG2: Biobanks and Bioresources

**Aim:** The ISO/TC 276 Working Group 2 Biobank and Bioresources agreed to compile a package of international standards in the biobanking field that include human, animal, plant and microorganisms.

**Achievements:**

- **Delivering BBMRI-ERIC's comments to Working Group 2:** The quality expert working groups provided their comments to standard developments.
- **Participation in ISO/TC Working Group 2 webinar meetings** 7<sup>th</sup> March 2016, 7<sup>th</sup> September 2016
- **Participation in ISO/TC 276 Plenary meetings:** The 4<sup>th</sup> meeting was held from 9<sup>th</sup> – 13<sup>th</sup> May 2016 in Washington DC and the 5<sup>th</sup> from 24<sup>th</sup> – 28<sup>th</sup> October 2016 in Dublin.

**Outlook:** In 2017, there will be further contribution to international standard development.

### 6.3. Workstream: WG3 Analytical Methods

**Aim:** The ISO/TC Working Group 3 Analytical methods is elaborating standards for molecules and entities, including nucleic acids, proteins and cells.

**Achievements:**

- **Including experts** BBMRI.it nominated experts for the development of Cell Counting – Part 1: General guidance on cell counting methods and Cell Counting – Part 2: Experimental design and statistical analysis to quantify counting method performance.

**Outlook:** In 2017, there will be further contribution to international standard development.

### 6.4. Workstream: WG4: Bioprocessing

**Aim:** The ISO/TC 276 Working Group 4 Bioprocessing is identifying standardisation needs in four major technology spaces (component material control, bioreactor processes, collection/separation/purification/formulation, and handling/transporting/storage). The Role of BBMRI-ERIC is to keep track of the developments of the Working Group 4 and to act as an information hub for the BBMRI-ERIC community.

**Achievements:**

- **Participation in Working Group meetings and Dissemination and Commenting on new technologies** The ISO/TC 276 Working Group 4 Bioprocessing mainly focuses on new technologies such as material technology, purification and formulation methods. The new technologies are not, however, linked to biobanking and is therefore irrelevant to BBMRI-ERIC at present.

**Outlook:** In 2017, contribution to the international standard development will continue. Working Group 4 will monitor if any interface to biobanking occurs.

## 6.5. Workstream: WG5: Data Processing and Integration

**Aim:** ISO/TC 276 Working Group 5 develops standards necessary for reliable and reproducible upstream data integration, i.e., further processing data generated using standards delivered by Working Groups 2-4. There are several parallel activities in this Working Group: from bringing community standards from the systems biology domain to international standard level, to semantic descriptions of generated data and provenance information management.

### **Achievements:**

- **BBMRI-ERIC proposed a substantial part of the initial set of use cases** for this Working Group during the meeting in Japan in 2015 and further maintained these use cases throughout the year.
- **BBMRI-ERIC proposed developing a standard on provenance information**, which allows linking the complete chain starting with the source of the biological material, its repositories and including any data generated. Consensus was reached within the Working Group that this is an important issue and BBMRI-ERIC started developing of a formal Preliminary Work Item (PWI) after the meeting on 24<sup>th</sup> – 28<sup>th</sup> October 2016 in Dublin.

**Outlook:** In 2017, we expect the PWI to be presented for voting to the whole ISO/TC 276.

## 7. Work Plan: Bioimaging

### 7.1. Workstream: Biobanks Meet Imaging

**Aim:** The goal of the workstream is to maintain the collaboration between BBMRI-ERIC and the European Society of Radiology (ESR), to develop common data models for imaging and biobanking and integrate imaging biobanks into the BBMRI-ERIC Directory.

**Achievements:**

- The **BBMRI-ERIC/ESR meeting in Vienna** was organised as a part of the 2016 European Congress of Radiology in March 2016.
- The joint **MIABIS-Imaging Working Group was set up** in May 2016 with the aim to define high-level descriptors for the collections in imaging biobanks and imaging collections in other types of biobanks. The data model was delivered in September 2016 and presented at the 2016 *Europe Biobank Week*.<sup>41</sup> The data model and several imaging biobanks were included into the Directory 3.0 – see also Workstream 1.1 – Development of IT Gateway to European Biobanks (page 21).
- **ESR was invited to the 2016 Europe Biobank Week meeting** that included a dedicated Session C1 – ‘Medical imaging and biobanking (radiology and digital pathology)’ organised on 15<sup>th</sup> September 2016.

**Outlook:** Integration of ESR imaging biobanks into the BBMRI-ERIC Directory. Further development of the metadata model if needed.

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<sup>41</sup> Holub, P & Gibaud, B: *Biobanks and Imaging: the Bioinformatic Challenge, from MIABIS to DICOM Europe Biobank Week 2016* (EBW2016). 2016. doi:10.5281/zenodo.274544.

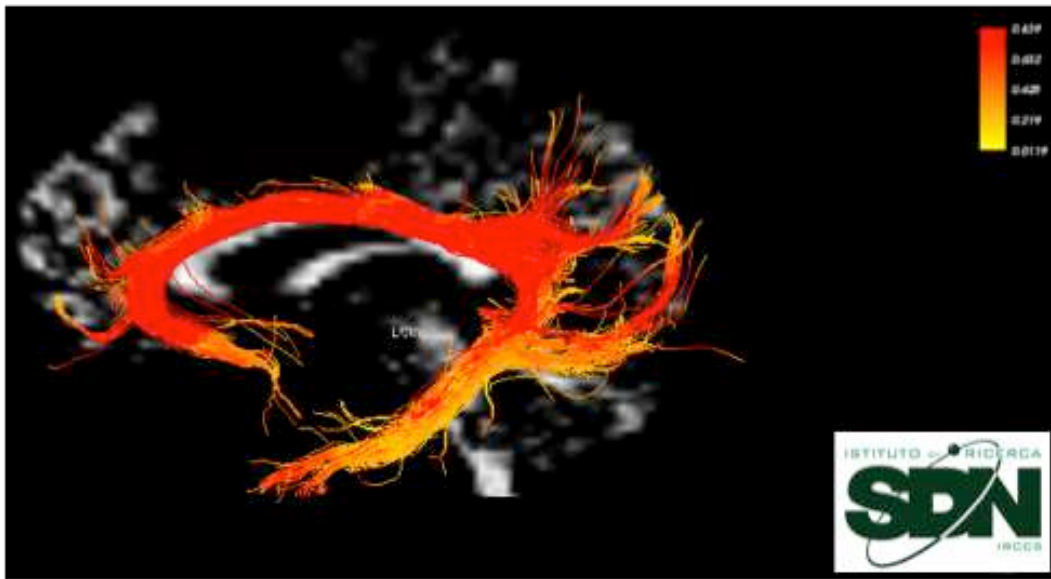


Figure 12.: Virtual dissection of Cingulum, the white matter fibers in the brain allowing the communication between components of the limbic system. Image: courtesy of IRCCS SDN, a consortium partner in BBMRI-ERIC ATMA BBMRI-ERIC Associated Expert Centres/Trusted Partners for molecular and imaging biomarkers.

## 8. Work Plan: Assessment and Improvement of BBMRI-ERIC

### 8.1. Workstream: BBMRI-ERIC Evaluation

**Aim:** Carrying out a self-evaluation of BBMRI-ERIC in terms of statutes review, governance model, Common Services principal rules, internal rules, administrative processes, and the work programme.

**Achievements:**

- **Planning self-evaluation:** The self-assessment procedure was discussed at several BBMRI-ERIC governance meetings in 2016. Additionally, a meeting with Joanneum Research Forschungsgesellschaft GmbH Policies – Institute for Economic and Innovation Research took place in April 2016 to explore their potential to operate as an external party evaluating the operations of BBMRI-ERIC.
- **Scientific Retreat:** Performance indicators for the self-evaluation were discussed and re-worked during the scientific retreat in May 2016.

Deferred:

- **Self-evaluation in conjunction with AoM meeting:** The process for the self-evaluation will be discussed in 2017.

**Outlook:** In-depth discussions on the process of the self-evaluation of BBMRI-ERIC shall be continued during the AoM#9 in May 2017. Decisions on the next steps and time-line are yet to be reached.

### 8.2. Workstream: Integrating Activities of National Nodes

**Aim:** Exploring the way the National Nodes and their national/regional activities can benefit from the ERIC status (e.g., by establishing a framework agreement so that nodes can benefit from VAT exemption).

Deferred:

- **Draft process document ready:** The drafting process for the document template for a framework agreement with regard to VAT exemption was initiated in 2016. So far, there have been exchanges with three National Node Directors (Austria, France, Italy).

- ***Assembly of Members approves 2016 Work Programme amendments including process:*** Postponed to 2017.
- ***Quarterly Finance Committee sessions:*** The Finance Committee had one teleconference on the 17<sup>th</sup> October 2016 to discuss the 2017 budget.

**Outlook:** In-depth discussions shall be continued and ultimately finalised in the form of a template framework agreement to be adopted by BBMRI-ERIC Members in 2017.



Figure 13.: Alex Felice (Director of BBMRI.mt)



## 9. Work Plan: Biobank Outreach

### 9.1. Workstream: Biobanking Conference (formerly HOBBS)

**Aim:** The conference is a yearly event of BBMRI-ERIC hosted by a National/Organisational Node.

**Achievements:** The 2016 conference was titled 2016 *Europe Biobank Week: Biobanking for Health Innovation*<sup>42</sup> and took place 13<sup>th</sup> – 16<sup>th</sup> September 2016 in Vienna, Austria. The conference was co-organised by BBMRI-ERIC and ESBB reaching a total audience of 700 participants and 150 industrial partners.

**Outlook:** In autumn 2016, ISBER joined BBMRI-ERIC and ESBB to form a strategic to co-organise one biobanking conference jointly. The conference will take place on 13<sup>th</sup> – 15<sup>th</sup> September 2017 in Stockholm, Sweden. It is titled the 'Global Biobank Week: Towards Harmony in Biobanking'.



Figure 14.: The forces behind 2016 *Europe Biobank Week*: Cornelia Stumptner (BBMRI.at), Erik Steinfelder (President-Elect 2016 ESBB), Kurt Zatloukal (Director of BBMRI.at) and Jan-Eric Litton (Director General BBMRI-ERIC).

<sup>42</sup> <http://europebiobankweek.eu/>

## 10. Work Plan: Continued Workstreams

### 10.1. Workstream: Scientific Retreat with the BBMRI-ERIC National Nodes

The BBMRI-ERIC Scientific Retreat #3 took place in Athens in May 2016. BBMRI-ERIC presented its 2015 Annual Report while the National Nodes shared their reports as well as the challenges they face. There was also some group effort geared towards the documentation and selection of BBMRI-ERIC performance indicators.



Figure 15.: Scientific Retreat in Greece, May 2016: Outi Törnwall (BBMRI-ERIC), Anu Jalanko (Director of BBMRI.fi), Andres Metspalu (Director of BBMRI.ee) and Michaela Th. Mayrhofer (BBMRI-ERIC).

## 10.2. Workstream: Central Executive Management Office

The BBMRI-ERIC Headquarters in Graz are led by Director General Prof. Jan-Eric Litton (since 2014). He is responsible for the executive management of BBMRI-ERIC and the coordination/co-ordination of the H2020 ADOPT BBMRI-ERIC (page 130), Rltrain (page 139) and CORBEL (page 134) projects. The Headquarters will continue its activities as specified in Article 13 of the BBMRI-ERIC Statutes.



Figure 16.: Central Executive and Management Office/Headquarters. From left: Nadja Palko (Communication Officer), Meghan McCarroll (Secretary/Receptionist), Petr Holub (Senior IT/Data Protection Manager and Chief Information Officer of the Common Service IT), Michaela Th. Mayrhofer (Senior Project Manager and Chief Policy Officer of the Common Service ELSI), Andrea Wutte (Quality Manager), Jan-Eric Litton (Director General), Carmen Cirstea (Finance/Administration Assistant), Markus Pasterk (Administrative Director), Outi Törnwall (EU Project Manager) and Luc Deltombe (Finance/Communication Assistant).

## 10.3. Workstream: Communication

BBMRI-ERIC's communications and media relations strategy is designed to provide customised information to its user community and stakeholders in a timely manner. It builds on the following key elements:

- a public website (relaunched by way of silent release in August 2016, featuring a new design);
- media engagement (esp. press releases and briefings);
- public and internal information campaigns using new media (Twitter, LinkedIn), a monthly e-Newsflash (disseminated via MailChimp including 5,000+ subscribers), mailing lists;
- graphic design and marketing material.

## 10.4. Workstream: Webinars

Informational thematic webinars as well as virtual working sessions on specific topics such as quality, ELSI and IT were organised on a regular basis.

For example, webinars for Quality Expert Working Groups:

For example: Expert Working Group 1–5:	Initiation:	3 webinars
Expert Working Group 1:	snap frozen tissues (35 participants):	7 webinars
Expert Working Group 2:	FFPE tissues (36 participants):	7 webinars
Expert Working Group 3:	Venous whole blood (39 participants):	7 webinars
Expert Working Group 4:	Metabolomics (28 participants):	3 webinars
Expert Working Group 5:	QMS (37 participants):	7 webinars

## 10.5. Workstream: Biobanks Europe Newsletter/Magazine

Issue #4 and #5 of *Biobanks Europe*, a periodical magazine of BBMRI-ERIC, available in print and as pdf download were published. Special issue #6 on quality was prepared late 2016 and will be published in 1Q 2017.

## 10.6. Workstream: Education and Training

The Working Party for Education & Training Strategy met during the 2016 *Europe Biobank Week* to discuss the potential alignment of the five existing Master's programmes in biobanking offered by the Catholic University of Lyon, the Catholic University of Valencia, King's College London, the Medical University Graz, and the Université Côte d'Azur. During this meeting, potential funding instruments for better cooperation such as Marie Curie network applications in H2020, an ERASMUS application or a COST action were explored. Further follow-up meetings are foreseen.

## 10.7. Workstream: Infectious Material

In 2016, BBMRI-ERIC and EVAg signed an agreement to explore options for integrating EVAg into BBMRI-ERIC as a Common Service. This may include joint education and training activities. The aim of this workstream is to develop a common strategy on how biobanks with infectious material should be integrated into BBMRI-ERIC based on the cooperation with ERINHA<sup>43</sup> and EVAg.<sup>44</sup>

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<sup>43</sup> European Research Infrastructure on Highly Pathogenic Agents, <http://www.erinha.eu/>

<sup>44</sup> European Virus Archive goes global, <http://www.european-virus-archive.com/>

## 10.8. Workstream: Expert Centres

BBMRI-ERIC Associated Expert Centres/Trusted Partners<sup>45</sup> are non-profit organisations representing a novel public-private partnership model. They are responsible for the analysis of samples in the country of origin according to international standards and for the generation of primary data. BBMRI-ERIC Associated Expert Centres/Trusted Partners integrate pre-competitive public and private research and development activities by providing access to both biological samples and medical data and to the broad spectrum of medical and scientific expertise related to the samples and data, as well as relevant analysis. In order to guarantee excellence, BBMRI-ERIC evaluates all candidates applying for the status of BBMRI-ERIC Associated Expert Centre/Trusted Partner before their inclusion and approval.

In June 2016, CBmed GmbH<sup>46</sup> was certified as the first BBMRI-ERIC Associated Expert Centre/Trusted Partner. CBmed GmbH, an Austrian funded competence center, combines an excellent research infrastructure with scientific expertise and medical knowledge and provides a link to national and international industry partners for systematic medical biomarker research.

In October 2016, the ATMA-EC<sup>47</sup> consortia became the second certified BBMRI-ERIC Associated Expert Centre/Trusted Partner for biomarker research. The ATMA-EC Expert Centre links Centro di Riferimento Oncologico – CRO, Aviano (PN), Italy; IRCCS SDN – Napoli, Italy; Università degli Studi di Milano Bicocca, Milan, Italy and Associazione Nazionale per lo Sviluppo delle Biotecnologie – As-sobiotech, Milan, Italy.

The EXCEMET<sup>48</sup> consortia were identified as an Expert Centre candidate for metabolomics.

## 10.9. Workstream: Fundraising Activities

BBMRI-ERIC continued its activities to receive additional funding for its core activities (in 2016, for call topics under H2020-JTI-IMI2-INT-2015-03239, H2020-EINFRA-2016-2017, MSCA-RISE-2016, H2020-FETOPEN-1-2016-2017, COST OC-2016-1, H2020-INFRADEV-2016-2017, H2020 WIDESPREAD-2016-2016, H2020-SwafS, and H2020-SC1-2016-2017). BBMRI-ERIC participated in research project consortia as (co-/)coordinator, participant/contributor or associated organisation that supports research consortia with a letter of intent. Between January and October 2016, BBMRI-ERIC participated in 18 proposals. Between 2014 and 2016, BBMRI-ERIC has been involved in a total number of 42 H2020 calls (thereof: three as coordinator/co-coordinator), of which 11 proposals were accepted and are active in 2016 (thereof: all three as coordinator/co-coordinator). **This equals an overall success rate of 26%, in contrast to the average rate of 14%.** BBMRI-ERIC is non-discriminatory as regards the scope of the project, whether scientific or infrastructural. BBMRI-ERIC assessed each project application within its Management Committee which consists of the Director General of BBMRI-ERIC, the Directors of the National/Organisational Nodes and the Directors of the Common Services. As a general principle, BBMRI-ERIC encouraged the inclusion of one or more National/Organisational Nodes, depending on the specific aims of the proposed project or their areas of expertise (e.g., rare diseases, cancer).

<sup>45</sup> Wutte, A & Litton, JE: *BBMRI-ERIC-Associated Expert Centres/Trusted Partners V2.0* 2015. doi:10.5281/zenodo.164634.

<sup>46</sup> <http://www.cbmed.org/en/index.php>

<sup>47</sup> <http://atma-ec>

<sup>48</sup> <http://www.excemet.org>



Figure 17.: CBmed became the first BBMRI-ERIC Associated Expert Centre/Trusted Partner in 2016.

The BBMRI-ERIC Working Group Financial Workflows continued (a) to simplify the Linked Third Party Agreement which enables National/Organisational Nodes to participate in H2020 applications and (b) to explore if and how National/Organisational Nodes can benefit from BBMRI-ERIC's VAT exemption to purchase equipment and services. The template for the Framework Agreement for Linked Third Parties was finalised with support of the Finance Committee chair during summer 2016 (implementation ongoing). The VAT exemption is specified in the Framework Agreement Template as specified in Workstream 8.2 Integrating Activities of National Nodes.

## 10.10. Workstream: Stakeholder Forum

Stakeholders can affect or be affected by an organisations actions, objectives and policies. For BBMRI-ERIC, it is thus of high strategic importance to learn about the perspectives, concerns and interests of key stakeholders such as patient organisations, industry, learned societies and user communities. In 2016, it became necessary re-conceptualising the Stakeholder Forum (details see Work Programme 2017, pages 29–31).

The chairperson of the Stakeholder Forum shall be a patient advocacy group representative and will be automatically a member of the BBMRI-ERIC SEAB. Currently, Alastair Kent (Genetic Alliance UK) is the chair. In Q2 2016, the patient chapter was established and the stakeholder engagement initiative was officially relaunched. Having identified patients as the most crucial stakeholder group,

BBMRI-ERIC firstly met with representatives of patient advocacy groups representing areas of expertise on genetics, rare diseases, chronic diseases, healthy ageing/prevention, degenerative diseases, cancer, obesity, and infectious diseases to explore the relaunch of BBMRI-ERIC’s stakeholder engagement with them. The patient group stakeholders included the European Institute of Women’s Health, the European Cancer Patient Coalition, EURORDIS – Rare Diseases Europe, Genetic Alliance UK, Alzheimer Europe, and the Dutch VSOP. The meeting took place in Brussels on 19<sup>th</sup> April 2016. It marked the beginning of a transparent consultation and participatory stakeholder engagement process, which will be enlarged by additional chapters involving industry and learned societies representatives in 2017 (e.g., EFPIA, ESR, etc).

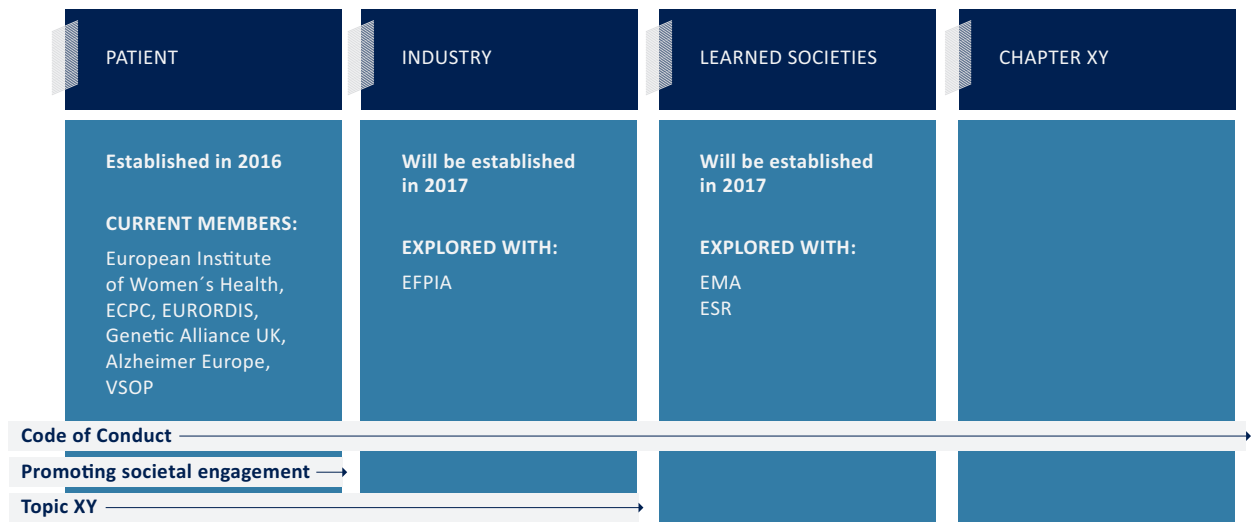


Figure 18.: Stakeholder Forum: organisational chapters and thematic topics.

**Part II.**

**2016 Activities and Achievements  
BBMRI-ERIC National/Organisational  
Nodes**



## 11. Members and Observers

### BBMRI.at (Member)

#### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €306.4 billion

**Population:** 8.6 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
4 biobanks

#### National Node

**Start date:** 1<sup>st</sup> December 2013

**Director:** Kurt Zatloukal

**Total staff (FTE/year and headcount):** 7.5 FTE/year and 36 persons on the 2016 payroll (employment ranging from 5–100% and 1–12 months)

**Total funding (period):** €3.5 million

**Funding body:** Federal Ministry of Science, Research and Economy (BMWF) (GZ 10.470/0016-II/3/2013)

**Legal entity of/hosting institution of National Node:** Medical University of Graz

**Partners (total 7):** *Medical University of Graz; Medical University of Vienna; Medical University of Innsbruck; University of Veterinary Medicine, Vienna; Paracelsus Medical Private University, Salzburg; Life Science Governance Institute, Vienna (until Oct 2016), and University of Vienna (since Nov 2016); and Alpen-Adria-University Klagenfurt.*

**Web:** <http://www.bbmri.at>

**National Catalogues:** <http://catalog.bbmri.at/>

### About

With its partner universities and biobanks, BBMRI.at establishes and further develops the Austrian biobanking research infrastructure and integrates it into BBMRI-ERIC. It increases the close co-operation and harmonisation between Austrian biobanks with respect to sample, data and quality management and engages its stakeholders, particularly citizens/patients and industry stakeholders. This is a prerequisite for facilitating access to biological samples and data for academic and industrial research and for fostering their use.

## Specific Strengths

- Expert contribution to CEN/TS and ISO standards (e.g., CEN/TC 140, ISO/TC 212, ISO/TC 276)
- Development of a Self-Assessment Tool to assess conformity with CEN/TS and its joint development for pan-European use with the BBMRI-ERIC QM expert group
- Organisation of hands-on training courses for pre-analytical sample processing,<sup>49</sup> building biobanks,<sup>50</sup> as well as a MSc (Master of Science) in Biobanking<sup>51</sup>
- Biobank Graz<sup>52</sup> – one of the largest biobanks in Europe awarded with several prizes
- Commitment of all BBMRI.at-associated biobanks to QM cross-audits (starting 2017)
- Conduction of Citizen Expert Panels and workshops with citizens/patients and experts (from ethics committee, patient organisations, biobanks)
- VetBiobank<sup>53</sup> with non-human/animal biospecimens and data
- Translational Science Forum with industry representatives
- 1<sup>st</sup> BBMRI-ERIC expert center for biomarkers (CBmed)
- Standardised Biomaterial Material Transfer Agreement (MTA) templates (human, animal) jointly developed by interdisciplinary experts from universities and industry

## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

### *e-Infrastructure*

- All BBMRI.at biobanks in the BBMRI.at Catalogue and BBMRI-ERIC Directory 2.0
- Initiation of a national digital pathology infrastructure to complement biobank tissue samples with digital image information
- Development of BIBBOX<sup>54</sup> —a repository for biobank open source software—and further development of this tool within B3Africa
- Active participation in the BBMRI-ERIC Common Service IT
- Report on the potential use of ELGA for BBMRI.at

### *Quality*

- Expert contribution to CEN/TS and ISO standards
- Providing and developing BBMRI.at's CEN/TS Self-Assessment Tool to BBMRI-ERIC
- Participation in 5 BBMRI-ERIC QM Expert Groups; co-lead in Blood QM Expert Group
- Advanced implantation of CEN/TS in biobanking workflows
- Comparative study of metabolome profiles of large European cohorts (in BBMRI-LPC (page 132))

### *Clinical Biobanks*

- Contribution to the development of a set of data on colon cancer collections in ADOPT BBMRI-ERIC (page 130)
- Development of a show case to use the colon cancer cohort for imaging biomarkers colon cancer in ADOPT BBMRI-ERIC (page 130)
- Biobank Graz elected 'Best European Academic Biobank'

<sup>49</sup> [http://bbmri.at/news/-/asset\\_publisher/xLKisOx4tBQH/content/3-days-laboratory-course-on-pre-analytical-sample-processing-in-biobanking](http://bbmri.at/news/-/asset_publisher/xLKisOx4tBQH/content/3-days-laboratory-course-on-pre-analytical-sample-processing-in-biobanking)

<sup>50</sup> [https://www.medunigraz.at/veranstaltungen/detail/cal/2015/09/16/event/tx\\_cal\\_phpicalendar/how\\_to\\_build\\_a\\_biobank\\_learning\\_by\\_doing/](https://www.medunigraz.at/veranstaltungen/detail/cal/2015/09/16/event/tx_cal_phpicalendar/how_to_build_a_biobank_learning_by_doing/)

<sup>51</sup> <http://postgraduate-school.medunigraz.at/universitaetslehrgaenge/masterlehrgaenge/msc-in-biobanking/>

<sup>52</sup> <https://www.medunigraz.at/biobank/>

<sup>53</sup> <http://www.vetmeduni.ac.at/de/vetcore/research/researchunits/vetbiobank/>

<sup>54</sup> <http://demo.bibbox.org/>

- Participation in the 2<sup>nd</sup> ERINHA preparatory phase (biobanking in high security labs)

#### *Population-based Cohorts*

- Cooperation with the Human Biomonitoring Platform Austria, a member of the European Human Biomonitoring Initiative for harmonising human biomonitoring initiatives (HBM4EU)<sup>55</sup>

#### *ELSI*

- Organising three Citizen Expert Panels (Vienna, Graz, Innsbruck)
- 1<sup>st</sup> public workshop titled 'Use of Patients' Health Data in Biobanking' with citizens, ethic committees, patient organisations, ELSI and biobanking experts (at 2016 *Europe Biobank Week*)
- Definition of technical, ethical, legal and governance-related requirements for the implementation of the General Data Protection Regulation
- Jointly developed and recognised informed consent and Standard Material Transfer Agreement Templates and Guidelines for human and animal biomaterial<sup>56</sup>
- Participation in the BBMRI-ERIC Common Service ELSI (Task Force Societal Issues) as ELSI experts
- Public activities, e.g., at 'Lange Nacht der Forschung', and contribution to documentary movie 'Golden Genes',<sup>57</sup> including participation in the premieres and panel discussions (Vienna, Graz)

#### *Expert Centres*

- Support of the application of CBmed GmbH<sup>58</sup> as 1<sup>st</sup> 'BBMRI-ERIC Associated Expert Centre/Trusted Partner' (granted in June 2016)
- Further development of the Expert Centre model for other research infrastructures (in CORBEL (page 134))
- Expert opinion on intellectual property in the context of open innovation in CORBEL (page 134)

#### *Education & Training*

- Co-initiator and local organiser of the 2016 *Europe Biobank Week* in Vienna, Sept 2016
- Co-organisation of the BBMRI National Node Meeting (Nice, FR) together with BBMRI.fr, BBMRI.it and BBMRI-ERIC
- Offering courses (e.g., on pre-analytics, building a biobank) and master in biobanking

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<sup>55</sup> [http://www.umweltbundesamt.at/en/news\\_events\\_reports/news\\_eaa/en\\_news\\_2017/news\\_en\\_170203/](http://www.umweltbundesamt.at/en/news_events_reports/news_eaa/en_news_2017/news_en_170203/)

<sup>56</sup> <http://bbmri.at/biomaterial-mta>

<sup>57</sup> [http://bbmri.at/news/-/asset\\_publisher/xLKisOx4tBQH/content/movie-film-goldene-gene-biobanking-goes-cinema](http://bbmri.at/news/-/asset_publisher/xLKisOx4tBQH/content/movie-film-goldene-gene-biobanking-goes-cinema)

<sup>58</sup> <http://www.cbmed.at/en/index.php>

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10. Wallner-Liebmann, S, Tenori, L, Mazzoleni, A *et al.*: Individual Human Metabolic Phenotype Analyzed by (1)H NMR of Saliva Samples. *Journal of proteome research* **15**, 1787–1793 (2016).
11. Viertler, C, Kap, M, Kruhoffer, M *et al.*: 'Comprehensive characterization of ischemia effects on gene expression in human liver'. *VIRCHOWS ARCHIV* **469**. [Poster] (2016), S197–S197.
12. Oberauner-Wappis, L, Loibner, M, Ulz, C *et al.*: 'Application of the GeneReader NGS System in Analyzing a Diverse Set of Cancer Clinical Samples'. *Journal of Molecular Diagnostics* **18**. [Poster] (2016), 1038–1038.

## BBMRI.be (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €455.1 billion

**Population:** 11.4 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:** 13 biobanks, 22 collections and 3 networks

### National Node

**Start date:** 1<sup>st</sup> January 2013

**Director:** Annelies Debuquoy (Deputy: Karin Haustermans/Sofie Bekaert/Etienne Marbaix)

**Total staff (FTE/year and headcount):** 1.25 FTE/year and 4 members of staff

**Total funding (period):** The different biobank networks are funded by several funding bodies. The Belgian Science Policy Office (BELSPO) contributes with the annual BBMRI-ERIC membership fee. The Belgian Cancer Registry is financed by the Belgian Ministry of Public Health for the setup of the Coordination Office and the BBMRI.be IT platform. The Belgian Virtual Tumorbank (BVT) and 11 local partner biobanks receive funding from the Belgian Ministry of Public Health from 2009 on for an indefinite period. BWB is supported by DGo6 (Walloon region) and Innoviris (Brussels capital region). The Flemish Biobank Initiative is financed by IWT and by the Flemish Government.

**Funding body:** BELSPO, Belgian Ministry of Public Health, DGo6, Innoviris, IWT and Flemish Government

**Legal entity of/hosting institution of National Node:** Belgian Cancer Registry **Partners (total 13):** *Brugmann University Hospital; University Hospital of Liege; University Hospital of Mont-Godinne; Institut de Pathologie et de Génétique; St-Luc University Hospital; Erasme Hospital; Jules Bordet Institute; University Hospital of Ghent; University Hospital of Antwerp; University of Hasselt; University Hospital Leuven; University Hospital Charleroi; University Hospital Brussels.*

**Web:** <http://www.bbmri.be>

**National Catalogues:**

<http://www.virtualltumourbank.kankerregister.be/>

<http://www.biotheque-wallonie-bruxelles.be/>

<https://vlaamsebiobank.cmi-vzw.be/>

## About

Belgium's scientific participation in BBMRI-ERIC is exerted by a National Node, which collaborates closely with the Central Executive Management Office and involves the three Belgian network biobank initiatives, i.e., the Belgian Virtual Tumorbank project assigned to the Belgian Cancer Registry (BVT-BCR; Federal Initiative), the Bibliotheque de la Fédération Wallonie-Bruxelles (BWB; Walloon Initiative) and the Flemish Biobank Network (Flemish Initiative). Altogether, this network connects 13 biobanks that are linked to public institutions such as hospitals, universities and research centres.

## Specific Strengths

- High number of clinical biobanks with high quality samples and associated data.
- Three sample locators with sample-level data available; one with oncological samples and two sample locators with samples and data collected from patients with a broad range of diseases (e.g., hepatotropic viruses, diabetes, inflammatory bowel disease, rheumatoid arthritis etc.).

## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

### *e-Infrastructure*

- All BBMRI.be biobanks are included in the BBMRI-ERIC Directory.
- On 29<sup>th</sup> January 2016, the three biobank networks of BBMRI.be (BVT, BWB, CMI) presented their Sample Locators in a webinar organised by the BBMRI-ERIC Common Service IT.
- BBMRI.be representatives completed a questionnaire about the available services in the local biobanks provided by the Common Service IT (WP4).

### *Quality*

- Ten BBMRI.be Quality Experts joined the BBMRI-ERIC Quality Working Group that developed the Self-Assessment Surveys for CEN/TS and quality management systems.

### *Clinical Biobanks*

- Nine BBMRI.be biobanks expressed their interest in participating in the colon cancer collection project initiated by ADOPT BBMRI-ERIC (page 130)

### *Population-based Cohorts*

- Currently, no biobank specialised in population-based cohorts is a member of BBMRI.be
- Negotiations with two Belgian biobanks with population-based cohorts to be included within BBMRI.be are ongoing

### *ELSI*

- BBMRI.be has seconded two ELSI experts to BBMRI-ERIC
- Feedback was given about WMA Consultation on its Draft Declaration on Health Databases and Biobanks
- Contribution to the OECD questionnaire about recommendations of the OECD Council on human biobanks and genetic research databases.
- Attendance of Common Service ELSI meetings: Towards Mutual RECOgnition, ELSI Team meeting and 2016 *Europe Biobank Week* on Data Protection Code of Conduct.

### *Expert Centres*

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### *Education & Training*

- At the different Belgian universities, several biobank-related courses are organised as part of the Master of Science in Biomedical Sciences and the Bachelor in Biomedical Laboratory Technology with a focus on courses about quality and ELSI, e.g., Quality Management for Biomedical Laboratories; Good Laboratory Practice; Bio-Ethics in Experimental Medicine; Proteomics, Genomics, Metabolomics.

- One day symposium (22<sup>nd</sup> June 2016) on personalised medicine co-organised by the Flemish Biobank Network: “From Person to Medicine: Connecting and Collecting for the Future”
- Biobank managers meeting (15<sup>th</sup> November 2016): meeting organised by the Belgian Cancer Registry to update biobank managers about the new rules and regulations in the biobanking field and give training concerning the registration of tumour samples in the Belgian Virtual Tumorbank
- Biobanking symposium. ULB Network (3<sup>rd</sup> December 2016)

## **Publications**

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## BBMRI.ch (Observer)

### Country

**Year joining BBMRI-ERIC:** 2015

**GDP:** €485.13 billion

**Population:** 8.1 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
0 biobanks

### National Node

**Start date:** 1<sup>st</sup> January 2015

**Director:** Cristine Currat

**Total staff (FTE/year and headcount):** 6.8 FTE/year

**Total funding (period):** €3.2 million (2015–2018)

**Funding body:** Swiss National Science Foundation (SNSF)

**Legal entity of/hosting institution of National Node:** Swiss Biobanking Platform Association

**Partners (total):**

**Web:** <http://www.bbMRI.ch> or <http://www.swissbiobanking.ch>

**National Catalogues:** under construction

## About

The Swiss Biobanking Platform (SBP) is the newly created national coordination platform for human and non-human biobanks. It was initiated by the Swiss National Science Foundation (SNSF) in response to increasing requests from biomedical researchers regarding quality and the interconnectedness of biobanks for research purposes.

SBP's vision is to help Switzerland consolidate its position at the forefront of biomedical research by facilitating access and optimal usage of its existing and future biobanked specimens. SBP's mission is to develop a reliable, customer-oriented, network of biobanks in Switzerland using harmonised processes.

## Specific Strengths

Support and harmonisation of biobanking activities within the five University Hospitals through:

- Development of a quality strategy aligned with the future ISO norm on biobanking and serving the majority of biobanks
- Public engagement
- Broad consent for research: implementation and communication strategy
- Development of an IT strategy that allows professionalisation and interconnection of biobanks



## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

### *e-Infrastructure*

- Development of an internal database (DB) aggregating information on multiple biobanks in collaboration with the Swiss Institute of Bioinformatics (SIB). This DB allows a first overview of the Swiss biobanks with a manual input by SBP hub coordinators, in a standardised manner. In a second step, once BIMS systems have been deployed in the different biobanks, the DB will use the BIMS API to programmatically get information from the biobanks, thus allowing an automatic update of sample information
- SBP will work on the standardisation of data and, if not possible, the DB will be used to create conversion tables to get a web catalogue summarising sample availability and characteristics in Switzerland for sharing purposes.
- Development of a BIMS solution integrating a common basic module with a minimal dataset for biobanks (preanalytic data that should be documented and variables that should be used). Interface between the BIMS and the catalogue should be constructed as well. SBP evaluated the BIMS user side while SIB compared the different solutions in terms of interoperability and connectivity.

### *Quality*

- Sample quality: SBP shall promote sample sharing. In order to do so, comparable and good quality samples are needed. A prerequisite is standardising or at least harmonising practices. This is within the responsibility of the different working groups on tissue, liquid and microbiology that have been launched in order to support change management in the respective areas.

Quality Management System (QMS): In order to bring added value to biobanks, SBP will raise the level of quality management around biobanking by developing the following:

- Standardisation: SBP will develop guidelines for good biobanking practice for the management, operation, access and use of biobanks to guide biobanks towards quality.
- Quality support: development of a self-assessment tool, ELSI QC tools and toolkits. SBP also aims to propose audits or training in the long term.

### *Clinical Biobanks*

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### *Population-based Cohorts*

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### *ELSI*

- Broad, national consent for research is in consultation in Switzerland, and SBP will be the body responsible for its implementation in the different hospitals. Best practices have been developed and reviewed by a multidisciplinary panel of experts from ethics committees to patients' associations.
- SBP plans to support Swiss institutions to be aligned with the Declaration of Taipei on Ethical Considerations in Health Databases and Biobanks, adopted by the World Medical Association in October 2016. To that end, SBP will promote establishing what clear governance issues in hospitals are in terms of biobanking.

- SBP is developing a “one stop shop” approach to promote better usage and access to biological samples and data for research following clear, harmonised processes. This includes proposing material transfer agreements, biobank regulations as well as a reflexion on sample prices. All the information will be collected and used to develop access and benefit sharing guidelines for researchers from academic and private companies.

*Expert Centres*

-

*Education & Training*

-

*Publications*

-

## BBMRI.cy (Observer)

### Country

**Year joining BBMRI-ERIC:** 2016

**GDP:** €17.37 billion

**Population:** 848,300

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
2 biobanks

### National Node

**Start date:** Not yet established

**Director:** –

**Total staff (FTE/year and headcount):** –

**Total funding (period):** –

**Funding body:** –

**Legal entity of/hosting institution of National Node:** Ministry of Health (tbc) **Partners (total 2):** *University of Cyprus, The Cyprus Institute of Neurology and Genetics*

**Web:** –

**National Catalogues:** <http://www.ucy.ac.cy/mmrc> and <http://www.cing.ac.cy>

## About – University of Cyprus

BBMRI.cy is still at initial stages mainly because of limited state funding. There is minimal state support and it operates on research grants, also funded partly by the hosting organisation, the University of Cyprus. Nevertheless, the biobanking community in Cyprus is making serious efforts to convince state authorities of the need to provide permanent annual support for maintaining this research infrastructure. During the past few years, biobanking has led to positive results with regard to upgrading research and diagnostic procedures in inherited disorders. It is a positive sign that more people are interested in using the small, high-quality repositories created so far. Considering that the Biobank is presently focused on inherited disorders, the achievements are obvious in terms of novel discoveries and introduction of new diagnostics. The Biobank is operated within the Molecular Medicine Research Center, an independent research unit and infrastructure at UCY.

## Specific Strengths

- The two biobanks operating in Cyprus specialise in inherited disorders and are mainly funded through research projects. In the case of the University of Cyprus/Molecular Medicine Research Center (UCY/MMRC) Biobank, there is substantial internal funding for maintaining the operation of the infrastructure. There is cooperation with public hospitals and doctors in the private domain.
- The infrastructure enables genetics/genomics work including next generation sequencing technology and cell biology work.
- The personnel has specific expertise and a strong track record in inherited kidney disorders with European and global presence.

- The MMRC has strong links with the nephrology medical community and close contacts and collaborations with the patients' organisations as major stakeholders in our field of activity.

## **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

We have expertise regarding inherited kidney disorders and inherited cancers. The particularities of the Cypriot gene pool have allowed Cypriot researchers to generate data that do not only have an impact on the local, but also the global population. However, being Observers and without adequate independent funding it is difficult to contribute substantially to the BBMRI-ERIC pan-European effort.

### *e-Infrastructure*

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### *Quality*

- We have not been able yet to implement specific quality measures through ISO certification, but we make every effort to maintain high quality material.

### *Clinical Biobanks*

- The UCY/MMRC Biobank has been specializing on polycystic kidney disease and other monogenic rare kidney disorders. Based on research funding during the past several years there is focus on inherited glomerulopathies with the follow-up of two cohorts, one with Alport syndrome and thin basement membrane nephropathy and one with C3 glomerulopathy/CFHR5 nephropathy with positive results and high impact publications. A third unique cohort is for medullary cystic kidney disease 1 (more recently renamed MUC1 kidney disease), with more than 160 patients, mostly at the south-west part of the island. Importantly, these specific cohorts are characterised by the inheritance of founder mutations. These cohorts and additional archived records attracted already the interest of local and external academic organisations and a pharmaceutical company for exploiting the biological material for innovative research aimed at identifying new genes and new targets for therapy.

### *Population-based Cohorts*

-

### *ELSI*

- ELSI is mainly monitored by the Cyprus National Bioethics Committee which must evaluate and approve every research project that includes human beings and/or human biological material. Also, researchers need to have permission from the Cyprus Commissioner of the Protection of Personal Data.

### *Expert Centres*

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### *Education & Training*

- The MMRC Center is a popular training destination for younger researchers and hosts several fellows every summer

- As part of the UCY, it constantly hosts students completing their diploma BSc theses or their MSc and PhD dissertations

### **Publications**

1. Savva, I, Pierides, A & Deltas, C: RAAS inhibition and the course of Alport syndrome. *Pharmacol. Res.* **107**, 205–210 (2016).
2. Gross, O, Kashtan, CE, Rheault, MN *et al.*: Advances and unmet needs in genetic, basic and clinical science in Alport syndrome: report from the 2015 International Workshop on Alport Syndrome. *Nephrol. Dial. Transplant.* (2016).
3. Papazachariou, L, Demosthenous, P, Pieri, M *et al.*: Frequency of COL4A3/COL4A4 mutations amongst families segregating glomerular microscopic hematuria and evidence for activation of the unfolded protein response. Focal and segmental glomerulosclerosis is a frequent development during ageing. *PLoS ONE* **9**, e115015 (2014).
4. Voskarides, K, Stefanou, C, Pieri, M *et al.*: A functional variant in NEPH3 gene confers high risk of renal failure in primary hematuric glomerulopathies. Evidence for predisposition to microalbuminuria in the general population. *PLoS ONE* **12**, e0174274 (2017).

### **About – The Cyprus Institute of Neurology and Genetics**

Aim: To establish and operate a national biobanking infrastructure that will provide well-annotated biological samples for the needs of the Cypriot clinical and academic research community. To assimilate and integrate existing collections into the biobank in order to provide valuable resources for fostering innovative research. To align the national biobank with EU protocols and procedures and to connect the Cyprus research community with the EU, through BBMRI.

### **Specific Strengths**

- The Cyprus Institute of Neurology and Genetics has pioneered the application of genetics and molecular biology to investigate the genetic causes for a plethora of common and rare inherited diseases. As a result of this 25-year presence, CING has developed the largest collection of biological samples and databases. These are now being assimilated to create an envious biobank featuring a population specific biological resource.
- CING has developed unique infrastructures and has already established high throughput genomic and proteomic technologies. The biobank adds substantial value to the infrastructures already available at CING and supports conducting high-calibre research on a national level.
- CING has direct links with many national stakeholders
- Organises meetings with patient advocacy associations

### **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

CING receives an annual subsidy from the Cyprus Ministry of Health to deliver specialised services in neurology, covering 10,000 patients and 75,000 laboratory diagnostic tests which cover molecular diagnostics for a range of common and rare disorders. In this context, CING operates as a national and regional referral centre in the above areas of specialization.

- CING has capacity, critical mass

- CING has unique expertise in neurology, clinical genetics and biomedical sciences
- Advanced IT infrastructure
- Efficient and successful networking with both public and private health sector

#### *e-Infrastructure*

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#### *Quality*

- Quality assurance schemes in operation
- All laboratory services are ISO15189-accredited

#### *Clinical Biobanks*

- Several collections of biological samples already available at CING

#### *Population-based Cohorts*

- CING has the largest collection of DNA samples
- CING has population-wide samples and data at its disposal, representing disorders such as thalassemia, diabetes, and cancer, amongst many others.

#### *ELSI*

- The operation and establishment of CING Biobank has been approved by the Cyprus National Bioethics Committee. The operation of the CING Biobank has also been notified to the Cyprus Commissioner for the protection of personal data.

#### *Expert Centres*

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#### *Education & Training*

- CING has established the Cyprus School of Molecular Medicine (CSMM)
- CSMM offers postgraduate programs at MSc and PhD level
- CSMM carries out executive training programs targeting professionals such as doctors and scientists
- Programs include workshops/training in biobank procedures

#### **Publications**

1. Oikonomopoulou, K, Yu, H, Wang, Z *et al.*: Association between Echinococcus granulosus infection and cancer risk - a pilot study in Cyprus. *Clin. Chem. Lab. Med.* **54**, 1955–1961 (2016).
2. Loizidou, MA, Hadjisavvas, A, Pirpa, P *et al.*: BRCA1 and BRCA2 mutation testing in Cyprus; a population based study. *Clin. Genet.* **91**, 611–615 (2017).
3. Kakkoura, MG, Sokratous, K, Demetriou, CA *et al.*: Mediterranean diet-gene interactions: A targeted metabolomics study in Greek-Cypriot women. *Mol Nutr Food Res* **61** (2017).
4. Kouis, P, Yiallourous, PK, Middleton, N, Evans, JS, Kyriacou, K & Papatheodorou, SI: Prevalence of primary ciliary dyskinesia in consecutive referrals of suspect cases and the transmission electron microscopy detection rate: a systematic review and meta-analysis. *Pediatr. Res.* **81**, 398–405 (2017).

## BBMRI.cz (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €152.6 billion (2015)

**Population:** 10.5 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
5 biobanks.

### National Node

**Start date:** 7<sup>th</sup> October 2010

**Director:** Dalibor Valík

**Total staff (FTE/year and headcount):** 3.75 FTE/year and 119 employees per the network and hospital-affiliated specialist staff

**Total funding (period):** €5 million

**Funding body:** Ministry of Education, Youth and Sports (MEYS)

**Legal entity of/hosting institution of National Node:** Masaryk Memorial Cancer Institute

**Partners (total 5):** *Masaryk Memorial Cancer Institute; First Faculty of Medicine, Charles University, Prague; Faculty of Medicine, Charles University, Hradec Králové; Faculty of Medicine, Charles University, Pilsen; Faculty of Medicine, Palacký University, Olomouc*

**Web:** <http://www.bbmri.cz>

**National Catalogues:** <https://index.bbmri.cz> (web version under preparation)

## About

The Biobank of Clinical Samples is an existing large infrastructure founded and maintained by the Masaryk Memorial Cancer Institute (MMCI) and functionally bound to the Centre for Basic and Translational Cancer Research, RECAMO. In 2000, Masaryk Memorial Cancer Institute (MMCI) formally instituted a biobanking unit spanning its two departments, the Department of Pathology and the Department of Experimental and Clinical Biochemistry, and started to support it with institutional funding. This was complemented by the hospital-integrated IT bank of biological material (BBM) module linking clinical and laboratory data to biobanking aliquots in 2004. From then on, institutional development continued until 2009, when MMCI applied in the first call of the Research Infrastructure funding with the project "Bank of Clinical Specimens" focused on cancer (BBMRI\_CZ), that was granted and initiated in October 2010. The aim of the Czech BBMRI\_CZ infrastructure was to operate a network of medical research biobanks that preserve biological samples from cancer patients long-term and under secured, standardised and accredited conditions. Otherwise, such material would be permanently lost for future biological and medical research. This process led to establishing a network of cancer research biobanks comprised of the BBM MMCI, the BBM of the 1<sup>st</sup> Faculty of Medicine at Charles University (BBM 1FM CU), the BBM of the Faculty of Medicine at Hradec Králové Charles University (FM HK CU), the BBM of the Faculty of Medicine at Pilsen Charles University (FM CU Pilsen), and the BBM of the Faculty of Medicine at Palacký University in Olomouc, (FM PU Olomouc). These biobanks are integrally linked to key healthcare providers in the Czech Republic and operate as the BBMRI\_CZ research infrastructure.

## Specific Strengths

- BBMRI\_CZ's development ambitions include assuming leadership in the field of research-oriented clinical biobanking in the Czech Republic, including setting up a network of regional biobanks to focus on the premorbid period in cancer in the context of regional exposure in the Czech Republic. At the academia-industry interface, BBMRI\_CZ will increase its role as a leading partner for innovative industrial activities to enhance the introduction of new potential medicinal products to provide an improved service to the patient community in the Czech Republic. Direct socio-economic impacts of BBMRI\_CZ are related to activities defining key documents of health policies in the Czech Republic, such as clinical practice guidelines on the use of clinical laboratory and predictive testing in oncology. Indirect impacts may focus on the medical applications of biomarkers to be discovered and characterised with the use of collected biological material connected to clinical data and tested through a comprehensive system of clinical trials. Search for relevant biomarkers specific to certain disease using archived human tissues is a critical component in the design of innovative medicinal products and diagnostic procedures in human diseases.

## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

### *e-Infrastructure*

- Connection of biobank information system and related hospital information systems in which sample and patient data are saved
- Ongoing development of the central structure of the BBMRI\_CZ Index,<sup>59</sup> in particular based on feedback regarding biobank operativeness
- Involvement of the infrastructure into BBMRI-ERIC IT infrastructure

Apart from connecting with national partners, efforts towards integrating with the established BBMRI-ERIC infrastructure were continuously made. Information about Czech biobanks is sent to the Directory service, which creates a metadata repository of European biobanks and thus represents the first step to their IT-based integration.

### *Quality*

- The source laboratories for the BBMRI\_CZ network (i.e., the labs sampling part of the patient biological material for biobanking storage) are currently accredited either by CAI according to the ISO 15189 standard or by NASKL according to the ISO standard 15189.
- The biobanking and sampling processes are supervised by qualified medical staff.

### *Clinical Biobanks*

- The overall organisational concept and implementation of the BBMRI\_CZ system were described and published in 2012.<sup>60</sup> The overall research infrastructure is realised through the organisational structures of partner institutions as described therein.

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<sup>59</sup> <http://index.bbMRI.cz/>

<sup>60</sup> Holub, P, Greplová, K, Knoflíčková, D, Nenutil, R & Valík, D: The biobanking research infrastructure BBMRI\_CZ: a critical tool to enhance translational cancer research. *Klin Onkol* **25 Suppl 2**, 78–81 (2012).



### Population-based Cohorts

- At present, BBMRI\_CZ primarily focuses on cancer research, however, a future focus on population cohorts is being envisaged for the near future. This trend is dictated by the fact that, for personalised medicine, long-term cohorts may be a significant source of knowledge.

### ELSI

- BBMRI\_CZ has a nominee in the Common Service ELSI, Mr. Radek Halouzka.

### Expert Centres

- Not yet implemented the EC/Trusted Partner mechanism

### Education & Training

- Students benefit from the expertise of staff linked to the research infrastructure (pathologists, molecular biologists, experts in laboratory medicine (I.), of a subject of choice or other special educational activities focused on biobanking (II.). We support training IT students – they are “pilot” students at the interface of IT services and medical activities – we harness this expertise to develop a “school of interdisciplinary medical collaboration”.

### Publications

1. Koudeláková, V, Trojanec, R, Vrbková, J *et al.*: Frequency of chromosome 17 polysomy in relation to CEP17 copy number in a large breast cancer cohort. *Genes, chromosomes & cancer* **55**, 409–417 (2016).
2. Ryška, A: Molecular pathology in real time. *Cancer metastasis reviews* **35**, 129–140 (2016).
3. Dudakova, L, Sasaki, T, Liskova, P, Palos, M & Jirsova, K: The presence of lysyl oxidase-like enzymes in human control and keratoconic corneas. *Histology and histopathology* **31**, 63–71 (2016).
4. Dvořáková, M, Jeřábková, J, Procházková, I, Lenčo, J, Nenutil, R & Bouchal, P: Transgelin is upregulated in stromal cells of lymph node positive breast cancer. *Journal of proteomics* **132**, 103–111 (2016).
5. Hezova, R, Kovarikova, A, Srovnal, J *et al.*: MiR-205 functions as a tumor suppressor in adenocarcinoma and an oncogene in squamous cell carcinoma of esophagus. *Tumour biology : the journal of the International Society for Oncodevelopmental Biology and Medicine* **37**, 8007–8018 (2016).
6. Drábek, J, Smolřková, M, Kalendar, R *et al.*: Design and validation of an STR hexaplex assay for DNA profiling of grapevine cultivars. *Electrophoresis* **37**, 3059–3067 (2016).
7. Mlcochova, H, Machackova, T, Rabien, A *et al.*: Epithelial-mesenchymal transition-associated microRNA/mRNA signature is linked to metastasis and prognosis in clear-cell renal cell carcinoma. *Scientific reports* **6**, 31852 (2016).
8. Klement, GL, Arkun, K, Valik, D *et al.*: Future paradigms for precision oncology. *Oncotarget* **7**, 46813–46831 (2016).
9. Thorenoor, N, Faltejskova-Vychytilova, P, Hombach, S *et al.*: Long non-coding RNA ZFAS1 interacts with CDK1 and is involved in p53-dependent cell cycle control and apoptosis in colorectal cancer. *Oncotarget* **7**, 622–637 (2016).

## BBMRI.de (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €2.7 trillion

**Population:** 82 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:** 10

### National Node

**Start date:** 1<sup>st</sup> November 2013

**Director:** Michael Hummel

**Total staff (FTE/year and headcount):** 2 FTE/year

**Total funding (period):** €1.5 million (11/2013-4/2017)

**Funding body:** Federal Ministry of Education and Research (BMBF)

**Legal entity of/hosting institution of National Node:** Charité – Universitätsmedizin Berlin

**Partners (total +15)**

**Web:** <http://www.bbmri.de>

**National Catalogues:** <https://www.biobanken.de/>

## About

The German Biobank Node (GBN) is the central contact and exchange point for the German biobanking community - not only for researchers, but also for politics, the media, and representatives of patients, industry and funding institutions. In addition, GBN represents Germany within BBMRI-ERIC. The German Biobank Node (GBN/BBMRI.de) was launched as a project funded by the Federal Ministry for Education and Research (BMBF) at the end of 2013. The idea behind the project was for GBN to represent the German national biobanking community at the BBMRI-ERIC Management Committee and to function as the national hub for BBMRI-ERIC. So far, the GBN project has had its focus on four work packages (WPs) dealing with the central office at the Charité in Berlin, the IT infrastructure, quality management and ELSI/public relations. During this first funding period of three years, the primary goal for GBN has been to develop concepts within the WPs. These concepts for IT networking, quality assurance and public relations should lay the base for implementing a German Biobank Network that enables efficient and broad interaction at national level. Representing Germany within BBMRI-ERIC is the GBN's other main responsibility.

## Specific Strengths

- Expert contribution to the CEN/TC Technical Specifications and related standards.
- Strong involvement in the development and coordination of the Common Service IT.
- Expert contribution to Common Service ELSI activities also with respect to the new GDPR.



Figure 19.: BBMRI.de

## **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

### *e-Infrastructure*

- The coordinator of BBMRI.de, Michael Hummel, is the director of the Common Service IT and therefore intensely involved in all ongoing IT activities of BBMRI-ERIC. Two research groups are involved in the Common Service IT: Frank Ückert and his team at the DKFZ in Heidelberg are responsible for WP2/sample locator; while Hans-Ulrich Prokosch and his team at the University of Erlangen work on ontologies in WP8.

### *Quality*

- Close cooperation regarding BBMRI-ERIC activities and international standardisation activities (ISO/CEN) has already been established. Several German experts are involved in the working groups for the QM-CEN standardisation process. Bettina Meinung from the University of Jena is co-chair of WG5. Michael Kiehntopf from the University of Jena and Karl- Friedrich Becker from Munich are both very active in the international ISO working group.

### *Clinical Biobanks*

- Contribution to the development of a set of data on colon cancer collections within ADOPT BBMRI-ERIC (page 130)

### Population-based Cohorts

- The two major population-based cohorts are the German National Cohort<sup>61</sup> and KORA- Co-operative health research in the Region of Augsburg.<sup>62</sup> Both are part of BBMRI-LPC: Erich Wichmann (IMSE, Munich) is PI of the Work Package 4 *Transnational access*. It provides financial support to provide free access to biospecimen and associated data in large prospective cohorts for selected scientific projects. Cohorts are reimbursed for their efforts. To this end, a tool is being developed to calculate costs in population-based cohorts, aiming at reimbursing cohorts for access to their sample and data. An extension of the existing BBMRI catalogue for population-based cohorts is also part of WP4. In addition, the Helmholtz Institute in Munich (Melanie Waldenberger at AME/HMGU) participates in Work Package 8, 'Access to Upgraded Data', by generating expanded data sets from genotyping and metabolome analysis of samples from participating cohorts.

### ELSI

- As for the Common Service ELSI, BBMRI.de plays a very active role in developing and setting-up the services. Two persons representing BBMRI.de are involved: Irene Schlünder (Berlin) as a legal expert and Roland Jahns (Würzburg) as an expert for ethical aspects. In her role as a member of the Common Service ELSI team, Irene Schlünder is involved in several tasks: She is member of the task force GDPR dealing with the impact of the new data protection regulation on biobanking; she co-chairs the task force for monitoring international organisations (e.g., WMA, OECD) preparing new legislation, recommendations, and guidelines; she chairs the task force 'Tool Integration' which aims to integrate ELSI tools (such as hSERN, LAT, Legal Wiki) that were developed in previous projects and which will be used in the context of the Common Service ELSI help desk; and she is in several CORBEL working groups, e.g., to develop a consent template.

### Expert Centres

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### Education & Training

- Workshops on Quality Management, IT workshops, hackathons, educational workshops (Practical Implementation of International Quality Standards for Biobanks) and stakeholder engagement for biobanks.

### Publications

1. *Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz* (eds Pigeot, I & Hummel, M) **3**. Special issue (2016).
2. Bernemann, I, Kersting, M, Prokein, J, Hummel, M, Klopp, N & Illig, T: [Centralized biobanks: a basis for medical research]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* **59**, 336–343 (2016).
3. Herpel, E, Schmitt, S & Kiehntopf, M: Qualität von Biomaterialien im Biobanking von Flüssig-und Gewebeproben. *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz* **59**, 325–335 (2016).
4. Jahns, R: Errichtung und Betrieb von Humanbiobanken. *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz* **59**, 311–316 (2016).

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<sup>61</sup><http://nako.de>

<sup>62</sup><http://www.helmholtz-muenchen.de/kora>

5. Kirsten, R & Hummel, M: Die Sicherung der Nachhaltigkeit von Biobanken. *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz* **59**, 390–395 (2016).
6. Kuhn, KA, Bild, R, Anton, G, Schuffenhauer, S & Wichmann, HE: Vernetzung von Biobanken großer europäischer Kohorten (EU-Projekt BBMRI-LPC). *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz* **59**, 385–389 (2016).
7. Kadioglu, D, Mate, S, Leb, I, Prokosch, HU, Ückert, F *et al.*: Strategien zur Vernetzung von Biobanken. *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz* **59**, 373–378 (2016).
8. Pigeot, I & Hummel, M: Biobanken–eine entscheidende Ressource für erfolgreiche biomedizinische Forschung. *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz* **59**, 301–303 (2016).
9. Strech, D, Bein, S, Brumhard, M *et al.*: A template for broad consent in biobank research. Results and explanation of an evidence and consensus-based development process. *Eur J Med Genet* **59**, 295–309 (2016).
10. Lesch, W: 'Strategisch kommunizieren: In vier Phasen zum effektiven Kommunikationskonzept. Gesundheitsforschung kommunizieren, Stakeholder Engagement gestalten'. *Schriftenreihe der TMF e.V.* **14** (Medizinisch Wissenschaftliche Verlagsgesellschaft, 2016), 13–24.
11. Lesch, W, A., S & Jahns, R: 'Biobanken in der öffentlichen Wahrnehmung: Verständnis, Interesse und Motivation von Probenspendern in Deutschland. Gesundheitsforschung kommunizieren, Stakeholder Engagement gestalten'. *Schriftenreihe der TMF e.V.* **14** (Medizinisch Wissenschaftliche Verlagsgesellschaft, 2016), 113–121.
12. Lesch, W, A., S & Jahns, R: 'Was erwarten Wissenschaftler von zentralisierten Biobanken? Eine qualitative Stakeholder-Analyse'. *Schriftenreihe der TMF e.V.* **14** (Medizinisch Wissenschaftliche Verlagsgesellschaft, 2016), 161–173.

## BBMRI.ee (Member)

### Country

**Year joining BBMRI-ERIC:** 2015

**GDP:** €17.4 billion

**Population:** 1.325 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
7 biobanks

### National Node

**Start date:** 1<sup>st</sup> January 2013

**Director:** Andres Metspalu

**Total staff (FTE/year and headcount):** 3.3 FTE/year and 1, total: 480/year and 45

**Total funding (period):** €36,887 (2016), total 3.5 million (2016)

**Funding body:** Estonian Research Council (ETAG), Foundation Archimedes

**Legal entity of/hosting institution of National Node:** Estonian Genome Center,  
University of Tartu

**Partners (total 8):** *Estonian Ministry of Education and Research; Estonian Genome Center, University of Tartu; Estonian Biocenter, Tartu University Hospital; The North Estonia Medical Centre; East-Tallinn Central Hospital; Competence Centre on Reproductive Medicine & Biology; National Institute for Health Development*

**Web:** <http://www.bbmri.ee>

**National Catalogue:**

## About

In its role as BBMRI-ERIC Member, the Estonian Ministry of Education and Research has nominated the Estonian Genome Center at the University of Tartu to represent Estonia in BBMRI-ERIC activities as its National Node. The Estonian Genome Center ([www.biobank.ee](http://www.biobank.ee)) is a research institute of the University of Tartu (EGCUT) with a population-based, prospective and longitudinal biobank, the Estonian Biobank. EGCUT maintains and manages the biobank by storing samples of DNA, plasma and buffy coat, and periodically renewing and updating the health information. The Estonian Biobank cohort is a volunteer-based sample of the Estonian resident adult population (aged ≥18 years). The current number of participants, which is close to 52,000, represents a large proportion, i.e. 5%, of the Estonian adult population, making it ideally suited for population-based studies. The entire EGCUT database makes it possible to carry out research to find links between genes, environmental factors, lifestyle habits and their contribution to complex diseases or other traits. An aim of EGCUT is to facilitate the development of personalised medicine in Estonia by implementing the genomic data among all other medically relevant information on the patient in medical care. In Estonia, the national node activities were funded by grant Estonian Centre for Genomics (Estonian Roadmap grant no 3.2.0304.11-0312) in the period of 2011–December 2015. Funding for the second period (2016–2020) has also been obtained, but the node activities are not supported any more through the roadmap grant.



Figure 20.: BBMRI.ee

### Specific Strengths

- The biobank is actively used by researchers worldwide, with hundreds of projects underway.
- Transparent and simple rules for access to biobank samples and data.
- All legal and societal issues of biobanking are well covered by a special law: The Human Genes Research Act of Estonia.
- In summer 2017, genome (Illumina GSA chip) information for 52,000 samples will be available.
- Data are continuously updated through periodical linking to national electronic databases and registries.
- EGCUT is not just a population-based biobank, but also a leading research institution in the field of genomics, consisting of four work groups: biostatistics (head is Dr. Krista Fischer), bioinformatics (head is Dr. Reedik Mägi), microbiomics (head is Dr. Elin Org) and genomics (head is Dr. Tõnu Esko). There is a team of 51 people plus support staff (40 FTE) working at the research unit, at the biobank, and at the sequencing and genotyping core lab (head is Dr. Lili Milani).

### National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

#### *e-Infrastructure*

- Majority of Estonian biobanks included in the Directory 2.0
- According to the tasks from the ADOPT BBMRI-ERIC grant, we will help with validating the new algorithms for performing fine search in the new database.

#### *Quality*

- EGCUT uses ISO 9000-2008. Also, the sequencing and genotyping core lab is an Illumina CPro (Certified Service Provider) one. All biological samples have been collected and processed following standardised LIMS-assisted protocols with various checkpoints, and are stored in LN2. Storage conditions are logged and monitored, and LN2 refilling is automated.

- As a training centre for Eastern European biobanks in the EU grant BBMRI-LPC and as a model for new emerging biobanks, the Estonian Node is willing to share its SOPs for designing an international biobank quality standard.

#### *Clinical Biobanks*

- Collection of data for BBMRI-LPC directory
- Contribution to the development of a set of data on colon cancer collections (ADOPT BBMRI-ERIC project)

#### *Population-based Cohorts*

- The biggest Estonian biobank is a population-based biobank (52,000 samples), which is at the same time the National Node representative: The Estonian Genome Center, University of Tartu.

#### *ELSI*

- The EGCUT representative is member of the BBMRI-ERIC ELSI expert group and the Ethical Committee of the University of Tartu. She helped compiling the draft for the BBMRI-ERIC Ethics Check.
- The ELSI representative from EGCUT has shared Estonian experiences regarding consent and biobank legislation. EGCUT has been using broad consent forms since the recruitment of biobank participants started in 2002. The Estonian Human Genes Research Act is legislation that regulates the maintenance and use of biobanks as well as the re-contacting of participants. It permits the retrieval of additional information from national registries and gives participants the right to receive individual research results.

#### *Expert Centres*

- As the Estonian node of BBMRI-ERIC is responsible for providing training to emerging biobanks within the BBMRI-LPC project, it has turned into a training centre for several Eastern European and Asian biobanks. Some countries (Switzerland, South Korea, Qatar, Vietnam, Japan, USA, India, Moldova, Georgia, Russia, Ukraine, Balkan countries, etc.) have sent a representative to the Estonian node to study the processes inside the national biobank in order to improve or set up their own biobank later on.
- The Estonian Genome Center is nominated as Centre of Excellence for Genomics and Translational Medicine<sup>63</sup> (funding from the European Regional Development Fund (ERDF) for 2016–2023) and is an object of the Estonian Roadmap (funded through the grant “Estonian Centre for Genomics”, 2017–2022).

#### *Education & Training*

- Organised several courses and conferences: Geneforum 2016<sup>64</sup>; Course in Statistical Practice in Epidemiology Using R<sup>65</sup>; WS Personal Genomes – The Public Health Perspectives<sup>66</sup>; PhD courses at the University of Tartu: Statistical Methods in Genetics and Genetic and Genomic Epidemiology.
- Involvement in the organising committee of 2016 *Europe Biobank Week*, where bbmri.ee had 3 oral presentations.

<sup>63</sup> <https://sisu.ut.ee/gentransmed/home-0>

<sup>64</sup> <http://www.geneforum.ee/GF2016>

<sup>65</sup> <http://www.geenivaramu.ee/en/news/course-statistical-practice-epidemiology-using-r-0>

<sup>66</sup> <https://sisu.ut.ee/epermed/geneforum>



## Publications

1. Leitsalu, L, Alavere, H, Tammesoo, ML, Leego, E & Metspalu, A: Linking a population biobank with national health registries-the estonian experience. *Journal of personalized medicine* **5**, 96–106 (2015).
2. Leitsalu, L, Alavere, H, Jacquemont, S *et al.*: Reporting incidental findings of genomic disorder-associated copy number variants to unselected biobank participants. *Personalized Medicine* **13**, 303–314 (2016).
3. Laisk-Podar, T, Lindgren, CM, Peters, M *et al.*: Ovarian Physiology and GWAS: Biobanks, Biology, and Beyond. *Trends in endocrinology and metabolism: TEM* **27**, 516–528 (2016).
4. Spjuth, O, Krestyaninova, M, Hastings, J *et al.*: Harmonising and linking biomedical and clinical data across disparate data archives to enable integrative cross-biobank research. *European Journal of Human Genetics (EJHG)* **24**, 521–528 (2016).
5. Leitsalu, L & Metspalu, A. *Genomic and Precision Medicine (Third Edition)* (eds Ginsburg, GS & Willard, HF) Third Edition, 119–129 (Academic Press, Boston, 2017).  
doi:<http://dx.doi.org/10.1016/B978-0-12-800681-8.00008-6>.

## BBMRI.fi (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €191.5 billion

**Population:** 5.4 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
8 biobanks

### National Node

**Start date:** 15<sup>th</sup> March 2011

**Director:** Anu Jalanko

**Total staff (FTE/year and headcount):** 4.5 FTE/year and 10

**Total funding (period):** €1.8 million (2015–2018)

**Funding body:** Ministry of Education and Culture / Academy of Finland

**Legal entity of/hosting institution of National Node:** National Institute for Health and Welfare

**Partners (total 8):** *Auria Biobank, University of Turku, Hospital districts of Southwest Finland, Satakunta and Vaasa; THL Biobank, National Institute for Health and Welfare; FHRB Biobank, Finnish hematology association, Finnish Red Cross Blood Service and University of Helsinki Institute for Molecular Medicine (UH/FIMM); Helsinki Biobank, Hospital districts of Helsinki and Uusimaa, CAREA, Eksote and UH; Biobank of Eastern Finland, Hospital District of Northern Savo, University of Eastern Finland and Hospital Districts of Itä-Savo and Etelä-Savo and North Karelia Central Hospital and Honkalampi Centre; Northern Finland Biobank Borealis, Oulu University Hospital, University of Oulu, NordLab and the healthcare districts of Kainuu, Lapland, Central Ostrobothnia and Länsi-Pohja; Finnish Clinical Biobank Tampere, Pirkanmaa Hospital District, University of Tampere, the joint municipal authority of the Etelä-Pohjanmaa hospital district and the joint municipal authority of the Kanta-Häme hospital district; Biobank of Central Finland, University of Jyväskylä and Central Finland Health Care District*

**Web:** <http://www.bbmri.fi>

**National Catalogue:** <http://www.bbmri.fi> and <https://kite.fimm.fi>

## About

BBMRI.fi is a National Node of BBMRI-ERIC and operates under collaboration between all of the eight national biobanks. BBMRI.fi serves as interface for the national network of biobanks and biological resources and coordinates their activities with those of BBMRI-ERIC. Overall, BBMRI.fi aims to create an internationally leading biobank infrastructure providing strategic support to biomedical research, healthcare and the biomedical industry. BBMRI.fi is operated by the following working groups with participation from all the national biobanks:

- BBMRI.fi network coordination
- Coordination of biobank IT infrastructure development
- Harmonisation of activities within BBMRI.fi

- Biobank quality issues
- Ethical and legal issues

### **Specific Strengths**

- Joint legal framework, nationally harmonised wide consents
- Registered biobanks cover all university hospitals and universities
- Large population cohorts with genome data
- Access to EMR data of six large hospital biobanks
- Internationally recognised DNA processing services

### **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

#### *e-Infrastructure*

- All Finnish biobanks included in the Directory 2.0
- BBMRI.fi acts as a co-coordinator of the BBMRI-ERIC Common Service IT

#### *Quality*

- Active participation in BBMRI-ERIC quality expert working groups

#### *Clinical Biobanks*

- Six large clinical biobanks with EMR data available from more than two million participants
- Contribution to development of data set on colon cancer collections (ADOPT BBMRI-ERIC project)

#### *Population-based Cohorts*

- Large population cohorts with successful activities in genome research
- Coordination of BBMRI-LPC

#### *ELSI*

- National helpdesk services and yearly ELSI clinics
- Expert participation in the BBMRI-ERIC Common Service ELSI

#### *Expert Centres*

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#### *Education & Training*

- National networking and training of biobank experts

### **Publications**

1. Merino-Martinez, R, Loreana Norlin, DvE, Anton, G *et al.*: Towards Global Biobank Integration by Implementation of the Minimum Information About Biobank data Sharing (MIABIS 2.0 Core). *Biopreservation and Biobanking* **14** (4 2016).

## BBMRI.fr (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €2 trillion

**Population:** 66.5 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
89 biobanks

### National Node

**Start date:** 1<sup>st</sup> September 2011

**Director:** Georges Dagher

**Total staff (FTE/year and headcount):** 13 FTE/year and 10

**Total funding (period):** €17 million over a ten-year period (2011–2020)

**Funding body:** National Research Agency (ANR)

**Legal entity of/hosting institution of National Node:** Institut national de la santé et de la recherche médicale (Inserm)

**Partners (total 6):** *CNRS; Inra; Institut Pasteur; CEA; CNCR; Université Claude Bernard (Lyon); GRAM*

**Web:** <http://www.biobanques.eu>

**National Catalogues:** <http://catalogue.biobanques.eu/>

## About

BIOBANQUES/BBMRI.fr is a distributed infrastructure dedicated to biomedical research. It aims to: (1) foster translational research and biomarker development, (2) elicit national and international consortia and (3) develop public-private-partnerships. It builds on a landscape of 88 biobanks distributed all over France including disease-oriented studies and population-based cohorts. It covers the entire spectrum of human diseases with more than 700 on-going biological and clinical research programs, including 45 follow-up prospective surveys of a population of 300,000 individuals included in the studies. It interfaces with BBMRI-ERIC, thus constituting the French National Node of the pan-European research infrastructure. It also interfaces with MIRRI, thus constituting the French node for the pan-European research infrastructure for microorganisms. The national infrastructure BIOBANQUES is included in the French roadmap 2016 for research infrastructures which comprises 95 French entities that have listed their contribution to the European strategic roadmap (ESFRI). They are divided in four categories:

- International Organisations (IO)
- Very Large Research Infrastructures (VLRI)
- Research Infrastructures (RI, 65)

As for projects, BIOBANQUES is part of the 25 French health and biology research infrastructures with funding of about €17 million over a ten-year period (2011–2020). At international level, it is committed in BBMRI-ERIC.

## Specific Strengths

- The network of biobanks has been active since 2000.

## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

### *e-Infrastructure*

- Participation in the MIABIS meetings.

### *Quality*

- In order to follow the contribution of biobanks to published results, BIOBANQUES implemented a unique identifier for biobanks (Bioresource Research Impact Factor, BRIF) at all 88 biobanks in France.
- Setting up and coordinating a working group at the international level (ISO TC 276) to develop a set of international standards for biobanks. The infrastructure is also participating in the European SPIDIA-4P project aiming to tackle the standardisation and improvement of pre-analytical procedures for in vitro diagnostics, leading to a set of 14 technical standards (CEN/TS).
- Training of quality managers, i.e., advising biobanks on quality control and quality management issues; replying to 21 requests from biobanks including 15 internal audits.
- Organising a 3-days international congress entitled *Quality Matters: Improving the Quality of Biological Resources* ( $\approx 120$  attendees) followed by a two-day practical laboratory course on pre-analytical sample processing in biobanks.
- Funding of a national project for elaborating a new detecting kit assessing mycoplasma contamination in cell cultures valorised at various levels (i.e., international publication & European patent application,...).
- Participation in the 2016 *Europe Biobank Week* in Vienna with a lecture on preservation of DNA at room temperature by encapsulation with its technological platform, ALIX.

### *Clinical Biobanks*

- Contribution to development of a set on colon cancer collection (ADOPT BBMRI-ERIC project) by recruiting 17 French cancer centres for samples and data collection of 10,000 samples.

### *Population-based Cohorts*

- Most of the French Biological Resource Centres in the network participate in collecting and storing samples/clinical data arising from 21 national population-based cohorts.

### *ELSI*

- Active participation in the frame of the EU directive on data protection, for sharing and access to data and human biospecimens (access policy), resulting in a FAQ on the EU GDPR document<sup>67</sup> for the French network of biobankers; implementation of ELSI tools and operating the French ELSI Helpdesk.
- Contributions to the public consultation of the European Council draft declaration on health databases and biobanks. Dissemination at various levels by lecture and attending national and international congresses.

### *Expert Centres*

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<sup>67</sup> Available on <http://www.biobanques.eu>.

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### *Education & Training*

- Organisation of a master's course in biobanking in France. In partnership with the Catholic University at Lyon, the University of Nice awards the diploma.
- Training of 55 quality managers to implement quality management in biobanks, three training sessions co-organised with Inserm and one with QUARES (French association for quality in research and higher education).
- Contribution on data protection issues to master's courses for lawyers, contribution to PhD courses for biomedical researchers and medical doctors.

### **Publications**

1. Chassang, G, Combon-Thomsen, A, Rial-Sebbag, E & Dagher, G: *Ethique et réglementation des biobanques en recherche* 231 (Biobanques, Paris, 2016).
2. Doucet, M, Becker, KF, Björkman, J *et al.*: Quality Matters: 2016 Annual Conference of the National Infrastructures for Biobanking. *Biopreservation and biobanking*. doi:10.1089/bio.2016.0053 (2016).
3. Jean, A, Tardy, F, Allatif, O, Grosjean, I, Blanquier, B & Gerlier, D: Assessing mycoplasma contamination of cell cultures by qPCR using a set of universal primer pairs targeting a 1.5 kb fragment of 16S rRNA genes. *PLoS ONE* **12**, e0172358 (2017).
4. Doucet, M, Yuille, M, Georghiou, L & Dagher, G: Biobank sustainability: current status and future prospects. *Journal of Biorepository Science for Applied Medicine* **5**, 1–7 (2017).

## BBMRI.gr (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €194.6 billion (2015)

**Population:** 11.03 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**

1 biobank

### National Node

**Start date:** 1<sup>st</sup> January 2013

**Director:** Dimitris Thanos

**Total staff (FTE/year and headcount):** 2.5 FTE

**Total funding (period):** –

**Funding body:** –

**Legal entity of/hosting institution of National Node:** Biomedical Research Foundation of the Academy of Athens (BRFAA)

**Partners (total 10):** *Foundation for Research and Technology Hellas (FORTH); Center for Research and Technology Hellas (CERTH); University of Athens; University of Patras; University of Crete; University of Ioannina; University of Thessaly; Demokritian University of Thrace; Evangellismos Hospital; Metaxa Hospital*

**Web:** <http://www.bbmri.gr>

**National Catalogues:** –

## About

BBMRI.gr aims to establish a state-of-the-art biobanking infrastructure in Greece and to achieve closer cooperation and harmonisation between biobanks. For this purpose, a network comprising almost all medical schools and two independent hospitals is being established. BBMRI.gr considers the formation of a functional network as a prerequisite to facilitating access and fostering the use of biological samples and data for academic and industrial research. Biological samples and data collected in biobanks are valuable resources for innovations in personalised medicine, and the development of biomarkers, diagnostics and therapeutics.

## Specific Strengths

Existing collections in specified areas:

- Disease-oriented biobanks: lymphomas, Parkinson's disease, childhood obesity
- Population biobank: umbilical cord samples

## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

Participation in the Education Committee and the Common Service ELSI

### *e-Infrastructure*

- Under construction, based on recently awarded national funding

### *Quality*

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### *Clinical Biobanks*

- Existing collections on lymphomas, Parkinson's disease, childhood obesity

### *Population-based Cohorts*

- Umbilical cord samples

### *ELSI*

BBMRI.gr is actively engaged regarding the increase of public awareness on biobanking and relevant ELSI issues (e.g., data protection, privacy breach, incidental findings etc.). Through the active participation of Dr. Olga Tzortzatou, who was appointed as the Greek's National Node ELSI expert of the Common Service ELSI, the Node contributed to drafting the FAQs on the GDPR in May 2016 and participated in the 2016 *Europe Biobank Week* held in Vienna in September. The FAQs will also be translated into Greek and distributed within the Node. In 2016, a communication channel regarding the GDPR's effect on research and on the role the scientific community could eventually play in the implementation of the GDPR was also opened with the Greek Data Protection Authority. This step is considered to be of major importance for the future of biobanking research in Greece. One of the initiatives regarding ELSI issues taken by the Greek Node towards the end of 2016 includes organising a Workshop on 'Biomedical Research and Bioethical Concerns', set to take place during the summer of 2017. It will explore the most important biobanking-related ethical and legal concerns of the Greek research community, among other issues. Hosted by the Biomedical Research Foundation of the Academy of Athens in collaboration with the Academy of Athens, the workshop aims to significantly increase public awareness.

### *Expert Centres*

- The Greek Genome Center has been operational for two years now and is aiming to become a prototype expert centre for Greece and beyond. Detailed information about the equipment available and the capabilities can be found in the enclosed document (GGC info). A formal application as Expert Centre/Trusted Partner is being considered.

### *Education & Training*

- There are no biobanking courses organised in Greece. We anticipate that interested fellows will be encouraged to enrol in courses suggested/organised by BBMRI-ERIC and promote participation nationwide.

## **Publications**

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## BBMRI.it (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €1.6 trillion

**Population:** 60.4 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:** 64

### National Node

**Start date:** 8<sup>th</sup> October 2013

**Director:** Marialuisa Lavitrano

**Total staff (FTE/year and headcount):** 10 FTE and 18

**Total funding (period):** €4.2 million (2013–2018)

**Funding body:** Ministry of Education, Universities and Research (MIUR). Ministry of Health contributes with the annual BBMRI-ERIC membership fee.

**Legal entity of/hosting institution of National Node:** University Milano Bicocca, Milano

**Partners (total 0):** –

**Web:** <http://www.bbmri.it>

**National Catalogues:** <http://www.bbmri.it/network-board>

## About

Established in 2013, the Italian Node of BBMRI (BBMRI.it) is a distributed infrastructure consisting of biobanks and biological resource centres located throughout Italy and a large community of researchers involved in disease-oriented projects that rely on the use of collections of biological resources. BBMRI.it includes the National Institute of Health, CNR, 18 universities, 23 research hospitals (IRCCS), 40 hospitals, 8 associations of patients and 90 biobanks, biological resources centres and collections organised in thematic networks and regional networks with a matrix architecture. BBMRI.it has developed a web portal, while Common Services for ICT, quality and ELSI have been set up to support the network. The Common Service IT adopted the BBMRI-ERIC standards and created the national IT infrastructure developing tools to improve the interoperability of research databases. The Common Service Quality has been implemented, with the objective of monitoring biobanks and biomolecular resources, providing information on guidelines/best practices, harmonising operational procedures, developing criteria for the accreditation and certification of biobanks, implementing the quality management system criteria of BBMRI-ERIC in the Italian network, and promoting training on quality issues. The Common Service ELSI works as an instrument at the service of all stakeholders, from biobanks to ethics committees. It acts as a liaison between the National Node and the European infrastructure regarding current ELSI issues.

## Specific Strengths

- Number and quality of Italian biobanks (population, genetic, disease-oriented and archived tissues biobanks) with high-quality samples and associated data
- Link between biomedical research and clinical care in the IRCCS network

- Close collaboration with patient associations, the scientific community and the bio-industries
- Thematic networks of excellence (i.e., Telethon Network of Genetic Biobanks, NIPAB network of archived tissues biobanks)
- Expert contributions to CEN/TC Technical Specifications (CEN/TS) and ISO standards
- Development of a Self-Assessment Tool to assess the compliance with quality and ELSI requirements included in the BBMRI-ERIC Partner Charter
- BBMRI-ERIC Expert Centre ATMA for imaging and molecular biomarkers validation
- Expert contributions to Common Service ELSI and IT activities

## **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

### *e-Infrastructure*

- Involvement in development and coordination of BBMRI-ERIC Common Service IT
- Active participation in the development of the BBMRI-ERIC Directory
- Interface to other e-infrastructures and IT-related projects
- BBMRI.it biobanks included in the BBMRI.it catalogue and in BBMRI-ERIC Directory 2.0

### *Quality*

- Several BBMRI.it experts contributions to QM-CEN/TS and ISO Working Groups
- Involvement in the 2.1 Workstream: Quality Self-Assessment and Audit Systems Expert Working Groups 1–7
- Co-ordination WG5 Quality Management
- Implementation of the CEN/TS in the biobanking workflow
- BBMRI.it has implemented the Common Service Quality (CSQ) to monitor biobanks and biomolecular resources, to provide information on guidelines and best practices, to harmonise operational procedures, to develop criteria for the accreditation and certification of biobanks, to implement the quality management system criteria of BBMRI-ERIC in the Italian network, to improve interoperability, to promote training on quality issues. CSQ provides support to Italian hospitals, universities and research institutes that are planning to build new facilities, and already existing research collections in the path to a fully established quality management system.

### *Clinical Biobanks*

- Contribution to the development of a set of data on colon cancer collections in ADOPT BBMRI-ERIC
- BBMRI.it leads the Archived Tissues, Liquid Biopsies and Immortalised Cell Lines Work Groups, and the Biomedical Imaging Work Plan
- BBMRI.it co-ordinates the Healthcare Integrated Biobanking Work Plan
- BBMRI.it leads Work Packages 2 and 7 in ADOPT BBMRI-ERIC

### *Population-based Cohorts*

- National network of biobanks specialised in population-based cohorts
- Participation in the BBMRI-LPC project

### *ELSI*

- M. Lavitrano is co-director of the Common Service ELSI
- Coordination of Task Force S
- Develop cross-border engagement research actions

- Attendance of Common Service ELSI meetings: Towards Mutual RECOgnition, GDPR, Code of Conduct
- Early dialogue and involvement of Italian biobanks in the discussion and feedback on WMA Consultation on Ethical Considerations Regarding Health Databases and Biobanks and GDPR
- Involvement of Italian ethical committees in the Ethics Review of European Biobank Research meeting (qualitative interviews with committee presidents)
- Contribution to the development of the Ethics Check
- Collaboration with FAVO and European Cancer Patient Coalition (ECPC) on Modelling Together Understanding and Cancer Patient's Participation in Research Biobanking
- Several public activities

#### *Expert Centres*

- The ATMA Expert Centre (ATMA-EC) to Accelerate Clinical Research with a focus on imaging and molecular biomarker verification and validation. ATMA-EC is supported by BBMRI.it.

#### *Education & Training*

- Training for quality managers to implement quality management in biobanks
- Organisation of hands-on courses on archived tissues
- Active participation in 2016 *Europe Biobank Week*, Vienna
- Dissemination of CoBRA (Citing of Bioresources in Research Articles) and BRIF (Bioresource Research Impact Factor). Development of the e-educational tool How to use CoBRA

#### **Publications**

1. Mabile, L, De Castro, P, Bravo, E *et al.*: Towards new tools for bioresource use and sharing. *Information Services & Use* **36**, 133–146 (2016).
2. Napolitani, F, Calzolari, A, Cambon-Thomsen, A *et al.*: Biobankers: Treat the Poison of Invisibility with CoBRA, a Systematic Way of Citing Bioresources in Journal Articles. *Biopreserv Biobank* **14**, 350–352 (2016).
3. Ciaburri, M, Napolitano, M & Bravo, E: Business Planning in Biobanking: How to Implement a Tool for Sustainability. *Biopreserv Biobank* **15**, 46–56 (2017).
4. Doucet, M, Becker, KF, Björkman, J *et al.*: Quality Matters: 2016 Annual Conference of the National Infrastructures for Biobanking. *Biopreservation and biobanking*. doi:10.1089/bio.2016.0053 (2016).
5. Grassilli, E, Pisano, F, Cialdella, A *et al.*: A novel oncogenic BTK isoform is overexpressed in colon cancers and required for RAS-mediated transformation. *Oncogene* **35**, 4368–4378 (2016).
6. Conconi, D, Sala, E, Bovo, G *et al.*: Using Copy Number Alterations to Identify New Therapeutic Targets for Bladder Carcinoma. *Int J Mol Sci* **17**, 271 (2016).
7. Romano, G, Santi, L, Bianco, MR *et al.*: The TGF- $\beta$ 2 pathway is activated by 5-fluorouracil treatment in drug resistant colorectal carcinoma cells. *Oncotarget* **7**, 22077–22091 (2016).
8. Conconi, D, Redaelli, S, Bovo, G *et al.*: Unexpected frequency of genomic alterations in histologically normal colonic tissue from colon cancer patients. *Tumour Biol.* **37**, 13831–13842 (2016).
9. Paterson, RR, Lima, N, Brooksbank, C, Guarini, E, Pasterk, M & Lavitrano, M: Microbiology Managers: Managerial Training in the Rltrain Project. *Trends Microbiol.* (2017).
10. Fina, E, Necchi, A, Bottelli, S *et al.*: Detection of Circulating Tumour Cells in Urothelial Cancers and Clinical Correlations: Comparison of Two Methods. *Dis. Markers* **2017**, 3414910 (2017).
11. Fina, E, Necchi, A, Giannatempo, P *et al.*: Clinical Significance of Early Changes in Circulating Tumor Cells from Patients Receiving First-Line Cisplatin-Based Chemotherapy for Metastatic Urothelial Carcinoma. *Bladder Cancer* **2**, 395–403 (2016).

12. Veneroni, S, Dugo, M, Daidone, MG *et al.*: Applicability of Under Vacuum Fresh Tissue Sealing and Cooling to Omics Analysis of Tumor Tissues. *Biopreserv Biobank* **14**, 480–490 (2016).
13. Stanta, G, Jahn, SW, Bonin, S & Hoefler, G: Tumour heterogeneity: principles and practical consequences. *Virchows Arch.* **469**, 371–384 (2016).
14. Bonin, S, Donada, M, Bussolati, G *et al.*: A synonymous EGFR polymorphism predicting responsiveness to anti-EGFR therapy in metastatic colorectal cancer patients. *Tumour Biol.* **37**, 7295–7303 (2016).
15. Baldo, C, Casareto, L, Renieri, A *et al.*: The alliance between genetic biobanks and patient organisations: the experience of the telethon network of genetic biobanks. *Orphanet J Rare Dis* **11**, 142 (2016).
16. Casati, S: *Regist-RARE to infrastruc-tu-RARE. Patients and POs as proactive partners* ECRD. 2016.
17. Casati, S, Parodi, B, Milanese, L & Lavitrano, M: *A Participatory Survey: the open ELSI priorities from Italian biobanks perspective* Europe Biobank Week, Wien. [http://www.bbmri.it/documents/10180/40770/Poster+EBW+2016\\_BB+survey.pdf](http://www.bbmri.it/documents/10180/40770/Poster+EBW+2016_BB+survey.pdf) (2016).
18. Parodi, B: *BBMRI.it, the Italian Node of BBMRI-ERIC* Europe Biobank Week, Wien. 2016.

## BBMRI.lv (Member)

### Country

**Year joining BBMRI-ERIC:** 2016

**GDP:** €22 billion

**Population:** 2 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**

2 biobanks

### National Node

**Start date:** 25<sup>th</sup> August 2016

**Director:** Janis Klovins

**Total staff (FTE/year and headcount):** 4.0 FTE/year and 5

**Total funding (period):** €119,521 (2016)

**Funding body:** The National Health Service (direct administrative institution subordinate to the Ministry of Health of the Republic of Latvia)

**Legal entity of/hosting institution of National Node:** Latvian Biomedical Research and Study centre

**Partners (total 7):** *University of Latvia: Faculty of Medicine, Faculty of Biology, Institute of Clinic and Prophylactic Medicine of University of Latvia, Riga East University Hospital, P. Stradins Clinical University Hospital, Riga Stradins University, and Oncology Institute of Riga Stradins University.*

**Web:** <http://bmc.biomed.lu.lv/en/about-us/related-organisations/lgdb/>

**National Catalogue:**

## About

BBMRI.lv is a biobank network that unites and coordinates efforts of biobanking research communities in Latvia. Currently, the main tasks for the national network is to help biomaterial collectors and users to set up quality related standards (sample collection, processing, storage and application) within a framework of ELSI related issues (regarding international and national regulations and norms). This facilitates cooperation on the national level and furthers research activities in Latvia, contributing to BBMRI.lv goal to promote biomaterial availability for international health studies.

## Specific Strengths

- The Genome Database of the Latvian population contains disease-specific and population-based cohorts, as well as associated data. In specific project-based cohorts, extensive clinical information is available.
- BBMRI.lv coordinates biosample collection and research activities in Latvia (collaboration with hospitals, universities and research institutes), facilitates networking and infrastructure availability at national level and contributes to the recognition of small national collections at European level.

## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

### *e-Infrastructure*

- Two experts nominated for the BBMRI-ERIC Common Service IT.

### *Quality*

- Two experts nominated for the BBMRI-ERIC quality expert working groups.

### *Clinical Biobanks*

- Two experts nominated for BBMRI-ERIC Clinical Biobanks Working Group

### *Population-based Cohorts*

- The Genome Database of the Latvian population contains a population-based collection (3,807 recruited as volunteers invited based on information from Latvian Population Registry).

### *ELSI*

- One expert nominated for the BBMRI-ERIC Common Service ELSI.

### *Expert Centres*

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*Education & Training* Within the framework of the BBMRI-LPC, two national courses and one international course were organised:

- Lecture course ‘Development, Maintenance and Practical Application of Biosample Collections’ 23<sup>rd</sup> April 2014. National courses.
- Practical course “Application of Biobanks: Next Generation Sequencing Data Analysis” 31<sup>st</sup> March 2015 – 2<sup>nd</sup> April 2015. National courses.
- Practical course “From Blood to Sequence” 28<sup>th</sup> November 2016 – 2<sup>nd</sup> December 2016. International course.

## Publications

1. Dujic, T, Zhou, K, Yee, SW *et al.*: Variants in Pharmacokinetic Transporters and Glycaemic Response to Metformin: A MetGen Meta-Analysis. *Clinical Pharmacology & Therapeutics* (2016).
2. Zaharenko, L, Kalnina, I, Geldnere, K *et al.*: Single nucleotide polymorphisms in the intergenic region between metformin transporter OCT2 and OCT3 coding genes are associated with short-term response to metformin monotherapy in type 2 diabetes mellitus patients. *European Journal of Endocrinology* **175**, 531–540 (2016).
3. Peculis, R, Balcere, I, Rovite, V *et al.*: Polymorphisms in MEN1 and DRD2 genes are associated with the occurrence and characteristics of pituitary adenomas. *European Journal of Endocrinology* **175**, 145–153 (2016).
4. Franke, B, Stein, JL, Ripke, S *et al.*: Genetic influences on schizophrenia and subcortical brain volumes: large-scale proof of concept. *Nature neuroscience* (2016).
5. Sekar, A, Bialas, AR, de Rivera, H *et al.*: Schizophrenia risk from complex variation of complement component 4. *Nature* **530**, 177–183 (2016).
6. Bigdeli, TB, Ripke, S, Bacanu, SA *et al.*: Genome-wide association study reveals greater polygenic loading for schizophrenia in cases with a family history of illness. *American Journal of Medical Genetics Part B: Neuropsychiatric Genetics* **171**, 276–289 (2016).

7. Hamdi, Y, Soucy, P, Kuchenbaecker, KB *et al.*: Association of breast cancer risk in BRCA1 and BRCA2 mutation carriers with genetic variants showing differential allelic expression: identification of a modifier of breast cancer risk at locus 11q22. 3. *Breast cancer research and treatment* **161**, 117–134 (2017).
8. Lawrenson, K, Kar, S, McCue, K *et al.*: Functional mechanisms underlying pleiotropic risk alleles at the 19p13. 1 breast-ovarian cancer susceptibility locus. *Nature communications* **7** (2016).
9. Hollestelle, A, Van Der Baan, FH, Berchuck, A *et al.*: No clinical utility of KRAS variant rs61764370 for ovarian or breast cancer. *Gynecologic oncology* **141**, 386–401 (2016).
10. Couch, FJ, Kuchenbaecker, KB, Michailidou, K *et al.*: Identification of four novel susceptibility loci for oestrogen receptor negative breast cancer. *Nature communications* **7** (2016).
11. Dunning, AM, Michailidou, K, Kuchenbaecker, KB *et al.*: Breast cancer risk variants at 6q25 display different phenotype associations and regulate ESR1, RMND1 and CCDC170. *Nature genetics* (2016).
12. Meeks, HD, Song, H, Michailidou, K *et al.*: BRCA2 polymorphic stop codon K3326X and the risk of breast, prostate, and ovarian cancers. *Journal of the National Cancer Institute* **108**, djv315 (2016).
13. Inashkina, I, Jankevics, E, Stavusis, J *et al.*: Robust genotyping tool for autosomal recessive type of limb-girdle muscular dystrophies. *BMC musculoskeletal disorders* **17**, 200 (2016).
14. Igumnova, V, Capligina, V, Krams, A *et al.*: Genotype and allele frequencies of isoniazid-metabolizing enzymes NAT2 and GSTM1 in Latvian tuberculosis patients. *Journal of Infection and Chemotherapy* **22**, 472–477 (2016).

## BBMRI.mt (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €7 billion

**Population:** 450,000

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
1 biobank

### National Node

**Start date:** 1<sup>st</sup> January 2013

**Director:** Alex Felice

**Total staff (FTE/year and headcount):** 1.5 FTE/year

**Total funding (period):** €170,000

**Funding body:** Institutional Funds

**Legal entity of/hosting institution of National Node:** University of Malta

**Partners (total 0):**

**Web:** <http://www.um.edu.mt/biobank>

**National Catalogue:** <http://www.eurobiobank.org/en/services/CatalogueHome.html>

## About

The Malta BioBank / BBMRI.mt forms part of the new inter-faculty Centre of Molecular Medicine and BioBanking at the University of Malta. It hosts the Maltese National Node in BBMRI-ERIC. It is the first national archive of biological samples and holds a population bank and a clinical bank with specific collections. The Population Bank is a discovery tool for biobanking/population-led research and has a very large collection of random Maltese neonates, pooled neonatal samples, a Twin Bank and a cohort of healthy senior citizens. The business model of the Clinical Bank is based on close collaboration between the University of Malta, the Department of Health and Mater Dei Hospital's Departments including Pathology, Paediatrics, Neurology and Oncology. The Malta Bio-Bank is a founding partner in: EuroBioBank, RD-Connect and ITHANET and an associate partner in EUREnOmics

## Specific Strengths

- Euro-Mediterranean engagement
- Education and training
- Rare disease research and public awareness
- Science communication and public engagement
- ELSI expert contribution in the Common Service ELSI Task Force for Societal Issues.
- Expert contribution to CEN/TC Technical Specifications and related standards





Figure 21.: BBMRI.mt

## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

### *e-Infrastructure*

- The Malta BioBank is included in the BBMRI-ERIC Directory 2.0.
- BBMRI.mt has an on-line catalogue which will soon be hosted on the RD-Connect platform. Some collections will also be linked to patient registries on the RD-Connect platform.
- Molgenis software for BBMRI.mt catalogue management.
- Participation at Common Service IT meetings.
- Participation at the RD-Connect Work Package 3 Catalogue and Tools Workshop to integrate rare disease patient data into OpenSpecimens/BIBBOX.

### *Quality*

- Developing the Quality Management System (QMS) of the Malta BioBank.
- Contributing to the BBMRI-ERIC Quality Management expert working groups.

### *Clinical Biobanks*

- A new mitochondrial disorder patient register and collection (n=16) were set up. This collection was used to participate in the LPC BBMRI-03 project.
- A new collection of undiagnosed patients with undiagnosed neuropathies (n=8) was setup. This collection was used to participate in the LPC BBMRI-07 project.
- An ALS/MND Biobank was set up in collaboration with the ALS Malta patient society.
- Further development of the rare renal disorder collection.
- Globin Bank: RNA sequencing of families with the KLF1 mutation; Functional experiments on the KLF1 promoter mutations; exome sequencing of thalassaemia patients;
- A new colorectal cancer collection is being setup in ADOPT BBMRI-ERIC (page 130).

### *Population-based Cohorts*

- A new random Maltese population collection was setup (N=700) including ancestry data to study Maltese origins (N=700).
- The Maltese Genome Project is further developing the Population Bank.

### *ELSI*

- Meetings held with Research Ethics Committee chairs to discuss potential problematic issues related to local research proposals using the BBMRI.mt resources.
- Attendance at the first meeting of BBMRI-ERIC and BBMRI-LPC (page 125) Research Ethics Committees, entitled “Ethics Review of European Biobank Research: Towards Mutual RECOgnition” (12/9/16) in Vienna.
- Collaborating on ELSI experts Task Force for Societal Issues: survey to examine issues related to Informed Consent, and PPPs within the BBMRI community.
- Organised a public discussion on campus focusing on beliefs and attitudes towards genomic research and biobanking: “Your Tissues, Your Genes, Your Say”.
- Pilot survey fielded on beliefs and attitudes towards genomic research and biobanking.
- Developed an Intellectual Property Agreement Guide.

### *Expert Centres*

- The Centre of Molecular Medicine and BioBanking may apply to become a BBMRI-ERIC Expert Centre/Trusted partner.

### *Education & Training*

- The second National Colloquium on Research in Rare Disease (26/2/16).
- The second Euro-Mediterranean workshop in BioBanking at the University of Malta (18/3/16). Biobank representatives from: Italy, Serbia, Turkey, Greece, Cyprus, Lebanon, Jordan, Israel, Egypt, Libya, Morocco and Spain attended. Joint Mediterranean research will enable comparative population genomics in the Mediterranean.
- A DegreePlus ten week course in: “Communication, Medicine and the Public Imagination” which debated biobanking and genomic research.
- Lectures on the role of Research Ethics Committees were delivered in the MSc Clinical Ethics and Law course offered by the Faculty of Medicine and Surgery.
- Participated in the International Biomedical Laboratory Science Day: Latest Advances in Malta (15/4/16).
- Participated in the TrainMalta networking event through oral presentations (25-26/4/16).
- A Film—Lab to Life, was aired on national TV (1/5/16).
- A workshop in Haematological Diseases: from Genes to Innovative Targets and Therapies was organised at the Malta Life Sciences Park held jointly by the Faculty of Medicine and Surgery, University of Malta and Bart’s and the London School of Medicine and Dentistry, Queen Mary University of London (2/6/16).
- A Health and Rare Disease Research area was organised at Science in the City (European Researcher’s Night) (30/9/16).
- Organised a workshop in Genome Editing using CRISPR/Cas9technology, delivered by Prof. Xingxu Huang (3/11/16).
- Organised a scientific meeting in Genomics and Post-Genomics Medicine at the Malta Life Sciences Park jointly organised between the Faculty of Medicine and Surgery, University of Malta and Bart’s and the London School of Medicine and Dentistry, Queen Mary University of London (10/11/16).

## Publications

1. Mizzi, C, Borg, J & Felice, AE: The hidden history of the Maltese genome. *THINK* **16** (2016).
2. Eljali, S, Pace, NP, Vassallo, J & Felice, AE: 'Molecular screening of the human Melanocortin 4 Receptor (MC4R) gene in obese Maltese Type 2 Diabetic patients'. Poster presented at the ESHG Congress, IX Malta Medical School Conference (2015).
3. Vella, J, Borg, J, Mizzi, C, Camilleri, A & Bugeja, M: 'The Population Bank of BBMRI.mt'. Presented poster at the Europe Biobank Week 2016 (2016).
4. Camilleri, A, Galdies, R, Grech, L, Borg, J & Felice, AE: 'Retrospective searching of banked newborn samples with HbF Malta reveals a subpopulation with a high Hb F Malta I /  $\Sigma\gamma$  ratio'. Presented poster at the Europe Biobank Week 2016 (2016).
5. Borg, J, Mizzi, C, Grech, L & Felice, AE: 'Variable expression of the wildtype KLF1 in Maltese Families with HPFH due to KLF1 Haplo-Insufficiency and Compound Heterozygotes'. Presented poster at the 20th Biennial Hemoglobin Switching Conference (Asilomar Conference Grounds, Pacific Grove California, USA, 2016).
6. Grech, L, Cutajar, J, Caruana, MR & Felice, AE: 'The Molecular and Haematological Spectrum of KLF1 in Malta'. Presented poster at the 20th Biennial Hemoglobin Switching Conference (Asilomar Conference Grounds, Pacific Grove California, USA, 2016).

## BBMRI.nl (Member)

### Country

**Year joining BBMRI-ERIC:** 2013

**GDP:** €600.4 billion

**Population:** 17.1 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:** 230

### National Node

**Start date:** 2013

**Director:** Cisca Wijmenga (Scientific Director), Gerrit Meijer (Scientific Director) Ronald Stolk (Scientific Director a.i.), Erna Erdtsieck-Ernste (Operational Manager), Gert-Jan van Ommen and Ronald Stolk (National Node representatives to BBMRI-ERIC)

**Total staff (FTE/year and headcount):** 20 FTE/year and 70.

**Total funding (period):** €2-9.8 million (2000–2018). Overall BBMRI funding €32.8 million (2009–2018).

**Funding body:** Ministry of Education, Culture and Science (OCW)

**Legal entity of/hosting institution of National Node:** University Medical Center Groningen

**Partners (total 19):** *Academic Medical Center, Erasmus Medical Center, Leiden University Medical Center, Maastricht University Medical Center+, Radboud University Medical Center, University Medical Center Utrecht, University Medical Center Groningen, Netherlands Cancer Institute, University of Groningen, VU University Medical Center, Free University Amsterdam, Lygature, Parelsnoer Institute, PALGA, Netherlands Heart Institute, SURFsara, Dutch Techcentre for Life Sciences, Legal Pathways, The Hyve*

**Web:** <http://www.bbmri.nl>

**National Catalogue:** <https://catalogue.bbmri.nl/>

## About

BBMRI-NL builds and implements the Dutch National Biobank Infrastructure, i.e. collecting, managing and making accessible data, samples and images for personalised medicine & health research. BBMRI-NL enables the (re)-use of human samples, data and images to advance biomedical research in compliance with ethical, legal and privacy demands and allowing active participation of donors.

A strong feature of BBMRI-NL is the contribution of population imaging. Linked to 'traditional' biobank measurements like life style, clinical characteristics, biomarkers, omics the addition of image analysis broadens the scientific value of biobank/cohort studies. Within BBMRI-NL, both large scale image acquisition procedures as well as image processing pipelines have been developed.

BBMRI-NL coordinates the national support for ELSI aspects of biobank research. This includes national policy and legislation, often linked to European developments like the GDPR. In collaboration with other research organisations, information meetings and support sessions are organised.

The data and IT aspects of biobank research are well organised within BBMRI-NL, closely linked to the BBMRI-ERIC Common Service IT. There is a national catalogue of all biobank studies in the

Netherlands, as well as sample catalogue of the larger studies. This includes the national pathology archive, which includes the pathology samples of all Dutch hospitals.

BBMRI-NL, EATRIS-NL, and DTL/ELIXIR-NL have developed a common vision and roadmap on how The Netherlands can set course for a collective Personalised Medicine & Health Research infrastructure. The goal is to bundle and connect a wide range of resources, including biobanks, IT-technologies, facilities and data collections, into one large-scale research infrastructure named Health-RI.



Figure 22.: Gerrit Meijer, Scientific Director of BBMRI-NL, at the Health-RI Conference 2016. Health-RI is the joint initiative of BBMRI-NL, EATRIS-NL, and DTL/ELIXIR-NL towards a common vision and roadmap on how The Netherlands can set course for a collective Personalised Medicine & Health Research infrastructure.

Health-RI will stimulate and facilitate collaboration through the sharing of data, images and biomaterials among researchers, medical practitioners, and the general population (patients and healthy citizens) at a national level. This will facilitate the development of a continuously growing knowledge base available for research and data mining, with the ultimate goal of improving prevention, diagnosis and prognosis of diseases. Moreover, it will bring innovations faster to patients. A crucial factor for the success of Health-RI is the common commitment to invest in research and sharing resources. In addition, a national (e-)health system needs to be developed. This will give citizens full control over their personal data, while ensuring privacy protection. The Health-RI roadmap provides an important step in this direction.

Health-RI is a response to the ‘call for dreams’ on large infrastructures of the Royal Academy of Sciences (KNAW). It is based on the input of many colleagues in the field, the P4 (personalised, pre-

ventive, participatory and predictive) medicine and health research field in 2025, and has strong roots in programs of today.

For BBMR-NL 2.0, the Health-RI initiative is an important spot on the horizon driving the integration of complementary efforts dealing with data, tissue, samples, population imaging and IT in order to create the complete solution for translational research.

### **Specific Strengths**

- 4P biobanking: Personalised medicine – oriented; Donor participation
- Access to decentralised pathological tissue bank Dutch National Tissue Portal DNTP
- Multilevel 'Omics'- integration: Genotypes/epigenomics/transcriptomics/metabolomics imaging integration
- Legal expertise in synergy with BBMRI-ERIC Common Service ELSI
- ICT systems and application development in synergy with BBMRI-ERIC Common Service IT

### **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

#### *e-Infrastructure*

- Development of various systems and applications

#### *Quality*

- QC/QA systems not national but biobank-specific; participation in BBMRI-ERIC QA/QS expert working groups

#### *Clinical Biobanks*

- Coordinated activities in Pearl String Institute: decentralised activities of clinical biobanks in European disease specific projects, partly in connection with BBMRI-ERIC activities.

#### *Population-based Cohorts*

- Close ties between major population biobanks and epidemiology, BBMRI-ERIC and international infrastructure projects (e.g., BBMRI-LPC, Bioshare, ADOPT, CORBEL)

#### *ELSI*

- Two Patient and Public Advisory Council organised and data shared
- Jointly recognised informed consent templates for human biomaterial in preparation
- National ELSI expert meeting (Task Force Societal Issues)
- Dissemination of BBMRI-NL tool development in BBMRI-ERIC Common Service ELSI and Common Service IT respectively (e.g., Wiki-Legal, My Biobank, Miabis Catalogue development).

#### *Expert Centres*

- Expert Centre activities are in progress on Metabolomics, Biomarker discovery and Imaging IT. A formal application to establish or join one or more BBMRI-ERIC Expert Centres is under consideration.

## Education & Training

- Organised four courses: metabolomics workshop, BIKE Biobank summer course, Genomics workshop, Translational (TTraIT) workshop

## Publications

1. Abubakar, M, Howat, WJ, Daley, F *et al.*: High-throughput automated scoring of Ki67 in breast cancer tissue microarrays from the Breast Cancer Association Consortium. *J Pathol Clin Res* **2**, 138–153 (2016).
2. Abubakar, M, Orr, N, Daley, F *et al.*: Prognostic value of automated KI67 scoring in breast cancer: a centralised evaluation of 8088 patients from 10 study groups. *Breast Cancer Res.* **18**, 104 (2016).
3. Adams, HH, Hibar, DP, Chouraki, V *et al.*: Novel genetic loci underlying human intracranial volume identified through genome-wide association. *Nat. Neurosci.* **19**, 1569–1582 (2016).
4. Van den Akker, EB, Pitts, SJ, Deelen, J *et al.*: Uncompromised 10-year survival of oldest old carrying somatic mutations in DNMT3A and TET2. *Blood* **127**, 1512–1515 (2016).
5. Van den Berg, SM, de Moor, MH, Verweij, KJ *et al.*: Meta-analysis of Genome-Wide Association Studies for Extraversion: Findings from the Genetics of Personality Consortium. *Behav. Genet.* **46**, 170–182 (2016).
6. Boelema, SR, Harakeh, Z, van Zandvoort, MJ *et al.*: Executive functioning before and after onset of alcohol use disorder in adolescence. A TRAILS study. *J Psychiatr Res* **78**, 78–85 (2016).
7. Bonvanie, IJ, Oldehinkel, AJ, Rosmalen, JG & Janssens, KA: Sleep problems and pain: a longitudinal cohort study in emerging adults. *Pain* **157**, 957–963 (2016).
8. Brankovic, M, Akkerhuis, KM, Buljubasic, N *et al.*: Plasma cystatin C and neutrophil gelatinase-associated lipocalin in relation to coronary atherosclerosis on intravascular ultrasound and cardiovascular outcome: Impact of kidney function (ATHEROREMO-IVUS study). *Atherosclerosis* **254**, 20–27 (2016).
9. Castano-Betancourt, MC, Evans, DS, Ramos, YF *et al.*: Novel Genetic Variants for Cartilage Thickness and Hip Osteoarthritis. *PLoS Genet.* **12**, e1006260 (2016).
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## BBMRI.no (Member)

### Country

**Year joining BBMRI-ERIC:** 2013 (as an Observer), as of 2016 (full Member)

**GDP:** €376 billion

**Population:** 5.084 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
1 biobank

### National Node

**Start date:** 2011

**Director:** Kristian Hveem

**Total staff (FTE/year and headcount):** 10 FTE/year

**Total funding (period):**

**Funding body:** The Research Council of Norway

**Legal entity of/hosting institution of National Node:**

**Partners (total 10):** *University of Tromsø, University of Bergen, University of Oslo, Norwegian University of Science and Technology (Coordinator), Norwegian Institute of Public Health, Northern Norway Regional Health Authority, Central Norway Regional Health Authority, Western Norway Regional Health Authority, Eastern Norway Regional Health Authority, Cancer Registry of Norway.*

**Web:** <http://www.ntnu.edu/biobanknorway>

**National Catalogue:**

## About

BBMRI.no is a large-scale national biobank research infrastructure for health sciences, including almost all population-based and clinical biobanks in Norway. BBMRI.no shall maximise the use of biobanks as a basis for excellent research and innovation, and reinforce their ability to participate in international research projects. BBMRI.no shall provide internationally competitive biobanking services for basic, clinical, and epidemiological medical research. BBMRI.no is presently leading the Nordic Biobank Network.

## Specific Strengths

BBMRI.no builds upon a strong Norwegian tradition of ongoing population-based health surveys since the early 1970ies and including collection and storage of biological samples. A national network of all population biobanks was organised already in 2002. When BBMRI.no/Biobank Norway was funded as a national research infrastructure in 2010, all the clinical biobanks and the serum biobank of the Norwegian Cancer Registry were included as partners, constituting a rapidly growing network of biobanks with a wide range of well described, richly annotated biospecimens and corresponding health data. In parallel, a large number of active, dedicated biobankers throughout the entire country have involved themselves in developing and implementing Standard Operating Procedures and an interactive Best Biobanking Practice.

In recent years, almost 150,000 samples from the largest population biobanks have been genotyped and imputed, soon to be available for the research community.

## **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

### *e-Infrastructure*

- BBMRI.no has been involved in the development of both a national and Nordic biobank registry as well as the development of computer cloud solutions for the storage and processing of genetic data.

### *Quality*

- NTNU (coordinator BBMRI.no) is co-leader of Work Package 9 in the BBMRI-LPC project, where 25 European biobanks have contributed to the development of an evidence-based research platform for scientific evaluation of biobank samples and procedures, a web based Biobank BRISQ, quality studies of DNA and RNA across biobanks, as well as organised and participated in a number of workshops related to biobank quality issues. This activity will gradually be 'merged' with the BBMRI-ERIC quality work stream.
- Ten technical biobank experts from BBMRI.no are involved in the development of biobank quality standard for BBMRI-ERIC. Several Norwegian biobanks are already ISO-certified or accredited.

### *Clinical Biobanks*

- The new BBMRI.no work programme highly prioritises the development of prospective clinical biobanks as well as a national pilot study promoting the establishment of a national fresh frozen tissue sample biobank, using prostate cancer as a use case. A sample tracing and management system has already been implemented in several clinical biobanks.

### *Population-based Cohorts*

- Both the HUNT study (130,000) and the Tromso Study (50,000) are organizing new surveys (HUNT 4 and Tromso 7), using new sensor technologies, a variety of imaging procedures in addition to clinical examinations and extensive sampling of biological material. Both the HUNT study and the Mother and Child study (300,000) participate in BBMRI-LPC.

### *ELSI*

- ELSI has been a strong component in the BBMRI.no network, presently with special focus on ethical issues involved in genetic studies and Next Generation Sequencing. BBMRI.no has also established a national Common Service ELSI.

### *Expert Centres*

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### *Education & Training*

- BBMRI.no has organised PhD-courses in GWAS-analyses and is also part of an annual, national PhD-course in molecular medicine
- A newly established national Common Service biobanking offers guidance and training opportunities through internships.

## Publications

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16. Kolstad, E, Veiby, G, Gilhus, NE & Bjørk, M: Overweight in epilepsy as a risk factor for pregnancy and delivery complications. *Epilepsia* **57**, 1849–1857 (2016).
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## BBMRI.pl (Member)

### Country

**Year joining BBMRI-ERIC:** 2017

**GDP:** €446.69 billion

**Population:** 39 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:** 1

### National Node

**Start date:** 1<sup>st</sup> August 2016

**Director:** Lukasz Kozera

**Total staff (FTE/year and headcount):** 9.5 FTE/year and 1

**Total funding (period):** €9.4 million (2017–2021)

**Funding body:** Ministry of Science and Higher Education (MNiSW)

**Legal entity of/hosting institution of National Node:** Wroclaw Research Centre EIT+ Medical University of Gdansk; Medical University of Warsaw; Medical University of Lublin; Wroclaw Medical University, University of Lodz, Regional Science and Technology Centre Checiny

**Partners (total 6):** *Medical University of Gdansk, Medical University of Warsaw, Medical University of Lublin Wroclaw Medical University, University of Lodz, Regional Science and Technology Centre Checiny*

**Web:** In preparation

**National Catalogue:** In preparation

## About

BBMRI.pl in a newly formed biobanking network. Initially created by WRC EIT+ Biobank and six other partners. The aim of BBMRI.pl is to show the potential of Polish biobanks to European partners. The BBMRI.pl project, funded by the Ministry of Science and Higher Education, started in January 2017 and will dedicate funding towards the creation of national biobanking registry, common IT solutions, quality assurance tools, the National Node and ELSI aspects of research on human samples.

## Specific Strengths

- Expert contribution to CEN/TC Technical Specifications and ISO.
- Poland is actively involved in all work done towards IT, Quality Management, and ELSI.

### *e-Infrastructure*

- The majority of the funding received is directed towards IT infrastructure such as common biobanking software, linkage to the national registries and storage of large scale clinical data.

### *Quality*

- Three national experts collaborate in different fields of quality management.



Figure 23.: BBMRI.pl

### *Clinical Biobanks*

- The majority of Polish biobanks are located in clinical settings.

### *Population-based Cohorts*

- BBMRI.pl officially mapped two population-based biobanks and few smaller population-based cohorts.

### *ELSI*

- Nominated ELSI expert – Prof. Jakub Pawlikowski.

### *Expert Centres*

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### *Education & Training*

- BBMRI.pl members organise trainings and national conferences on a yearly basis.

### **Publications**

1. Witoń, M, Strapagiel, D, Gleńska-Olender, J *et al.*: Organization of BBMRI.pl: The Polish Biobanking Network. *Biopreservation and biobanking*. doi:10.1089/bio.2016.0091 (2017).
2. Clement, B, Yuille, M, Zaltoukal, K *et al.*: Public biobanks: calculation and recovery of costs. *Sci Transl Med* **6**, 261fs45 (2014).

## BBMRI.se (Member)

### Country

**Year joining BBMRI-ERIC:** 2009

**GDP:** €404.7 billion

**Population:** 9.8 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:** 114

### National Node

**Start date:** 1<sup>st</sup> January 2009

**Director:** (former Joakim Dillner), Acting Director since 1<sup>st</sup> March 2016: Gunnel Tybring

**Total staff (FTE/year and headcount):** 2 FTE/year and 1

**Total funding (period):** €0.8 million

**Funding body:** Swedish Research Council (VR.se)

**Legal entity of/hosting institution of National Node:** Karolinska Institutet

**Partners (total 6):** *Medical University of Lund, Medical University of Gothenburg, Medical University of Linköping, Medical University of Uppsala, Medical University of Umea and Medical University of Umea.*

**Web:** <http://www.bbmri.se>

**National Catalogue:** <http://www.bbmri.se>

## About

The Biobanking and Molecular Resource Infrastructure of Sweden (BBMRI.se) is the Swedish National Node of BBMRI-ERIC. It became a national infrastructure in 2010 after an agreement between the Swedish Research Council and Karolinska Institutet was concluded. The collaboration encompasses all medical faculties in Sweden including Stockholm, Umea, Uppsala, Örebro, Linköping, Gothenburg and Malmö/Lund.

The main activities during this first 5-year period consisted of establishing a common infrastructure that provides technical knowledge and services for sample and data handling as well as providing services on ethical, legal & societal issues (ELSI) on biobanking. The National Node at Karolinska Institutet now has 500,000 people, collected in various epidemiological and clinical studies. Automated handling of diagnostic cytology samples that allows DNA, RNA, proteins and intact cells to be used for research is now implemented as a part of routine diagnostics in several university hospitals in Sweden. One successful initiative is the Swedish Cohort Enrichment providing guidance on and access to cohorts in Sweden. BARCdb, a freely available web resource listing expertise and molecular resource capabilities, is available at research centres and biotech companies. Sweden has a strong record in biobanking with high competence in most aspects of biobanking including technology, biobank IT and ethico-legal governance. Furthermore, Sweden has a number of population-based cohorts as well as clinical and epidemiological studies on patients and healthy volunteers with high scientific impact.

BBMRI.se is presently being consolidated and will be a part of the newly formed national initiative Biobank Sweden, BIS, universities and health care providers in cooperation for a national and uniform biobank infrastructure.

BIS is aimed to:

- establish a nationally coordinated biobank infrastructure and strengthen the cooperation between health care providers, academia and the life science industry.
- expand healthcare integrated biobanks to be in operation at all university hospitals in Sweden and implement standardisation for the collection and handling of tissue and blood samples.
- provide professional and internationally competitive biobank services for clinical and epidemiological medical research.
- increase the accessibility and use of existing clinical biobanks as well as prospective cohorts and other sample collections in academic biobanks.
- develop better biobank information technology systems for sharing samples and data and thereby promote national and international research studies based on biobanks.
- develop new tools that link biobanks to clinical data and population based health registers.
- strengthen the Swedish participation in BBMRI-ERIC and thereby promote scientific excellence in medical research, technology and quality development and in ethical and legal aspects of biobanking.

## **Specific Strengths**

BBMRI.se has been actively involved and contributing to the development of the BBMRI-ERIC infrastructure. Substantial contributions have been made in particular to the Common Service ELSI, where the ELSI National Node of Sweden is represented both as one of four co-directors and in particular in specific task forces, e.g., for the development of a federated ELSI Helpdesk function, the elaboration of principles and procedures for access to and sharing of data and biobank samples, input into the work with an European General Data Protection Regulation.

### *e-Infrastructure*

- All sample collections stored in Swedish biobanks are included in the Directory 2.0.

### *Quality*

- BBMRI.se participates in BBMRI-LPC Work Package 9 together with more than 20 Nordic biobanks. We have organised annual workshops related to biobanks issues since the first meeting in 2013. We have contributed with an evidence based evaluation of sample handling procedures, equipment's and quality issues, including DNA and RNA quality that is summarised in a web based Biobank BRISQ. We plan to merge these activities with the Quality work in BBMRI-ERIC.  
BBMRI.se contributes to the ISO/CEN standardisation.

### *Clinical Biobanks*

- Clinical healthcare-integrated biobanks will be an important part of the newly established biobank infrastructure biobank.se.

### *Population-based Cohorts*

- Population-based cohorts are listed in the Directory 2.0.

### *ELSI*

- Jointly recognised informed consent templates for human and animal biomaterial prepared.
- Intellectual Property Agreement Guide developed
- Code of Practice for access to and sharing of data and biospecimens.

- ELSI experts providing customised help to research groups.
- Leading Global Alliance for Genomics and Health (GA4GH) Task Force on a harmonised and effective rule for sharing and access to data and samples Task Force was chaired by Co-director Mats Hansson).

#### Expert Centres

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#### Education & Training

- BBMRI.se and Karolinska Institutet have organised a one week the post graduated course; Biobanks as a resource for biomedical research.
- BBMRI.se Service Center for Southern Sweden at Lund University have organised a one week post graduated course combined with a scientific symposia in collaboration with Copenhagen University; The triple Helix in Biobanking, with focus on the interactions between the Health Care Sector, Academia and Industry.

#### Publications

1. Merino-Martinez, R, Loreana Norlin, DvE, Anton, G *et al.*: Towards Global Biobank Integration by Implementation of the Minimum Information About Biobank data Sharing (MIABIS 2.0 Core). *Biopreservation and Biobanking* **14** (4 2016).
2. Malm, L, Tybring, G, Moritz, T, Landin, B & Galli, J: Metabolomic Quality Assessment of EDTA Plasma and Serum Samples. *Biopreserv Biobank* **14**, 416–423 (2016).
3. Enroth, S, Hallmans, G, Grankvist, K & Gyllensten, U: Effects of Long-Term Storage Time and Original Sampling Month on Biobank Plasma Protein Concentrations. *EBioMedicine* **12**, 309–314 (2016).
4. Matimba, A, Tybring, G, Chitereka, J *et al.*: Practical Approach to Biobanking in Zimbabwe: Establishment of an Inclusive Stakeholder Framework. *Biopreserv Biobank* **14**, 440–446 (2016).
5. Gaignaux, A, Ashton, G, Coppola, D *et al.*: A Biospecimen Proficiency Testing Program for Biobank Accreditation: Four Years of Experience. *Biopreserv Biobank* **14**, 429–439 (2016).
6. Hansson, MG, Lochmuller, H, Riess, O *et al.*: The risk of re-identification versus the need to identify individuals in rare disease research. *Eur. J. Hum. Genet.* **24**, 1553–1558 (2016).
7. Bessani, A, Brandt, J, Bux, M *et al.* *Biomedical Data Management and Graph Online Querying: VLDB 2015 Workshops, Big-O(Q) and DMAH, Waikoloa, HI, USA, August 31 – September 4, 2015, Revised Selected Papers* (eds Wang, F, Luo, G, Weng, C, Khan, A, Mitra, P & Yu, C) 89–105 (Springer International Publishing, Cham, 2016). doi:10.1007/978-3-319-41576-5\_7.
8. Budin-Ljøsne, I, Mascalzoni, D, Soini, S *et al.*: Feedback of Individual Genetic Results to Research Participants: Is It Feasible in Europe? *Biopreserv Biobank* **14**, 241–248 (2016).
9. Ekstrand Ragnar, M, Tyden, T, Kihlbom, U & Larsson, M: Swedish parents' interest in preconception genetic carrier screening. *Ups. J. Med. Sci.* 1–6 (2016).
10. Evers, K: The contribution of neuroethics to international brain research initiatives. *Nature Reviews Neuroscience* **18**, 1–2 (2017).
11. Evers, K & Changeux, JP: Proactive epigenesis and ethical innovation: A neuronal hypothesis for the genesis of ethical rules. *EMBO Rep.* **17**, 1361–1364 (2016).
12. Gainotti, S, Turner, C, Woods, S *et al.*: Improving the informed consent process in international collaborative rare disease research: effective consent for effective research. *Eur. J. Hum. Genet.* **24**, 1248–1254 (2016).

13. Gholami, A, Lind, AS, Reichel, J, Litton, JE, Edlund, A & Laure, E: Design and implementation of the advanced cloud privacy threat modeling. *International Journal of Network Security & Its Applications* **8**, 103–122 (2016).
14. Johnsson, L & Eriksson, S: Autonomy is a Right, Not a Feat: How Theoretical Misconceptions have Muddled the Debate on Dynamic Consent to Biobank Research. *Bioethics* **30**, 471–478 (2016).
15. Klingström, T, Mendy, M, Meunier, D *et al.*: 'Supporting the development of biobanks in low and medium income countries'. *IST-Africa Week Conference, 2016* (2016), 1–10.
16. McCormack, P, Kole, A, Gainotti, S *et al.*: 'You should at least ask'. The expectations, hopes and fears of rare disease patients on large-scale data and biomaterial sharing for genomics research. *Eur. J. Hum. Genet.* **24**, 1403–1408 (2016).
17. Meraviglia, V, Wen, J, Piacentini, L *et al.*: Higher cardiogenic potential of iPSCs derived from cardiac versus skin stromal cells. *Front Biosci (Landmark Ed)* **21**, 719–743 (2016).
18. Niemiec, E, Borry, P, Pinxten, W & Howard, HC: Content Analysis of Informed Consent for Whole Genome Sequencing Offered by Direct-to-Consumer Genetic Testing Companies. *Hum. Mutat.* **37**, 1248–1256 (2016).
19. Niemiec, E & Howard, HC: Ethical issues in consumer genome sequencing: Use of consumers' samples and data. *Appl Transl Genom* **8**, 23–30 (2016).
20. Oliveri, S, Pravettoni, G, Fioretti, C & Hansson, MG: Let the Individuals Directly Concerned Decide: A Solution to Tragic Choices in Genetic Risk Information. *Public Health Genomics* **19**, 307–313 (2016).
21. Reichel, J: Nationella dataskyddmyndigheter som lagprövare av EU-rätten : en analys av EU-domstolens dom i mål C-362/14, Schrems (Safe harbor-målet). *Förvaltningsrättslig Tidskrift*, 161–170 (2016).
22. Reichel, J: Alternative Rule-Making within European Bioethics – Necessary and Therefore Legitimate? *Tilburg Law Review* **21**, 169–192 (2016).
23. Reichel, J: *Privacy Shield to once again ensure safe harbours for data transfers* 2016.
24. Reichel, J & Hellner, A. *Law Without State* : 62nd ed. (Hart, 2016).
25. Reichel, J, Lind, AS & Hansson, MG: *Research Data Inquiry investigating national exceptions under the General Data Protection Regulation* 2016.
26. Viberg, J, Segerdahl, P, Langenskiöld, S & Hansson, MG: Freedom of Choice About Incidental Findings Can Frustrate Participants' True Preferences. *Bioethics* **30**, 203–209 (2016).



## BBMRI.tr (Observer)

### Country

**Year joining BBMRI-ERIC:** 2014 (Observer)

**GDP:** €595.1 billion

**Population:** 595.1 billion

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
0 biobanks

### National Node

**Start date:** 1<sup>st</sup> January 2014

**Director:** Safiye Nese Atabey (since 2015), Kemal Baysal (until 2015)

**Total staff (FTE/year and headcount):** 1.5 FTE/year and 3

**Total funding (period):** €200,000 (2014–2017)

**Funding body:** Ministry of Development, Dokuz Eylul University, Istanbul Development Agency (ISTKA)

**Legal entity of/hosting institution of National Node:** Dokuz Eylul University, Izmir International Biomedicine and Genome Institute (IBG-izmir)

**Partners (total 3):** Hacettepe University Center for Biobanking and Genomics (HUBIGEM), Istanbul University, Institute of Experimental Medicine (DETAE) H. Behcet Life Science Center Biobank Facility.

**Web:** <http://biobank.gen.tr/>

**National Catalogue:** not yet

## About

BBMRI.tr focuses on the establishment of a national biobanking infrastructure in Turkey to create a national registry and to increase harmonisation between biobanks. This is very important in order to facilitate access to biobanks for researchers to improve research and innovation in life sciences. Training activities to assure the quality of biobanks and registries as well as educational activities to enhance awareness for biobanking have also been organised involving the general public's, policymakers, and health-care providers.



Figure 24.: BBMRI.tr

## Specific Strengths

- Hacettepe University Center for Biobanking and Genomics (HUBIGEM) is one of the largest rare disease biobanks in Europe and a member of the EuroBioBank network.
- Strong support from Turkish Health Institutions (TUSEB) to build a national biobank infrastructure.
- Support from TUSEB for the establishment of population-based biobanks and for increasing the sustainability of disease-based biobanks in Turkey.
- Clinical expertise on rare diseases and repository of large consanguineous families.

## National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

### *e-Infrastructure*

- BBMRI.tr actively participates in the creation of a national biobank registry and IT infrastructure for the storage and processing of samples and related genomic data in Turkey within the scope of the Turkish Genome Project.

### *Quality*

- BBMRI.tr actively participates in BBMRI-ERIC quality meetings with five experts, while BBMRI.tr quality management experts organised a quality workshop and prepared a guide for quality assurance.<sup>68</sup>

### *Clinical Biobanks*

- To increase awareness and contributions to the development of a data set on colon cancer collections (ADOPT BBMRI-ERIC), BBMRI.tr's Clinical Biobanking Group and the Turkish Pathology Societies Federation, Gastroenterology Working Group organised a workshop in November 2016.
- BBMRI.tr has been involved in the development of a national network infrastructure for rare disease, common disease and tumour biobanks.

### *Population-based Cohorts*

- No biobank within BBMRI.tr is specialised in population-based cohorts.

### *ELSI*

- The Turkish Law on the Protection of Personal Data, which is based on Directive 95/46/EC, was published on April 2016. In addition, secondary legislation regarding the protection of personal health data was adopted in October 2016. This new law and the regulation are a major step in aligning Turkey's legislative framework with the EU's and largely reflects the requirements under the current EU Directive.<sup>69</sup>
- A guide for 'Ethical and Legal Regulations on Biobanks' was published.<sup>70</sup>

### *Expert Centres*

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<sup>68</sup> Erbilgin, Y, Ugur Iseri, S, Khodzhaev, K & Haryanyan, G: *Protocols and Quality in Biobanks* 2016.

<sup>69</sup> Ibid.

<sup>70</sup> Tuncel, F, Oztezel, A & Kulahci, S: *Ethical and Legal Regulations In Biobanks* 2016.

### *Education & Training*

- A one-day workshop was organised to harmonise SOP's and to train biobankers on Quality Management Systems in biobanks: Protocols and Quality in Biobanks Workshop, 6<sup>th</sup> April 2016.
- A workshop titled "Ethics and Legal Framework of Biobanks" was held in Istanbul, 7<sup>th</sup> April 2016. During the workshop, ethical and legal issues in biobanks were discussed with interdisciplinary participation from, among others, lawyers, researchers and ethical committee members.
- The Turkish Pathology Societies Federation, Gastroenterology Working Group organised a workshop during the 26<sup>th</sup> National Pathology Congress, held in Antalya on 2<sup>nd</sup> – 6<sup>th</sup> November 2016, to increase contribution to data set development on colon cancer collections (ADOPT BBMRI-ERIC Work Package 2).
- Workshop 1 titled "Pre-Analytical Sample Processing in Biobanking: A Practical Laboratory Course in Istanbul on 27<sup>th</sup> – 28<sup>th</sup> May 2016.
- Workshop 2 titled "Data Analysis Approaches and Processing Tools in Biobanks" course in Istanbul on 30<sup>th</sup> – 31<sup>st</sup> May 2016.

### **Publications**

1. Erbilgin, Y, Ugur Iseri, S, Khodzhaev, K & Haryanyan, G: *Protocols and Quality in Biobanks* 2016.
2. Tuncel, F, Oztezel, A & Kulahci, S: *Ethical and Legal Regulations In Biobanks* 2016.

## BBMRI.uk (Member)

### Country

**Year joining BBMRI-ERIC:** 2015

**GDP:** €1.86 trillion

**Population:** 65.1 million

**Number of biobanks and stand-alone collections as specified in the Directory 2.0:**  
Submission in progress

### National Node

**Start date:** 1<sup>st</sup> December 2014

**Director:** Philip Quinlan

**Total staff (FTE/year and headcount):** 3 FTE

**Total funding (period):** €1,062,901 (£900,000) (2014–2017)

**Funding body:** Administered by the Medical Research Council

**Legal entity of/hosting institution of National Node:** University of Nottingham and UCL

**Partners (total 0):** –

**Web:** <http://www.biobankinguk.org>

**National Catalogues:** <https://directory.biobankinguk.org>

## About

The UK joined BBMRI-ERIC in April 2015, and nominated the UKCRC Tissue Directory and Coordination Centre (the Centre) as the UK's National Node (BBMRI.uk). The Centre was formed in December 2014 with support from a consortium of UKCRC funders. It is run as a partnership between University College London and the University of Nottingham and its main aim is to provide strong leadership in making progress towards the UKCRC Funders' Vision for Human Tissue Resources by increasing the quality, visibility and accessibility of the UK's world-class human tissue and biosample collections. Although managed by the Medical Research Council, we are supported by British Heart Foundation; Cancer Research UK; Chief Scientist Office (Scotland); National Institute for Health Research/Department of Health; Health and Social Care Research & Development Division, Public Health Agency, Northern Ireland; National Institute for Social Care and Health Research (NISCHR)/Welsh Government; and the Wellcome Trust.

The UK has recently set a new ethical standard for biobanks, essentially requiring anyone applying for research tissue bank status to register in the Directory as a condition of their favourable ethical permission. This is a significant step forward and one that potential sets an example for the rest of Europe and worldwide ethical review bodies.

## Specific Strengths

The focus in the UK is on making small but continual steps as a community ensuring that challenges are understood and solved together. As such the work in the UK brings a novel angle to the work undertaken by many other BBMRI countries. An example of this would be the user persona work

where we have characterised the different types of users who may use a national network. Biobanking is such a complex mix of different needs, desires, motivations and purpose and gathering understanding of these often conflicting measures is vital in delivering any form of network and coordinated effort. All the work the Centre undertakes in the UK is fed into the appropriate BBMRI group.

Directory<sup>71</sup> is the flagship product of the Centre and this has received significant interest and has already demonstrated successful research outputs that have begun as a direct result of researchers using the Directory to communicate with the Biobanks. The Centre is focused almost exclusively on facilitating greater use of existing infrastructure and this is achieved by seeking ways to assist in Biobanks and researchers communicating – an example being to add a chat function to our website, so if users cannot find what they are looking for they can speak to someone in the team quickly and efficiently.

The national showcase event was used a mechanism for trying to highlight what Biobanks exist but ensuring that a user-perspective was always central, i.e. avoiding Biobanks talking about Biobanks. An example, is the ‘Biobank of the Year’<sup>72</sup> competition that was run by asking users of the biobanks to make the case for why their nominated Biobank should be Biobank of the Year. The eventual winner was Ethical Tissue<sup>73</sup> from Bradford that was previously a relatively unknown entity within the national biobanks but was clearly demonstrating good research use and engagement.

Our engagement activities have been recognised with awards, notably the Biobank board game, but we also seek new ways to engage the public and researchers. We have a youtube channel<sup>74</sup> where biobanks can upload videos explaining their biobank. Our annual showcase launched with an unconventional animated video,<sup>75</sup> all designed to facilitate discussion, debate and progress.

## **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

*e-Infrastructure* The UKs current largest contribution is within the Common Service IT where we have sought to guide and advise based on our experiences and user-engagement activities. BBMRI.uk has nominated individuals to the majority of BBMRI work-packages and the Centre creating BBMRI.uk Centres of Excellence is extending this effort. These centres will bring together multiple experts from the UK and to form effectively a mirror committee and therefore ensuring those representing BBMRI.uk have support and greater breadth of knowledge from UK experts.

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<sup>71</sup> <https://directory.biobankinguk.org/>

<sup>72</sup> <http://www.bradford.ac.uk/news/2016/ethical-tissue-win-biobank-of-year.php>

<sup>73</sup> <https://www.youtube.com/watch?v=RhOsKXtB2t8>

<sup>74</sup> <https://www.youtube.com/channel/UC9-gOyEHkXTIzeEK69hnsFA>

<sup>75</sup> <https://www.youtube.com/watch?v=UDPhH8-RAgM>

## WHO/IARC (Observer)

### Organisational Node

**Year joining BBMRI-ERIC:** 2013

**Number of biobanks and stand-alone collections as specified in the Directory 2.0**  
none yet

**Organisational Node Director:** Maimuna Mendy

**Total staff** 11

**Legal entity of/hosting institution of National Node:** World Health Organisation

**Funding:** IARC regular and extra budget.

**Web:** <http://www.iarc.fr>

### About

The International Agency for Research on Cancer (IARC, henceforth also the Agency) is a unique organisation. For almost 50 years, since its creation by the World Health Assembly of the World Health Organisation (WHO), the Agency has been making important contributions to the global fight against cancer, notably through its capacity to bring together people and organisations from across the world that share common values and objectives. IARC is first and foremost a research organisation, providing new knowledge to reduce the global burden of cancer. In addition, its place within WHO and the wider United Nations family provides unparalleled opportunities to encourage cooperation and provide leadership among the international cancer community. Through the generosity and vision of its Governing Council, IARC has a global mandate, permitting a focus on developing countries where resources are most needed and cancer remains an often-neglected disease. Furthermore, the independence of IARC enables it to provide reliable and authoritative assessments of many facets of cancer information valued by scientists, governments, non-governmental organisations and the public the world over. The Agency is a catalyst for progress. At any one time about 300 people from some 50 countries are working for IARC at its Lyon headquarters. However, the number of people working with IARC worldwide stretches into the thousands through its wide network of collaborations and partnerships. With the excellent quality of its scientists and support staff, their integrity and their collective motivation to relieve cancer-related suffering, the Agency provides a rallying point for translating research into tangible benefits in improved health for people everywhere.

IARC has joined BBMRI-ERIC as International Organisation. IARC is the coordinator of BCNet, a biobank network for low and middle-income countries and a partner in the Horizon 2020 B3Africa (Bridging Biobanking and Biomedical Research across Europe and Africa) project. IARC per se has no national Roadmap. The Agency works closely with BCNet members, national and regional stakeholders in promoting ethics in biobanking including raising awareness of the benefit of sample and data sharing for research.

### Specific Strengths

- Low and Middle Income Country (LMIC) biobank networking (BCNet)
- international collaboration

- Ethics, Legal and Social Issues; conducting training for LMIC biobanks for personnel working upstream and down-stream of biobanking. In particular training on biobanking was organised for Pathologists attending the 10th Annual Scientific Conference of West African Division of International Academy of Pathology. The IARC education and training group is central to the development.

## **National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC**

### *Population-based Cohorts*

- IARC is the custodian of the EPIC biobank and several collections of multi-centre studies

*Other* IARC contributes specifically to the expansion of BBMRI outside of Europe.

## **Part III.**

# **Externally Funded Projects**



## 12. Active Projects

### 12.1. AARC2 (H2020)

#### Authentication and Authorisation For Research and Collaboration

**Topic:** H2020-EINFRA-2016

**Type of Action:** RIA

**Duration:** 24

**Start date:** 1<sup>st</sup> May 2017

**Grant agreement:** 730941

**Web:** (not yet available)

**Total request Grant by Consortium:** €2,999,893.75

**Total request Grant by BBMRI-ERIC:** €39,590.00

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**

none

**Benefit/tasks for BBMRI-ERIC:** Development of Levels of Assurance for authentication suitable for biomedical research applications.

**Status:** score 12 (threshold 10)

**Coordinator:** Licia Florio

**Abstract:** *Lead by GÉANT:* The goal of AARC2 is to design an AAI framework to develop interoperable AAI, to enable researchers to access the whole research and infrastructure service portfolio with one login. AARC2's objectives are: (1) enable federated access in research communities participating in AARC2, (2) assist research communities to map their requirements to concrete service offerings, (3) support research (e-)infrastructures to implement the integrated architecture and policies frameworks developed by AARC project (4) offer different trainings to adopt AARC/AARC2 results, (5) enhance the integrated architecture. AARC2 objectives will be achieved by: Piloting selected research community use-cases (SA1); Showcasing ready-to-use AAI solutions and pilot results to infrastructures (SA1-NA2); Developing a virtual Competence Centre where infrastructure representatives and AARC2 team discuss AARC2 results deployment and approaches to use-cases (all WPs); Promoting federated access and adoption of AARC2 results via training and outreach (NA2); Expand support for new technologies and policies (JRA1 and NA3); Follow a user-driven approach: development driven by use-cases and continuous community feedback on AARC2 work.

**List of Participants:** INFRAFRONTIER GmbH, Stichting EGI, Akademia Gorniczo-Hutnicza im. Stanisława Staszica w Krakowie, Istituto Nazionale di Astrofisica, Universidad de Cantabria, ETHNIKO DIKTYO EREVNAS TECHNOLOGIAS AE, European Molecular Biology Laboratory, Karlsruher Institut für Technologie, CESNET zájmové sdružení právnických osob, European Organization for Nuclear Research, Biobanks and BioMolecular resources Research Infrastructure Consortium, INSTRUCT Academic Services Limited, SURFnet bv, DAASI International GmbH, Forschungszentrum Jülich GmbH, Stichting voor Fundamenteel Onderzoek der Materie – FOM, Moravská zemská knihovna v Brně, Instytut Chemii Bioorganicznej Polskiej Akademii Nauk, Cardiff University, GÉANT Vereniging, Stichting LIBER, RETI SPA, Science and Technology Facilities Council, Consortium GARR, EISCAT Scientific Association

## 12.2. ADOPT BBMRI-ERIC (H2020)

### **implemEntation and Operation of the gateway for health into BBMRI-ERIC**

**Topic:** H2020-INFRADEV-3-2015      **Type of Action:** RIA      **Duration:** 36 months

**Start date:** 1<sup>st</sup> October 2015      **Grant agreement:** 676550

**Web:** <http://bbmri-eric.eu/adopt-bbmri-eric>

**Total request Grant by Consortium:** €4,950,860.00

**Total request Grant by BBMRI-ERIC:** €3,786,840.00 (Common Service IT, Common Service ELSI)

#### **Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**

(1) BBMRI.at/MUG; (2) BBMRI.fi/THL; (3) BBMRI.mt/UoM; (4) BBMRI.it/UNIMIB

**Benefit/tasks for BBMRI-ERIC:** Coordinated by BBMRI-ERIC, funding for key activities.

**Status:** score 12 (threshold 10)/accepted

**Coordinator:** Jan-Eric Litton

**Abstract:** *Lead by BBMRI-ERIC:* The ADOPT BBMRI-ERIC proposal aims at boosting and accelerating implementation of BBMRI-ERIC and its services. Its main deliverables are designed to complete or launch the construction of key Common Services as required for ESFRI-projects 'under implementation', reflecting the targets of the European Research Area (ERA). Revealing complex diseases (e.g., cancer) diseases will depend critically on the study of human biological samples and data from large numbers of patients and healthy individuals. The EU's ageing population is will result in an increase in many of those diseases and consequently an increased healthcare expenditure for senior citizens. BBMRI-ERIC is a specific European asset having become a fundamental component in addressing the ongoing and future requirements particularly of Europe's health service frameworks, including competitiveness and innovativeness of health-related industries. Its implementation is essential for the understanding of the diversity of human diseases, biological samples and corresponding data, which are required for the development of any new drug or diagnostic assay and are, therefore, critical for the advancement in health research, ultimately leading to personalised medicine. BBMRI-ERIC will provide a gateway access to the collections of the European research community, expertise and services building on the outcome of ADOPT BBMRI-ERIC.

**List of Participants:** BBMRI-ERIC incl. 3<sup>rd</sup> parties (namely MUG on behalf of BBMRI.at, THL on behalf of BBMRI.fi, UoM on behalf of BBMRI.mt, UNIMIB on behalf of BBMRI.it), BELSPO on behalf of BBMRI.be, Belgium; SNF on behalf of BBMRI.ch, Switzerland; MMCI on behalf of BBMRI.cz, Czech Republic; Charité on behalf of BBMRI.de, Germany; UT on behalf of BBMRI.ee, Estonia; INSERM on behalf of BBMRI.fr, France; AA on behalf of BBMRI.gr, Greece; LUMC and UMCG on behalf of BBMRI.nl, The Netherlands; NTNU on behalf of BBMRI.no, Norway; Kierujący Biobankiem Wrocławskiego Centrum; Badań EIT on behalf of BBMRI.pl, Poland; KI on behalf of BBMRI.se, Sweden; Dokuz Eylul University on behalf of BBMRI.tr, Turkey; IARC, France; TUM, Germany; IOR, Italy, University College London, United Kingdom

### 12.3. B3Africa (H2020)

#### **Bridging Biobanking and Biomedical Research across Europe and Africa**

**Topic:** INFRASUPP-6-2014      **Type of Action:** CSA      **Duration:** 36 months

**Start date:** 1<sup>st</sup> July 2015      **Grant agreement:** 654404

**Web:** <http://www.b3africa.org/>

**Total request Grant by Consortium:** €201,250.00

**Total request Grant by BBMRI-ERIC:** €70,000.00

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**  
none

**Benefit/tasks for BBMRI-ERIC:** contacts to Africa, ELSI activities will be informative for the work of the Common Service ELSI

**Status:** score 13 (threshold 10)/accepted

**Coordinator:** Erik Bongcam-Rudloff

**Abstract:** *Lead by Sverige Lantbruksuniversitet:* B3Africa - Bridging Biobanking and Biomedical Research across Europe and Africa will dramatically improve and facilitate the development of better predictive, preventive and personalised healthcare worldwide. The rapidly evolving African biobanks are an invaluable resource: The African population has the greatest genomic diversity on the planet and represents an incredible resource of information to advance biomedical research. B3Africa aims to implement a cooperation platform and technical informatics framework for biobank integration between Africa and Europe. The collaboration harmonises the ethical and legal framework, biobank data representation and bioinformatics pipelines for sharing data and knowledge among biobanks and allowing access for researchers from both continents. Main actors from the relevant initiatives including Human Heredity and Health in Africa project (H3Africa), European Biobanking and Biomolecular Resources research infrastructure (BBMRI-ERIC) and LMIC Biobank and Cohort Network (BCNet) collaborate in B3Africa to address the following objectives: a. Defining an ethical and regulatory framework for biobank data sharing between Europe and Africa. b. Defining data models for representing biobank and research data based on existing best practices, standards and ontologies. c. Designing an informatics platform using existing open-source software (with eBioKit and BiBBox as essential modules) integrating workflows for biobank applications. d. Implementation of an education and training system for information and capacity building. e. Validating the B3Africa concept with existing biobanks from both continents. B3Africa will provide the critical mass to maximise efficiency in biomedical research, supports defragmentation through integration and allows efficient leverage of existing biobanks and e-infrastructures in Europe and Africa. The technical informatics framework will be designed for easy upscaling and integration with other research infrastructures.

**List of Participants:** Swedish University of Agricultural Sciences; BBMRI-ERIC; Karolinska Institutet; Centre for Research Ethics and Bioethics; University of the Western Cape; Makerere University; University of Stellenbosch; IARC; International Livestock Research Institute; Medical University of Graz; Institute of Human Virology, Nigeria

## 12.4. BBMRI-LPC (FP7)

### Biobanking and Biomolecular Resources Research Infrastructure – Large Prospective Cohorts

**Topic:** INFRA-2012-1.1.9      **Type of Action:** CP&CSA      **Duration:** 48 months

**Start date:** 1<sup>st</sup> February 2013      **Grant agreement:** 313010

**BBMRI-ERIC as a full partner:** 1<sup>st</sup> April 2014

**Web:** <http://www.bbmri-lpc.org/>

**Total request Grant by Consortium:** €8,000,000

**Total request Grant by BBMRI-ERIC:** €14,552 (Common Service IT, Common Service ELSI)

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**

none

**Benefit/tasks for BBMRI-ERIC:** BBMRI LPC Forum

**Status:** score 13.5 (threshold 10)/accepted. A no-cost-extension has been allowed for BBMRI-LPC until October 2017.

**Coordinator:** Markus Perola

**Co-coordinator:** Gert-Jan van Ommen

**Abstract:** *Lead by THL:* Large prospective cohort (LPC) studies following up initially healthy participants for years or decades are considered more reliable and different diseases can be studied. LPC studies require large numbers of subjects, which are costly but particularly benefited from the advent of high throughput techniques providing opportunities for powerful study designs. This proposal unites the large study sets of the European Biobanking and Biomolecular Research Infrastructure (BBMRI) and the International Agency for Research on Cancer (IARC), thus achieving a worldwide unique scale of integration. Specifically, we aim to: 1) Evaluate/improve the harmonisation of individual data on health, lifestyle and other exposures; 2) Develop/implement harmonised definitions of diseases; 3) Improve biobanking and research technologies and develop innovative solutions facilitating high-quality, fair transnational access to samples and data; 4) Provide free transnational access by users, through study proposals selected by an open, pan-European call; 5) In the framework of these studies, generate and provide access to whole genome sequences, transcriptome, proteome, metabolome and methylome data; 6) Build new public-private partnerships involving large-scale prospective cohorts, and strengthening existing ones, allowing transparent industrial access to academic expertise; 7) Build a network transferring the expertise of established European large-scale biobanks to new biobank initiatives under development in other countries (BBMRI-LPC Forum).

**List of Participants:** UH-FIMM; LUMC; IARC-WHO; ICL; MUG; KI; WTSI; UMCG; HMGU; NTNU; UTARTU; UU; CNAG-CRG; UP; RI MUHC; LEGAL PATHWAYS; EHF (DECODE); THL; IPRI; LLBMC; CCGH; EIT+; TUM-MED; INSERM; MEDLAW; MU; NIPH; SSI; UBRIS; BBMRI-ERIC; UNIMIB.

## 12.5. cliniMARK (H2020)

### Good biomarker practice to increase the number of clinically validated biomarkers

**Topic:** H2020 OC-2016-1-20724      **Type of Action:** COST      **Duration:** 48 months

**Start date:** 14<sup>th</sup> March 2017      **Grant agreement:** CA16113

**Web:** [http://www.cost.eu/COST\\_Actions/ca/CA16113](http://www.cost.eu/COST_Actions/ca/CA16113)

**Total request Grant by Consortium:** –

**Total request Grant by BBMRI-ERIC:** –

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**  
none

**Benefit/tasks for BBMRI-ERIC:** Experts contributing to the establishment of best biomarker practices, networking

**Status:** approval date 24<sup>th</sup> October 2016

**Chair:** Theo M. Luider

**Vice Chair:** Antonia Vlahou

**Abstract:** *Lead by ERASMUS MC (main proposer of network):* Thousands of circulating proteins have been shown to be hallmarks of emerging disease, response to treatment, or a patients' prognosis. The identification of these small molecule biomarkers holds a great promise for significant improvement of personalized medicine based on simple blood tests. For instance, diagnosis and prognosis with biomarkers (e.g. carcinoembryonic antigen (CEA)) has significantly improved patient survival and decreased healthcare costs in colorectal cancer patients. Unfortunately, despite significant investments to increase the number of biomarker studies, only 150 out of thousands of identified biomarkers have currently been implemented in clinical practice. This is mainly caused by the time-consuming process of reliably detecting biomarkers, the irreproducibility of studies that determine a biomarkers' clinical value, and by a mismatch in studies that are performed by academia and what is required for regulatory and market approval. To increase the number of clinically validated biomarkers, rather than further increasing the number of biomarker discovery studies, CliniMARK will improve the quality and reproducibility of studies and establish a coherent biomarker development pipeline from discovery to market introduction.

CliniMARK aims to achieve said goal by creating a Best Biomarker Practice (BBP) community, which will provide guidance to:

- Classify biomarkers according to their characteristics, anticipated clinical use, and their phase of development,
- Select and validate appropriate research-grade biomarker detection tests,
- Select appropriately designed studies and biological samples to reliably and reproducibly validate biomarkers clinically, and
- Select and report on appropriate clinical data storage, biomarker data storage, data analysis protocols, privacy concerns, ethical issues, and statistical analysis methods.

**List of Participants:** Austria, Bosnia and Herzegovina, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Iceland, Ireland, Israel, Lithuania, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Switzerland, United Kingdom

## 12.6. CORBEL (H2020)

### Coordinated Research Infrastructures Building Enduring Life-science services

**Topic:** H2020 INFRADEV-4      **Type of Action:** RIA      **Duration:** 48 months

**Start date:** 1<sup>st</sup> September 2015      **Grant agreement:** 654248

**Web:** <http://www.corbel-project.eu/>

**Total request Grant by Consortium:** €14,000,000.00

**Total request Grant by BBMRI-ERIC:** €1,900,093.00 (including 3<sup>rd</sup> parties)

#### Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:

(1) bbmri.nl /LUMC €454,340.08, (2) bbmri.fi/THL €80,500.00, (3) bbmri.no/NIPH,NTNU €80,500.00, (4) bbmri.ee/UTARTU €80,500.00, (5) bbmri.at/MUG €177,850.00

**Benefit/tasks for BBMRI-ERIC:** Co-Coordinated by BBMRI-ERIC; WP3: case studies (National Nodes); WP5: Access; WP7: Common Service ELSI; WP9: Training

**Status:** score 11 (threshold 10)

**Coordinator:** Niklas Blomberg

**Co-coordinator:** Jan-Eric Litton

**Abstract:** *Lead by European Molecular Biology Laboratory, co-lead by BBMRI-ERIC:* CORBEL will establish a collaborative framework of shared services between the ESFRI Biological and Medical Research Infrastructures that transform the European research community from discovery of basic biological mechanisms to applied medical translation – through the provision of a unified interface, aligned services and coordinated user access to a range of advanced technology platforms.

**List of Participants:** EMBL, Universitair Medisch Centrum Utrecht, Fundacio Institut de Ciencies Fotoniques, Fundacio Centre de Regulacio Genomica, University of Dundee, BBMRI-ERIC, Foundation of Biomedical Research of the Academy of Athens, Erasmus University Medical Centre Rotterdam, EATRIS-ERIC, ECRIN-ERIC, University of Liverpool, Istituto di Ricerche Farmacologiche Mario Negri (IRCCS-IRFMN), Heinrich-Heine-Universitaet Duesseldorf, Infrafrontier GmbH, Helmholtz Zentrum Muenchen Deutsches Forschungszentrum fuer Gesundheit und Umwelt GmbH, INSTRUMENT, Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine, Agencia Estatal Consejo Superior de Investigaciones Cientificas, CNRS, Stazione Zoologica Anton Dohrn, The University Court of the University of St Andrews, Forschungsverbund Berlin e.V., Imperial College of Science, Technology and Medicine, Max Delbrueck Centrum fuer Molekulare Medizin, The University of Manchester, Stichting VU-VUMC, Deutsches Krebsforschungszentrum, Leibniz-Institut DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, Jacobs University Bremen GGmbH, Koninklijke Nederlandse Akademie van Wetenschappen, Tieteen Tietotekniikan Keskus Oy, CAB International, Medical University of Vienna, Academisch Ziekenhuis Groningen, Universita Degli Studi di Torino, Erasmus MC, Univ Groningen

## 12.7. EGI-Engage (H2020)

### Engaging the EGI Community towards an Open Science Commons

**Topic:** H2020 EGI-EINFRA-1-6      **Type of Action:** RIA      **Duration:** 30 months

**Start date:** 1<sup>st</sup> May 2015      **Grant agreement:** 654142

**Web:** <https://www.egi.eu/about/egi-engage/>

**Total request Grant by Consortium:** €8,000,000.00

**Total request Grant by BBMRI-ERIC:** €128,550.00

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**

BBMRI.cz, BBMRI.se, BBMRI.nl

**Benefit/tasks for BBMRI-ERIC:** BBMRI Competence Centre in WP6 (SA2) Knowledge Commons; cross-border procurement in WP2

**Status:** score 15 (threshold 10)/accepted

**Coordinator:** Yannick Legré

**Abstract:** *Lead by Stichting European Grid Initiative:* High-throughput technologies are more accessible to research-biobanking and the number of biobanks providing services that require large storage capability and parallel data analysis is increasing dramatically. Moreover, data from multiple biobanks must now be pooled to reach statistical power to elucidate meaningful associations, while complying with legal and regulatory issues. This BBMRI-ERIC EGI Competence Centre thus focuses on helping BBMRI-ERIC to bridge this gap with the implementation of big data storage in combination with data analysis and data federation using EGI federated cloud infrastructure.

**List of Participants:** Stichting European Grid Initiative, ÖAW, Vlaams Instituut voor de Zee VZW, Institute of Information and Communication Technologies, – Bulgarian Academy of Sciences, Swiss National Grid Association, CESNET, Zajmove Sdruzeni Pravnickyh OSOB, GWDG, Agnecia Estatal Consejo Superior de Investigaciones Cientificas, CSC-Tieteen Tietotekniikan Keskus Oy, Centre Nationale de la Recherche Scientifique, Institut National de la Recherche Agronomique, The Greek Research and Technology Network S.A., Sveuciliste u Zagrebu Sveučilišni Računski Centar, Magyar Tudományok Akadémia Számítástechnikai és Automatizálási Kutatóintézet, Istituto Nazionale di Fisica Nucleare, CIRMMP, Provincia Lombardo Veneta Ordine Ospedaliero di San Giovanni di Dio – Fatebenefratelli, CNR, Engineering – Ingegneria Informatica SpA, SURFsara B.V, Akademia Górniczo-Hutnicza im. Stanisława Staszica – Academic Computer Centre CYFRONET AGH, Laboratorio de Instrumentação e Física Experimental de Partículas, ICETA, Institut za Fiziku, Beograd, Uppsala Universitet – Swedish National Infrastructure for Computing, Ustav Informatiky, Slovenska Akademia Vied, Turkiye Bilimsel ve Teknolojik Arastirma Kurumu, Science and Technology Facilities Council, BBMRI-ERIC, EMBL, CERN, EISCAT Scientific Association, Food and Agriculture Organisation of the UN, Agro-Know I.K.E, Maat France SARL, The Trustees of Indiana University, Academia Sinica, Advance Science and Technology Institute, ITB-BHMN, Korea Institute of Science and Technology Information, Universiti Putra Malaysia, National Science & Technology Development Agency

## 12.8. EOSCpilot (H2020)

### The European Open Science Cloud for Research Pilot Project

**Topic:** INFRADEV-04-2016      **Type of Action:** RIA      **Duration:** 24

**Start date:** 1<sup>st</sup> February 2017      **Grant agreement:** 739563

**Web:** <https://eoscipilot.eu/>

**Total request Grant by Consortium:** €9,953,067.50

**Total request Grant by BBMRI-ERIC:** €78,405.00

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**  
none

**Benefit/tasks for BBMRI-ERIC:** Development and piloting of policies of medical data sharing as a part of European Open Science Cloud.

**Status:** score 11.5 (threshold 9)

**Coordinator:** Juan Bicarregui

**Abstract:** *Lead by Science and Technology Facilities Council:* The EOSCpilot project will support the first phase in the development of the European Open Science Cloud (EOSC) as described in the EC Communication on European Cloud Initiatives [2016].

- It will establish the governance framework for the EOSC and contribute to the development of European open science policy and best practice;
- It will develop a number of pilots that integrate services and infrastructures to demonstrate interoperability in a number of scientific domains; and
- It will engage with a broad range of stakeholders, crossing borders and communities, to build the trust and skills required for adoption of an open approach to scientific research.

These actions will build on and leverage already available resources and capabilities from research infrastructure and infrastructure organisations to maximise their use across the research community. The EOSCpilot project will address some of the key reasons why European research is not yet fully tapping into the potential of data. In particular, it will:

- reduce fragmentation between data infrastructures by working across scientific and economic domains, countries and governance models, and
- improve interoperability between data infrastructures by demonstrating how data and resources can be shared even when they are large and complex and in varied formats.

In this way, the EOSC pilot project will improve the ability to reuse data resources and provide an important step towards building a dependable open-data research environment where data from publicly funded research is always open and there are clear incentives and rewards for the sharing of data and resources.

**List of Participants:** CSC; MPG; EMBL, SURFSARA BV; EGI.eu; CNRS; KIT; UEDIN; LIBER; TRUST-IT; ATHENA RC; JISC; PRACE; CNR; INFN; DESY; INGV; BSC; UGOE; KNAW; ICOS ERIC; GEANT Assn; INAF; BBMRI-ERIC; ESS ERIC; NERC; GmBH; ECRIN ERIC, UNIMAN; PIN SCRL; CEA; CINECA



## 12.9. PhenoMeNal (H2020)

**PhenoMeNal: A comprehensive and standardised e-infrastructure for analyzing medical metabolic phenotype data**

**Topic:** H2020-EINFRA-1-2014

**Type of Action:** RIA

**Duration:** 36 months

**Start date:** 1<sup>st</sup> September 2015

**Grant agreement:** 654241

**Web:** <http://phenomenal-h2020.eu/>

**Total request Grant by Consortium:** €8,810,922.00

**Total request Grant by BBMRI-ERIC:** €145,076.00

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**

none

**Benefit/tasks for BBMRI-ERIC:** proposal trying to organise the metabolomics community at the European level, and we are keen to do it in full synergy with BBMRI.

**Status:** score 13 (threshold 10)/accepted

**Coordinator:** Christoph Steinbeck

**Abstract:** *Lead by: European Molecular Biology Laboratory:* During the next 10 years, a significant number of the a significant number of the 742,000,000 European citizens will have their genome determined routinely. This will be complemented with much cheaper measurement of the metabolome of biofluids which will link the genotype with data on the exposome of patients, which for the first time enables the development of a truly personalised and hand tailored medicine based on hard scientific measurement.

**List of Participants:** EMBL-EBI, Imperial College of Science, Technology and Medicine, Leibniz-Institut für Pflanzenbiochemie, Universitat de Barcelona, University of Birmingham, Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine, Universiteit Leiden, The Chancellor, Masters and Scholars of the University of Oxford, Swiss Institute of Bioinformatics, Uppsala Universitet, BBMRI-ERIC, Commissariat a l'entegie atomique et aux energies alternatives, Institut national de la recherche agronomique, SRI International, The Governors of the University of Alberta/University of Alberta

## 12.10. RD-CONNECT (FP7)

**RD-Connect: An integrated platform connecting registries, biobanks and clinical bioinformatics for rare disease research**

**Topic:** FP7-HEALTH-2012-INNOVATION      **Type of Action:** SP1 Collaboration      **Duration:** 72

**Start date:** 1<sup>st</sup> November 2012      **Grant agreement:** 305444

**BBMRI-ERIC as a full partner:** 1<sup>st</sup> April 2015

**Web:** <http://rd-connect.eu/>

**Total request Grant by Consortium:** €11,997,111.00

**Total request Grant by BBMRI-ERIC:** €100,000.00

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**  
none

**Benefit/tasks for BBMRI-ERIC:** Set and implement quality standards for rare disease biobanks, contribution to the biomaterial sharing work, incorporate new biobanks, develop synergies among BBMRI-ERIC and RD-Connect training activities, investigate sustainability options.

**Status:** score 13.5 (threshold 10)/accepted

**Coordinator:** Hanns Lochmüller

**Abstract:** *Lead by University Newcastle upon Tyne:* By developing robust mechanisms and standards for linking and exploiting these data, RD-Connect develops a critical mass for harmonisation and provide a strong impetus for a global 'trial-ready' infrastructure for rare diseases. Among other things, the integrated, user-friendly RD-Connect platform, built on efficient informatics concepts already implemented in international research infrastructures for large-scale data management, provides access to federated databases/registries, biobank catalogues, harmonised -omics profiles, and cutting-edge bioinformatics tools for data analysis. All patient data types will be linked via the generation of a unique identifier ('RD-ID') developed jointly with the US NIH. The RD-Connect platform will be one of the primary enablers of progress in IRDiRC-funded research and will facilitate gene discovery, diagnosis and therapy development.

**List of Participants:** University of Newcastle upon Thyne, Fundacio Parc Cientific de Barcelona, Université d'Aix Marseille, Instituto Superiore di Sanita, Uppsala Universitet, Academisch Ziekenhuis Leiden, Fundacion Centro Nacional de Investigaciones Oncologicas Carlos III, Fondazione Telethon, Universidade de Aveiro, Karolinska Institutet, University of Patras, EURORDIS, Interactive Biosoftware SARL, FINOVATIS, Institute de Salud Carlos III, INNOLYST Inc. Corporation Patientcrossroads, Medizinische Universität Graz, Université Paris Diderot – Paris 7, Università ta Malta, Fondation maladies rares, Universität Ulm, Universität Zurich, Uiverzita Karlova V Praze, United States Department of Health and Human Services, Murdoch University, Department of Health Government of Western Australia, European Molecular Biology Laboratory, BBMRI-ERIC, Academisch Ziekenhuis Groningen, Fundacio Centre de Regulacio Genomica

## 12.11. Rltrain (H2020)

### Research Infrastructures Training Programme

**Topic:** H2020 INFRASUPP-3      **Type of Action:** RIA      **Duration:** 48 months

**Start date:** 1<sup>st</sup> September 2015      **Grant agreement:** 654156

**Web:** <http://rltrain.eu/>

**Total request Grant by Consortium:** €1,999,075.95

**Total request Grant by BBMRI-ERIC:** €514,423.20

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**  
none

**Benefit/tasks for BBMRI-ERIC:** Coordinated by BBMRI-ERIC. Definition of required competences in distributed RIs throughout the lifecycle of an RI, from the initiation preparatory phase through to operational maturity.

**Status:** score 11.5 (threshold 10)/accepted

**Coordinator:** Markus Pasterk

**Abstract:** *Lead by BBMRI-ERIC:* The overarching goal of Rltrain is to identify the competency requirements for the leadership of European research infrastructures and design a training programme to fulfil these requirements. Our highest priority is reaching those professionals who are already working in research infrastructures, including directors, coordinators, senior project managers, legal representatives, heads of finance, human resources and communication. However, by designing a flexible, modular programme, we will also be able to provide a new qualification aimed at future leaders of research infrastructure – the Master in Research Infrastructure leadership. Another important consideration is that many research infrastructures, have a distributed operations structure, building on existing structures or networks. These therefore require a different set of unique competences to deal with issues such as multinational operations, transnational access and data flow; different social security systems, different administrative cultures, different legal systems etc. For a truly European Research Area it requires: (i) increased effectiveness of national research systems, (ii) improved transnational cooperation and competition including establishing and effectively operating key research infrastructures, (iii) a more open labour market for researchers, (iv) gender equality and main-streaming in organisations carrying out and selecting research projects and (v) optimal circulation and transfer of scientific information, including via digital means and broader and more rapid access to scientific publications and data.

**List of Participants:** Biobanking and BioMolecular resources Research Infrastructure –European Research Infrastructure Consortium (BBMRI-ERIC), European Molecular Biology Laboratory – European Bioinformatics Institute (EMBL-EBI), Medical University of Vienna (MUW), Infrafrontier GmbH, EATRIS-ERIC, ECRIN-ERIC, University of Minho (UMinho) on behalf of MIRRI, Institute of Molecular Genetics of the ASCR, v. v. i. on behalf of Euro-BioImaging (IMG), Imperial College London on behalf of ISBE (IMPERIAL), University of Milano-Bicocca (UNIMIB), Centre National de la Recherche Scientifique (CNRS) on behalf of DARIAH, SHARE-ERIC

## 12.12. SPIDIA4P (H2020)

### **SPIDIA for Personalized Medicine – Standardisation of generic Pre-analytical procedures for Invitro DIAGnostics for Personalized Medicine**

**Topic:** SC1-HCO-02-2016      **Type of Action:** CSA      **Duration:** 48 months

**Start date:** 1<sup>st</sup> January 2017      **Grant agreement:** 733112

**Web:** <http://www.spidia.eu/>

**Total request Grant by Consortium:** €1,999,972.50

**Total request Grant by BBMRI-ERIC:** €100,673.75 (Headquarters Quality Service)

**Assigned 3<sup>rd</sup> parties/BBMRI-ERIC Framework Agreement:**

none

**Benefit/tasks for BBMRI-ERIC:** standards to biobanks and reference centres, education and training programmes, industry-academia stakeholder workshop

**Status:** score 14.5 (threshold 10)/accepted

**Coordinator:** Uwe Oelmüller

**Abstract:** *Lead by Quiagen:* Molecular in vitro diagnostics and biomedical research have allowed great progress in personalised medicine but further progress is limited by insufficient guidelines for pre-analytical workflow steps (sample collection, preservation, etc.) as well as by insufficient quality assurance of diagnostic practice. This allows using compromised patients' samples with post collection changes in cellular and extra-cellular biomolecules' profiles thus often making diagnostic test results unreliable or even impossible. Thus, SPIDA4P aims to generate and implement a comprehensive portfolio of 22 pan-European pre-analytical CEN/TS and ISO/IS, addressing the important pre-analytical workflows applied to personalized medicine. These will be applicable to biomarker discovery, development and validation as well as to biobanks. Corresponding External Quality Assurance Schemes will be developed and implemented (survey the resulting quality of samples and diagnostic practice). Additionally, SPIDIA4P will ensure stakeholder involvement as well as training, education, and counselling. We will closely coordinate with large European public research consortia to obtain access to research and validation studies data serving as evidence for the new standards developments and achieved improvements of diagnosis, patient stratification and prognosis of disease outcome.

**List of Participants:** Qiagen GmbH (QIA), Lgc Limited (LGC), Technische Universität München (TUM), DIN Deutsches Institut fuer Normung E.V. (On Behalf Of CEN) (DIN), Preanalytix GmbH (PAX), Inivata Ltd (INIVATA), Cambridge Protein Arrays Ltd (CPA), Tataa Biocenter Ab (TATAA), Universita Degli Studi di Firenze (UNIFI), Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine (CIRMMP), Universita Degli Studi di Trieste (UNITIS), Universita Degli Studi di Torino (UNITO), Biobanks And Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC), Luxembourg Institute Of Health (IBBL), Medizinische Universitaet Graz (MUG), Institut National De La Sante Et De La Recherche Medicale (INSERM), Erasmus Universitair Medisch Centrum Rotterdam (EMC), Fundacio Centre De Regulacio Genomica (CNAG-CRG), Fondazione Irccs Istituto Nazionale Dei Tumori (INT).

**Part IV.**

**Finance**

## Introduction

In accordance with Article 10 of the BBMRI-ERIC Statutes, the Annual Report on Budgetary and Financial Management of BBMRI-ERIC for the calendar year 2016 (hereafter Annual Financial Report 2016), including the Financial Statement, and the Report of the External Auditor are submitted to the Assembly of Members for approval.

This is the 3<sup>rd</sup> Annual Financial Report since BBMRI-ERIC was established. Due to the very late finalisation of the Annual Accounts by our accountant, Deloitte Graz (agreement on the accounts concluded on 4<sup>th</sup> April 2017), this report could not be submitted to the Steering Committee in advance.

The Annual Financial Report 2016 and all accounts have been audited by the External Auditor Ernst & Young Vienna as nominated by the Assembly of Members during the 5<sup>th</sup> Session on 27<sup>th</sup> October 2015. The Report of the External Auditor is included here.

The Annual Financial Report 2016 highlights the healthy financial status of BBMRI-ERIC, giving a detailed overview of all expenses and earnings throughout the year.

## Financial Highlights

### Core Budget

At the 5<sup>th</sup> Session, taking place on 27<sup>th</sup> October 2015, the Assembly of Members approved a budget of €2,136,104 for the year 2016. This included membership contributions of €1,845,284 and €290,820 in Hosting Country contributions. In contrast to these earnings, expenses of €1,271,145 were foreseen for the HQs, while €864,959 were foreseen for the Common Services.

The annual accounts have shown earnings totalling €2,379,530 and expenditures totalling €2,354,376.

	expected 2016	actual 2016
Earnings	€2,136,104	€2,379,530
– Membership contributions	€1,845,284	€1,684,130
– Hosting country contributions	€290,820	€229,481
– Other earnings	€0	€465,920
Expenditures	€2,136,104	€2,354,376
– Headquarters	€1,271,145	€1,604,981
– Common Services	€864,959	€749,395

The overall result is €25,154 in net earnings. The reason for the lower amount in earnings is due to an unpaid membership contribution by the Republic of Greece and Latvia (noted in advance and paid in 2017), and due to non-joining of Ireland, Portugal, Croatia and Moldova, as well as the fact that Poland did not change from Observer to Member in 2015, but only at the end of 2016. Due to the current economic situation and liquidity crisis in Greece, the Director General of BBMRI-ERIC, who is responsible for preparing the financial statements, decided to book a 100% allowance for doubtful receivables relating to the already due 2016 member fee from Greece in line with generally

accepted, Austrian, accounting principles. The difference of €161,154 had to be taken into consideration with regard to the expenditures during the year. This resulted in reduced expenditures in the area of Common Services. However, postponing the start date for the Stakeholder Forum Secretariat to 2017 solved the problem. Also, some of the staffing and investments costs were not invoiced during the year (France, Greece). The earnings and expenditures of the 2016 *Europe Biobank Week* in Vienna were also included in the budget and, as a result, a small amount of net earning could be booked (7k). Detailed information can be found in the budget tables below.

## **External Funding**

During 2016, additional income in cash figures of €99,985 was generated thanks to major contributions from the RD-CONNECT (budget shift from Karolinska Institutet to BBMRI-ERIC) and the EGI-Engage projects as well as some minor contributions from other projects. The most obvious deviation from the estimate is due to the pre-financing payment from the H2020 ADOPT BBMRI-ERIC project (page 130), which was already made in 2015 in relation to other projects (originally expected for 2016 only).

## **Procurement and Tax Exemption**

According to the Statutes (Article 6), BBMRI-ERIC shall treat procurement candidates and tenders equally and without discrimination. During 2016, no major investments were made. The only significant purchase refers to two additional sets of room furniture, ordered using the same conditions as in 2014.

In accordance with the ERIC Regulation (Official Journal L 206, 2009), BBMRI-ERIC asked the local tax authorities for tax exemption. This was granted in late 2014 and BBMRI-ERIC is now treated like a company in terms of VAT. Exemptions also apply to local corporate tax and municipal tax. VAT paid on invoices from Austrian suppliers is claimed from the state on a 3 month basis and usually reimbursed with a few months' delay. For detailed figures please see the budget table under 'Core Budget' above.

**BBMRI-ERIC Core BUDGET 2016**

cash method of accounting

	2016 approved	2016 Q1-4 actual	2017 applied	2018 expected	2019 expected
<b>EARNINGS</b>					
<b>Membership contributions</b>					
Austria	61.639	61.639	62.402	59.446	57.775
Belgium	69.949	69.949	70.299	66.720	64.696
Cyprus	6.623	6.623	6.598	20.550	20.524
Czech Republic	43.250	43.250	43.134	41.701	40.890
Denmark	0		0	52.131	50.815
Estonia	22.083	22.083	22.239	22.062	21.962
Finland	47.898	47.898	48.275	46.436	45.396
France	267.858	267.858	267.462	248.303	237.470
Germany	344.394	344.394	355.865	329.721	314.937
Greece	48.273	0	45.115	43.526	42.627
Ireland	44.552		48.702	46.829	45.770
Italy	212.593	212.593	207.808	193.363	185.195
Latvia	6.787	0	22.666	22.455	22.336
Lithuania	0		7.227	7.130	7.075
Luxembourg	0		0	0	0
Malta	20.832	20.832	20.925	20.852	20.811
Netherlands	96.781	96.781	100.052	94.121	90.768
Norway	69.951	69.951	67.223	63.887	62.000
Poland	70.515	39.276	53.956	50.285	48.209
Portugal	13.501		0	43.148	42.268
Spain	0		0	40.324	38.731
Slovenia	0		24.210	9.877	23.689
Sweden	73.389	73.389	74.387	70.485	68.278
Switzerland	24.902	24.902	25.154	23.759	22.970
United Kingdom	247.866	247.866	284.360	263.866	252.277
Turkey	28.846	28.846	31.178	29.307	28.249
IARC	6.000	6.000	6.000	6.000	6.000
Correction (- Moldova, Croatia)	30.303				
<b>Subtotal</b>	<b>1.845.284</b>	<b>1.684.130</b>	<b>1.895.237</b>	<b>1.916.284</b>	<b>1.861.718</b>
<b>Hosting country contributions</b>					
Austria, hosting Headquarters	100.000	100.000	100.000	100.000	100.000
Hosting country CS ELSI	21.500	16.552	21.500	21.500	21.500
Hosting country CS IT	147.320	132.360	147.320	143.080	143.080
Hosting country SF	22.000	0	0	0	0
Reimbursement overpayment	0	-19.432	0	0	0
<b>Subtotal</b>	<b>290.820</b>	<b>229.481</b>	<b>268.820</b>	<b>264.580</b>	<b>264.580</b>
<b>other earnings</b>					
VAT reimbursement	0	40.694	40.000	36.000	37.000
Subcontracting space	0	7.374	5.163	5.163	0
other earnings (reimbursement)		3.297			
EBW16	0	414.556	4.000	10.000	15.000
<b>Subtotal</b>	<b>0</b>	<b>465.920</b>	<b>49.163</b>	<b>51.163</b>	<b>52.000</b>
<b>EARNINGS, total</b>	<b>2.136.104</b>	<b>2.379.530</b>	<b>2.213.220</b>	<b>2.232.027</b>	<b>2.178.298</b>
<b>Expenditures</b>					
<b>Headquarters</b>					
Salaries	-779.175	-693.430	-816.343	-776.270	-770.041
fringe benefits	-61.025	-66.839	-76.046	-122.446	-83.446
investment	0	-4.380	-8.000	-16.500	-6.500
rent	-190.195	-121.366	-185.633	-186.633	-188.133
consumables	-5.500	-17.924	-6.700	-13.750	-11.750
Colloquium (EBW16)		-397.213			
travel	-96.250	-107.411	-59.000	-98.750	-104.750
Contracts	-139.000	-196.418	-169.866	-152.000	-148.000
Reserve	0	0	0	0	0



<b>Subtotal</b>	<b>-1.271.145</b>	<b>-1.604.981</b>	<b>-1.321.589</b>	<b>-1.366.349</b>	<b>-1.312.620</b>
<b>Common Services</b>					
ELSI	-351.340	-326.980	-369.724	-369.724	-369.724
IT	-513.619	-422.415	-516.907	-490.954	-490.954
SF	-156.061	0	-5.000	-5.000	-5.000
calculation error Budget 2016	156.061				
<b>Subtotal</b>	<b>-864.959</b>	<b>-749.395</b>	<b>-891.631</b>	<b>-865.678</b>	<b>-865.678</b>
<b>EXPENDITURES, total</b>	<b>-2.136.104</b>	<b>-2.354.376</b>	<b>-2.213.220</b>	<b>-2.232.027</b>	<b>-2.178.298</b>
<b>NET EARNINGS</b>	<b>0</b>	<b>25.154</b>	<b>0</b>	<b>0</b>	<b>0</b>

## BBMRI-ERIC external funding 2016

cash method of accounting

	2016 approved	2016 Q1-4 actual	2017 expected	2018 expected	2019 expected
<b>external EARNINGS</b>					
FP7 BBMRI-LPC	14.552	0	2.176	0	0
FP7 RD-Connect	100.000	62.932	36.000	36.000	0
FP7 BioMedBridges	0	8.957			
IMI-EMTRAIN	4.485	0	0	0	0
H2020 EGI-Engage	43.386	47.590	12.855	0	0
H2020 CY-Biobank	43.521	-19.493	0	0	0
H2020 B3Africa	31.500	0	21.000	17.500	0
H2020 ADOPT BBMRI-ERIC	2.227.603	0	1.516.072	379.018	0
H2020 CORBEL	584.827	0	539.840	359.894	0
H2020 Ritrain	648.581	0	128.606	109.315	0
H2020 PhenoMeNal	65.284	0	50.777	29.015	0
H2020 DRYNET	0	0	13.500	13.500	13.500
H2020 EOSCpilot	0	0	39.203	39.203	0
H2020 AARC	0	0	4.949	29.693	4.949
H2020 SPIDIA4P	0	0	22.652	22.652	30.202
<b>external EARNINGS, total</b>	<b>3.763.739</b>	<b>99.985</b>	<b>2.387.628</b>	<b>1.035.788</b>	<b>48.651</b>
<b>external Expenditures</b>					
<b>Headquarters</b>					
personnel costs	-222.173	-227.915	-380.102	-269.105	-127.129
subcontracting	0	0	0	0	0
other direct costs	-175.909	-148.251	-308.505	-181.193	-54.664
indirect costs	-100.721	-103.712	-155.480	-90.478	-21.145
access costs	0	0	0	0	0
<b>Subtotal</b>	<b>-498.804</b>	<b>-479.877</b>	<b>-844.087</b>	<b>-540.776</b>	<b>-202.939</b>
<b>Common Services</b>					
ELSI	-140.719	-20.558	-256.854	-83.745	-15.625
IT	-299.970	-289.472	-449.955	-599.940	-149.985
SHFS	-25.000	0	-37.500	-50.000	-12.500
<b>Subtotal</b>	<b>-465.689</b>	<b>-310.030</b>	<b>-744.309</b>	<b>-733.685</b>	<b>-178.110</b>
<b>for linked 3rd parties</b>					
H2020 EGI-Engage	-31.901	0	-7.089	0	0
H2020 ADOPT BBMRI-ERIC	-196.329	-490.478	-392.659	-98.165	0
H2020 CORBEL	-136.926	-190.442	-344.921	-151.086	-43.883
<b>Subtotal</b>	<b>-365.156</b>	<b>-680.920</b>	<b>-744.669</b>	<b>-249.251</b>	<b>-43.883</b>
<b>for other parties/partner</b>					
H2020 ADOPT BBMRI-ERIC	-522.022	-756.601	-522.022	-116.005	0
H2020 PHENOMENAL	0	-58.141			
H2020 Ritrain	-481.394	0	-370.303	-314.757	0

Subtotal	-1.003.416	-814.741	-892.325	-430.762	0
external EXPENDITURES, total	-2.333.064	-2.285.568	-3.225.390	-1.954.474	-424.932
NET EARNINGS	1.430.675	-2.185.583	-837.762	-918.686	-376.281

## **BBMRI-ERIC, Graz**

Bericht über die Prüfung des  
Jahresabschlusses  
zum 31. Dezember 2016

#### 4. BESTÄTIGUNGSVERMERK <sup>\*)</sup>

##### Bericht zum Jahresabschluss

##### Prüfungsurteil

Wir haben den Jahresabschluss der

**Biobanking and BioMolecular resources Research Infrastructure -  
European Research Infrastructure Consortium (BBMRI-ERIC), Graz,**

bestehend aus der Bilanz zum 31. Dezember 2016, der Gewinn- und Verlustrechnung für das an diesem Stichtag endende Geschäftsjahr und dem Anhang, geprüft.

Nach unserer Beurteilung entspricht der beigefügte Jahresabschluss den gesetzlichen Vorschriften und vermittelt ein möglichst getreues Bild der Vermögens- und Finanzlage zum 31. Dezember 2016 sowie der Ertragslage der Gesellschaft für das an diesem Stichtag endende Geschäftsjahr in Übereinstimmung mit den österreichischen unternehmensrechtlichen Vorschriften.

##### Grundlage für das Prüfungsurteil

Wir haben unsere Abschlussprüfung in Übereinstimmung mit den österreichischen Grundsätzen ordnungsmäßiger Abschlussprüfung durchgeführt. Diese Grundsätze erfordern die Anwendung der International Standards on Auditing (ISA). Unsere Verantwortlichkeiten nach diesen Vorschriften und Standards sind im Abschnitt "Verantwortlichkeiten des Abschlussprüfers für die Prüfung des Jahresabschlusses" unseres Bestätigungsvermerks weitergehend beschrieben. Wir sind von der Gesellschaft unabhängig in Übereinstimmung mit den österreichischen unternehmensrechtlichen und berufsrechtlichen Vorschriften, und wir haben unsere sonstigen beruflichen Pflichten in Übereinstimmung mit diesen Anforderungen erfüllt. Wir sind der Auffassung, dass die von uns erlangten Prüfungsnachweise ausreichend und geeignet sind, um als Grundlage für unser Prüfungsurteil zu dienen.

Unsere Verantwortlichkeit und Haftung ist analog zu § 275 Abs 2 UGB (Haftungsregelungen bei der Abschlussprüfung einer kleinen oder mittelgroßen Gesellschaft) gegenüber der Gesellschaft und auch gegenüber Dritten mit insgesamt 2 Millionen Euro begrenzt.

##### Verantwortlichkeiten des gesetzlichen Vertreters für den Jahresabschluss

Der gesetzliche Vertreter ist verantwortlich für die Aufstellung des Jahresabschlusses und dafür, dass dieser in Übereinstimmung mit den österreichischen unternehmensrechtlichen Vorschriften ein möglichst getreues Bild der Vermögens-, Finanz- und Ertragslage der Gesellschaft vermittelt. Ferner ist der gesetzliche Vertreter verantwortlich für die internen Kontrollen, die er als notwendig erachtet, um die Aufstellung eines Jahresabschlusses zu ermöglichen, der frei von wesentlichen - beabsichtigten oder unbeabsichtigten - falschen Darstellungen ist.

Bei der Aufstellung des Jahresabschlusses ist der gesetzliche Vertreter dafür verantwortlich, die Fähigkeit der Gesellschaft zur Fortführung der Unternehmenstätigkeit zu beurteilen, Sachverhalte im Zusammenhang mit der Fortführung der Unternehmenstätigkeit - sofern einschlägig - anzugeben, sowie dafür, den Rechnungslegungsgrundsatz der Fortführung der Unternehmenstätigkeit anzuwenden, es sei denn, der gesetzliche Vertreter beabsichtigt, entweder die Gesellschaft zu liquidieren oder die Unternehmenstätigkeit einzustellen oder hat keine realistische Alternative dazu.

#### **Verantwortlichkeiten des Abschlussprüfers für die Prüfung des Jahresabschlusses**

Unsere Ziele sind, hinreichende Sicherheit darüber zu erlangen, ob der Jahresabschluss als Ganzes frei von wesentlichen - beabsichtigten oder unbeabsichtigten - falschen Darstellungen ist, und einen Bestätigungsvermerk zu erteilen, der unser Prüfungsurteil beinhaltet. Hinreichende Sicherheit ist ein hohes Maß an Sicherheit, aber keine Garantie dafür, dass eine in Übereinstimmung mit den österreichischen Grundsätzen ordnungsmäßiger Abschlussprüfung, die die Anwendung der ISA erfordern, durchgeführte Abschlussprüfung eine wesentliche falsche Darstellung, falls eine solche vorliegt, stets aufdeckt. Falsche Darstellungen können aus dolosen Handlungen oder Irrtümern resultieren und werden als wesentlich angesehen, wenn von ihnen einzeln oder insgesamt vernünftigerweise erwartet werden könnte, dass sie die auf der Grundlage dieses Jahresabschlusses getroffenen wirtschaftlichen Entscheidungen von Nutzern beeinflussen.

Als Teil einer Abschlussprüfung in Übereinstimmung mit den österreichischen Grundsätzen ordnungsmäßiger Abschlussprüfung, die die Anwendung der ISA erfordern, üben wir während der gesamten Abschlussprüfung pflichtgemäßes Ermessen aus und bewahren eine kritische Grundhaltung.

Darüber hinaus gilt:

- Wir identifizieren und beurteilen die Risiken wesentlicher - beabsichtigter oder unbeabsichtigter - falscher Darstellungen im Abschluss, planen Prüfungshandlungen als Reaktion auf diese Risiken, führen sie durch und erlangen Prüfungsnachweise, die ausreichend und geeignet sind, um als Grundlage für unser Prüfungsurteil zu dienen. Das Risiko, dass aus dolosen Handlungen resultierende wesentliche falsche Darstellungen nicht aufgedeckt werden, ist höher als ein aus Irrtümern resultierendes, da dolose Handlungen betrügerisches Zusammenwirken, Fälschungen, beabsichtigte Unvollständigkeiten, irreführende Darstellungen oder das Außerkraftsetzen interner Kontrollen beinhalten können.
- Wir gewinnen ein Verständnis von dem für die Abschlussprüfung relevanten internen Kontrollsystem, um Prüfungshandlungen zu planen, die unter den gegebenen Umständen angemessen sind, jedoch nicht mit dem Ziel, ein Prüfungsurteil zur Wirksamkeit des internen Kontrollsystems der Gesellschaft abzugeben.
- Wir beurteilen die Angemessenheit der vom gesetzlichen Vertreter angewandten Rechnungslegungsmethoden sowie die Vertretbarkeit der vom gesetzlichen Vertreter dargestellten geschätzten Werte in der Rechnungslegung und damit zusammenhängende Angaben.

- Wir ziehen Schlussfolgerungen über die Angemessenheit der Anwendung des Rechnungslegungsgrundsatzes der Fortführung der Unternehmenstätigkeit durch den gesetzlichen Vertreter sowie, auf der Grundlage der erlangten Prüfungsnachweise, ob eine wesentliche Unsicherheit im Zusammenhang mit Ereignissen oder Gegebenheiten besteht, die erhebliche Zweifel an der Fähigkeit der Gesellschaft zur Fortführung der Unternehmenstätigkeit aufwerfen kann. Falls wir die Schlussfolgerung ziehen, dass eine wesentliche Unsicherheit besteht, sind wir verpflichtet, in unserem Bestätigungsvermerk auf die dazugehörigen Angaben im Jahresabschluss aufmerksam zu machen oder, falls diese Angaben unangemessen sind, unser Prüfungsurteil zu modifizieren. Wir ziehen unsere Schlussfolgerungen auf der Grundlage der bis zum Datum unseres Bestätigungsvermerks erlangten Prüfungsnachweise. Zukünftige Ereignisse oder Gegebenheiten können jedoch die Abkehr der Gesellschaft von der Fortführung der Unternehmenstätigkeit zur Folge haben.
- Wir beurteilen die Gesamtdarstellung, den Aufbau und den Inhalt des Jahresabschlusses einschließlich der Angaben sowie ob der Jahresabschluss die zugrunde liegenden Geschäftsvorfälle und Ereignisse in einer Weise wiedergibt, dass ein möglichst getreues Bild erreicht wird.

#### Bericht zum Lagebericht

Gemäß § 243 Abs 4 UGB hat die Gesellschaft keinen Lagebericht erstellt.

Wien, am 28. April 2017

Ernst & Young  
Wirtschaftsprüfungsgesellschaft m.b.H.

  
Mag. Katharina Schrenk  
Wirtschaftsprüferin

  
ppa. Mag. Gerald Steckbauer  
Wirtschaftsprüfer

\*) Die Veröffentlichung oder Weitergabe des Jahresabschlusses mit unserem Bestätigungsvermerk darf nur in der von uns bestätigten Fassung erfolgen. Dieser Bestätigungsvermerk bezieht sich ausschließlich auf den deutschsprachigen und vollständigen Jahresabschluss. Für abweichende Fassungen sind die Vorschriften des § 281 Abs 2 UGB zu beachten.

*In accordance with Austrian law, the audit report is concluded in German, the official language of BBMRI-ERIC's host country. For a broader circulation, an English translation has been made available. However this document should be treated as a working translation and has no legal value.*

#### **4. AUDITOR'S REPORT**

Report on the Financial Statement

##### Audit opinion

We have audited the accompanying financial statements, including the accounting system, of Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium, Graz, for the fiscal year from January 1, 2016 to December 31, 2016. These financial statements comprise the balance sheet as of December 31, 2016, the income statement for the fiscal year ended December 31, 2016, and the notes.

In our opinion, the accompanying financial statements comply with the legal requirements and provide a true and fair view of the assets and financial position as of December 31<sup>st</sup> 2016 as well as the earnings situation of the company for the financial year in compliance with Austrian Commercial law.

##### Principles of the audit opinion

We conducted our audit in accordance with the Austrian principles of proper auditing. These principles require the application of International Standards on Auditing (ISA). Our responsibilities under these regulations and standards are described in the section "Auditor's Responsibility and Description of Type and Scope of the Statutory Audit" of our audit opinion. We are independent of the company in accordance with Austrian corporate and professional regulations and we have fulfilled our other professional duties in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to serve as the basis for our audit opinion.

Our responsibility and liability as auditor is analog to Section 275 UGB (liability regulations for the audit of small and medium-sized companies) limited with a total of 2 million EUR towards the Company and towards third parties.

##### Management's Responsibility for the Financial Statements and for the Accounting System

The Company's management is responsible for the accounting system and for the preparation and fair presentation of these financial statements in accordance with the Austrian Generally Accepted Accounting Principles. This responsibility includes: designing, implementing and maintaining internal controls relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making

accounting estimates that are reasonable in the circumstances.

In the preparation of the annual financial statements, the legal representative is responsible for assessing the company's ability to carry on the business, to specify matters relating to the continuation of the business activity, where applicable, and to apply the accounting principle for the continuation of the business activity in case the representative does not intend to either liquidate the company or cease business or has no realistic alternative to it.

#### Auditor's Responsibility and Description of Type and Scope of the Statutory Audit

Our objectives are to obtain reasonable assurance as to whether the annual financial statements as a whole are free from material misstatements, whether intentional or unintentional, and to issue an audit certificate that includes our audit opinion. Sufficient security is a high degree of security, but it does not guarantee that a final audit carried out in accordance with the Austrian principles of proper auditing, which requires the application of the ISA, will always reveal a material misrepresentation, if any. False representations may result from impious actions or errors and are deemed to be material if individually or reasonably expected to affect the economic decisions made by users on the basis of this annual financial statements.

As part of a final examination in accordance with the Austrian principles of proper final examination, which require the application of ISA, we exercise due discretion throughout the final audit and maintain a critical foundation.

In addition:

- We identify and assess the risks of material misstatements, whether intentional or unintentional, in the financial statements, plan audit procedures in response to these risks, and perform audits that are sufficient and appropriate to serve as a basis for our audit opinion. The risk that material misrepresentations resulting from fraudulent actions will not be revealed is higher than an error resulting from errors, since fraudulent acts may include fraudulent co-operation, counterfeiting, intentional incompleteness, misleading representations or the abolition of internal controls.
- We gain an understanding of the internal control system relevant to the audit to plan audit procedures that are appropriate in the circumstances, but not with the objective of issuing an opinion on the effectiveness of the company's internal control system.
- We assess the appropriateness of the accounting policies used by the legal representative, as well as the acceptability of the accounting estimates presented by the legal representative and related information.



- We draw conclusions on the appropriateness of the accounting principle of the continuation of the company's operations by the legal representative on the basis of the audit evidence obtained on whether there is material uncertainty about events or circumstances which raise serious doubts about the company's ability to continue its business activities. If we conclude that there is a material uncertainty, we are obliged to draw attention to the related items in the annual financial statements in our audit certificate or, if these disclosures are inappropriate, to modify our audit opinion. We draw our conclusions on the basis of the audit evidence obtained by the date of our audit opinion. However, future events or circumstances may result in the company's departure from the continuation of the company's activities.
- We assess the overall presentation, structure and content of the annual financial statements including the information as well as whether the annual financial statements reflect the underlying transactions and events in such a way as to achieve the most accurate picture possible.

#### Report on position report

The company does not provide a position report according to Section 243 UGB.

Vienna, April 28<sup>th</sup> 2017

ERNST & YOUNG

<b>Assets</b>	2016-12-31 EUR	2015-12-31 EUR
<b>A. Fixed Assets</b>		
I. Intangible Assets		
1. Software	2,560.32	3,840.48
II. Tangible Assets		
1. Fixtures and fittings	87,759.19	112,119.59
	<b>90,319.51</b>	<b>115,960.07</b>
<b>B. Current Assets</b>		
I. Receivables and other Assets		
1. Receivables arising from deliveries services	9,248.84	129.60
2. Other receivables and assets	136,239.20	93,049.25
	145,488.04	93,178.85
II. Cash on hand and Bank deposits	1,970,134.59	3,625,025.61
	<b>2,115,622.63</b>	<b>3,718,204.46</b>
<b>C. Prepaid expenses, deferred charges</b>	<b>3,581.31</b>	<b>250.00</b>
<b>Total assets</b>	<b>2,209,523.45</b>	<b>3,834,414.53</b>

<b>Liabilities and Owner´s Equity</b>	2016-12-31 EUR	2015-12-31 EUR
<b>A. Capital and Reserves</b>		
I. Profit Reserves		
1. Other reserves (free reserves)	326,097.41	2,193,362.27
II. Balance Sheet Profit	367,775.00	367,775.00
<i>thereof profit carried forward from the previous years</i>	<i>367,775.00</i>	<i>313,775.00</i>
	<b>693,872.41</b>	<b>2,561,137.27</b>
<b>B. Accruals</b>		
1. Other accruals	<b>52,799.55</b>	<b>24,669.46</b>
<b>C. Liabilities</b>		
1. Liabilities arising from deliveries and services	54,179.29	27,508.05
<i>thereof with a remaining maturity of up to one year</i>	<i>54,179.29</i>	<i>27,508.05</i>
2. Other liabilities	204,924.34	28,721.75
<i>thereof taxes</i>	<i>2,785.88</i>	<i>15,245.89</i>
<i>thereof social security</i>	<i>111.95</i>	<i>113.74</i>
<i>thereof with a remaining maturity of up to one year</i>	<i>204,924.34</i>	<i>28,721.75</i>
	<b>259,103.63</b>	<b>56,229.80</b>
<i>thereof with a remaining maturity of up to one year</i>	<i>259,103.63</i>	<i>56,229.80</i>
<b>D. Deferred income</b>	<b>1,203,747.86</b>	<b>1,192,378.00</b>
<b>Total Liabilities and Owner´s Equity</b>	<b>2,209,523.45</b>	<b>3,834,414.53</b>

**Part V.**

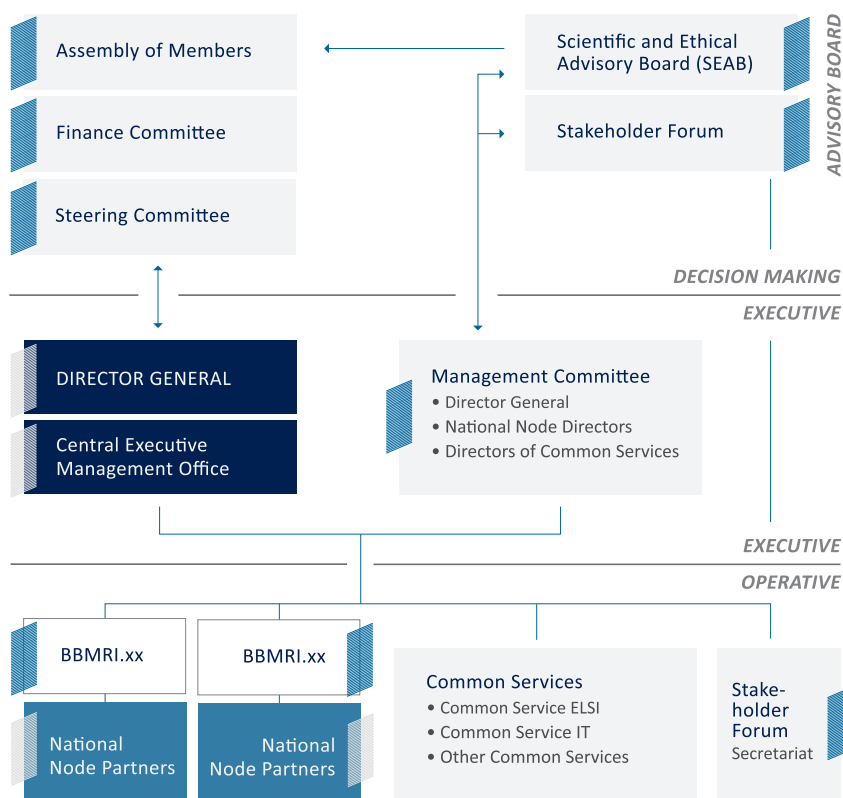
## **About BBMRI-ERIC**

# About

**Framework** On 3 December 2013, BBMRI was officially awarded the Community legal framework for a European Research Infrastructure Consortium (ERIC). This specific legal form is designed to facilitate the joint establishment and operation of research infrastructures of European interest.

**Values** The activities of BBMRI-ERIC shall be politically neutral and guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance and human values.

## Governance Structure



## Assembly of Members

**#6 – 28<sup>th</sup> April 2016, Vienna**

### *MEMBER STATES*

**AT** Hemma Bauer (Delegate)  
**AT** Oliver Mayer (Delegate)  
**CZ** Dalibor Valík (Delegate)  
**DE** Isabell Hahn (Chair of FC, Delegate)  
**EE** Toivo Räm (Delegate)  
**FI** Anneli Törrönen (Advisor)  
**FI** Riina Vuorento (Delegate)  
**FI** Olli Carpen (Delegate)  
**FR** Georges Dagher (Vice Chair of AoM, Delegate)  
**IT** Luca Sangiorgi (Vice Chair of FC, Delegate)  
**NL** Edvard Beem (Chair of AoM)  
**NL** Ronald Stolk (Delegate)  
**NO** Karianne Solaas (Delegate)  
**SE** Maria Anvret (Delegate)  
**SE** Katrin Brandt (Delegate)  
**UK** Claire Newland (Delegate)

### *OBSERVERS*

**CY** Constantinos Deltas (Delegate)  
**CY** Andreas Hadjisavvas (Delegate)  
**IARC** Maimuna Mendy (Delegate)  
**PL** Dominik Strapagiel (Delegate)

**#7 – 7<sup>th</sup> July 2016, Vienna**

### *MEMBER STATES*

**AT** Hemma Bauer (Delegate)  
**AT** Oliver Mayer (Proxy)  
**AT** Kurt Zatloukal (Delegate)  
**CZ** Jan Burianek (Delegate)  
**DE** Isabell Hahn (Chair of FC, Delegate)  
**EE** Toivo Räm (Delegate)  
**FI** Anneli Törrönen (Advisor)  
**FI** Riina Vuorento (Delegate)  
**FI** Anu Jalanko (Advisor)  
**FR** Georges Dagher (Vice Chair of AoM, Delegate)  
**GR** Dimitris Thanos (Delegate)  
**IT** Luca Sangiorgi (Vice Chair of FC, Delegate)  
**MT** Alex Felice (Delegate)  
**NL** Edvard Beem (Chair of AoM)  
**NL** Gert-Jan van Ommen (Delegate)  
**NL** Jeanette Ridder (Delegate)  
**SE** Katrin Brandt (Delegate)

### *OBSERVERS*

**CH** Stephanie Wyss (Delegate)  
**CY** Constantinos Deltas (Delegate)  
**PL** Dominik Strapagiel (Delegate)

### *GUESTS*

**MT** Joanna Vella

**#8 – 17<sup>th</sup> – 18<sup>th</sup> November 2016, Vienna**

*MEMBER STATES*

- AT** Hemma Bauer (Delegate)
- AT** Oliver Mayer (Delegate)
- AT** Kurt Zatloukal (Advisor)
- CZ** Dalibor Valik (Delegate)
- DE** Isabell Hahn (Chair of FC, Delegate)
- DE** Olaf Krueger (Advisor)
- EE** Priit Tamm (Delegate)
- FI** Anneli Törrönen (Advisor)
- FI** Riina Vuorento (Delegate)
- FI** Olli Carpen (Delegate)
- FR** Georges Dagher (Vice Chair of AoM, Delegate)
- IT** Luca Sangiorgi (Vice Chair of FC, Delegate)
- LV** Janis Klovinš (Delegate)
- LV** Marcis Leja (Delegate)
- MT** Alex Felice (Delegate)
- NL** Edvard Beem (Chair of AoM)
- NL** Martijnte Bakker (Delegate)
- NO** Karianne Solaas (Delegate)
- PL** Anna Chrościcka (Delegate)
- PL** Michał Rybicki (Delegate)
- SE** Maria Anvret (Delegate)

*OBSERVERS*

- CY** Constantinos Deltas (Delegate)

## **Steering Committee**

Edvard Beem (Chair of AoM)  
Georges Dagher (Vice Chair of AoM)  
Isabell Hahn (Chair of FC)  
Luca Sangiorgi (Vice Chair of FC)

## **Finance Committee**

Isabell Hahn (Chair)  
Luca Sangiorgi (Vice Chair)  
Hemma Bauer, Oliver Mayer,  
Philippe Desmeth, Dalibor Valík,  
Toivo Räm, Priit Tamm,  
Antti Hautaniemi, François  
Chambelin, Isabell Hahn,  
Dimitris Thanos, Luca Sangiorgi,  
Mark Debono, Christian Bonnici,  
Alex Felice, Edward Beem,  
Jeannette Ridder-Numan,  
Gert-Jan van Ommen, Karianne  
Solaas, Dominik Strapagiel,  
Roman Slaweta, Katrin Brandt,  
Stephanie Wyss, Fusun Atik Boyar,  
Kemal Baysal, Maimuna Mundy

## **Central Executive and Management Office/Headquarters**

Jan-Eric Litton (Director General)  
Michaela Th. Mayrhofer (Senior Project Manager  
and Chief Policy Officer of Common Service ELSI)  
Andrea Wutte (Quality Manager)  
Petr Holub (Senior IT/Data Protection Manager  
and Chief Information Officer of Common Ser-  
vice IT)  
Outi Törnwall (EU Project Manager)  
Markus Pasterk (Administrative Director)  
Nadja Palko (Communication Assistant)  
Ulrike Rohrer – on leave since 02/2016  
Carmen Cristea (Finance/Administration Assist-  
ant)  
Luc Deltombe (Finance/Communication Assist-  
ant)  
Meghan McCarroll (Secretary/Receptionist)

## **Management Committee**

Jan-Eric Litton (Chair)  
Marialuisa Lavitrano (Vice Chair)

Comprised of the Director General of BBMRI-  
ERIC, the National/Organisational Node Direct-  
ors, and the Directors of the Common Services.



## **National/Organisational Node Directors**

**BBMRI.at** Kurt Zatloukal

**BBMRI.be** Annelies Debucquoy / Karin  
Haustermans (until 3/2016)

**BBMRI.ch** Christine Currat

**BBMRI.cy** Constantinos Deltas and Kyriacos  
Kyriacou

**BBMRI.cz** Dalibor Valík

**BBMRI.de** Michael Hummel

**BBMRI.fi** Anu Jalanko

**BBMRI.fr** Georges Dagher

**BBMRI.gr** Dimitris Thanos

**BBMRI.ee** Andres Metspalu

**BBMRI.it** Marialuisa Lavitrano

**BBMRI.lv** Janis Klovinš

**BBMRI.mt** Alex Felice

**BBMRI.nl** Cisca Wijmenga and Gerrit Meijer;  
National Node/BBMRI-ERIC coordinator:  
Gert-Jan van Ommen

**BBMRI.no** Kristian Hveem

**BBMRI.pl** Łukasz Kozera

**BBMRI.se** Mats Hansson

**BBMRI.tr** Nese Atabey

**BBMRI.uk** Philip Quinlan

**WHO/IARC** Maimuna Mendy

## **Scientific and Ethical Advisory Board (SEAB)**

David Byrne

Thomas Hudson (until 4/2016)

Anders Ekblom

Carolyn Compton

Mark Daly

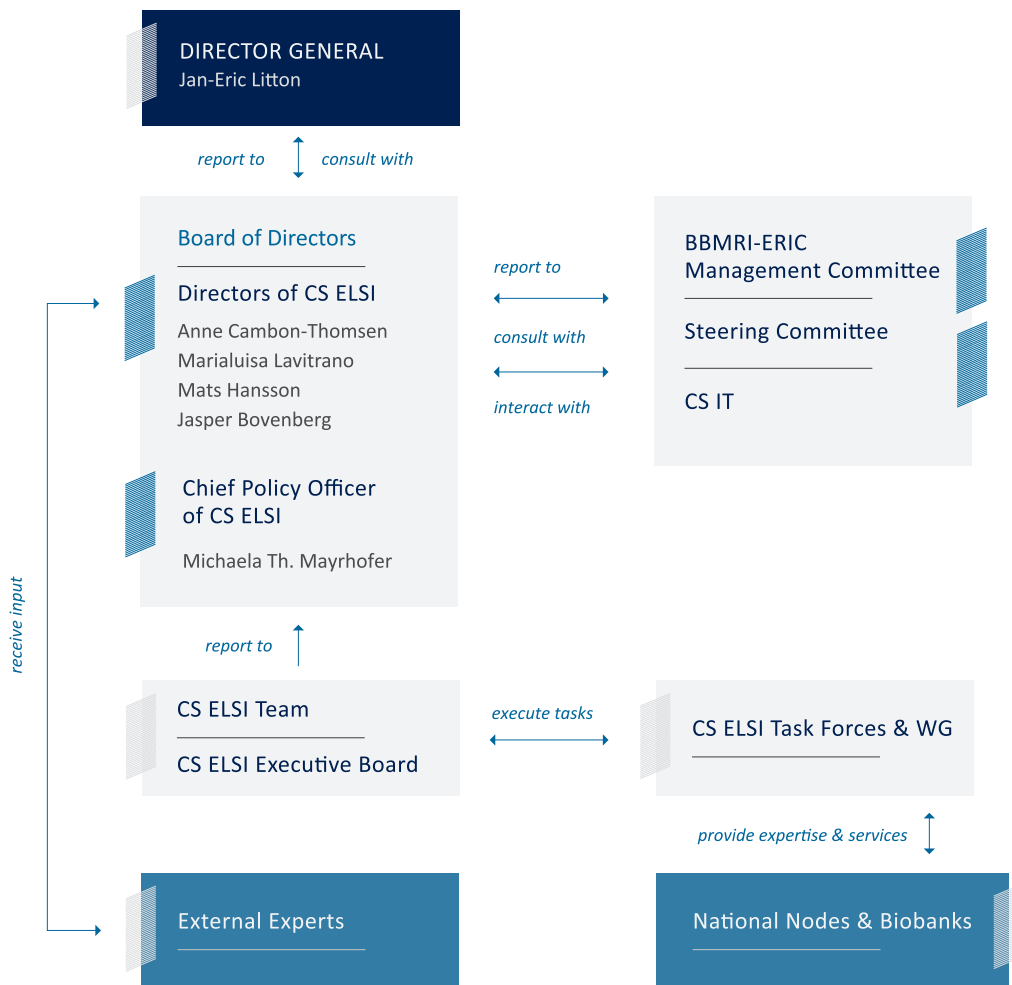
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## Common Service ELSI

**Board of Directors:** Anne Cambon-Thomsen (Co-Director, Coordinator), Jasper Bovenberg (Co-Director), Mats Hansson (Co-Director), Marialuisa Lavitrano (Co-Director), Maria del Rosario Sanchez-Albor (administrative support)

**Chief Policy Officer:** Michaela Th. Mayrhofer

**Common Service ELSI Team:** Gauthier Chassang Radek Halouzka, Moa Kindström, Heidi Howard, Olga Tzortzatou, Gillian Martin, Anna Durnova, Johannes Starkbaum, Tom Southerington, Liis Leitsalu, Martin Boeckhout, Irene Schlünder, Sara Casati, Myriam Rimmelink, Isabelle Huys, Victoria Chico, Alison Parry-Jones, Vents Silis, Berge Solberg

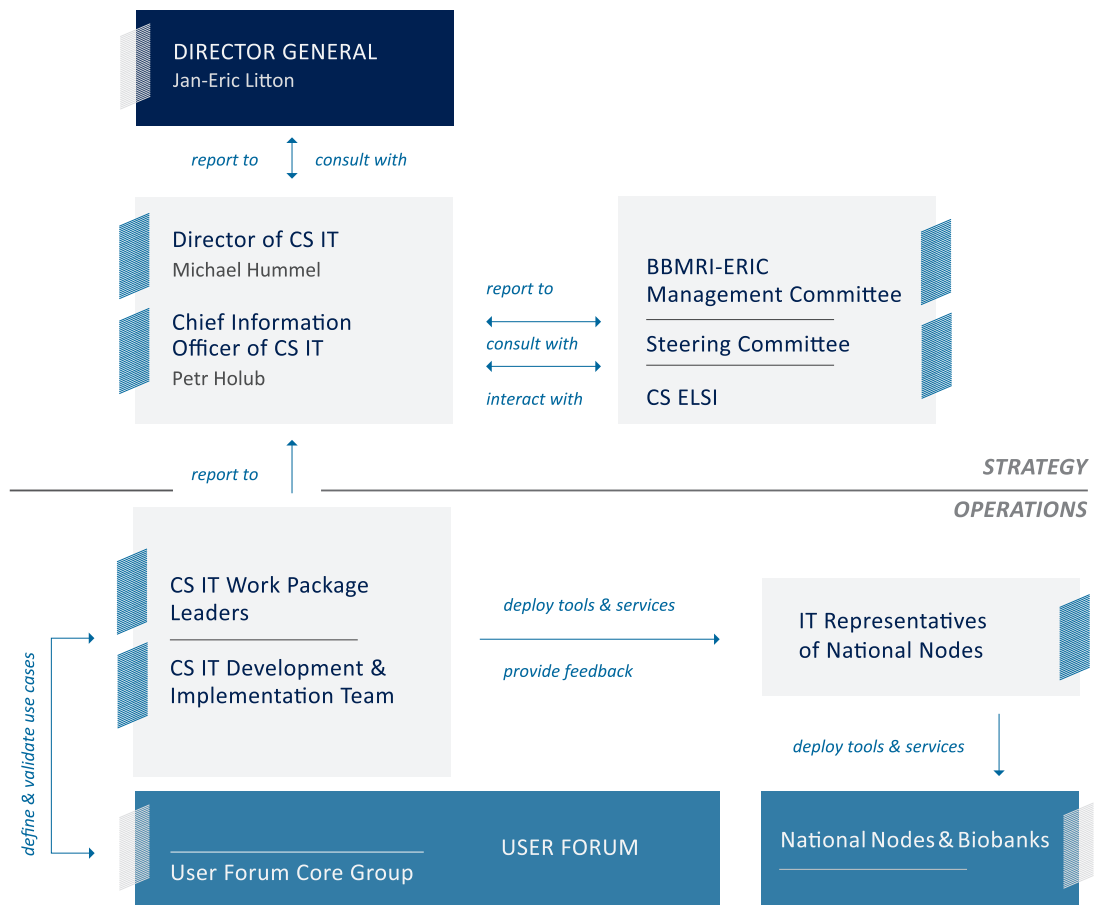


# Common Service IT

**Director:** Michael Hummel

**Chief Information Officer:** Petr Holub

**Common Service IT Team:** Diogo Alexandre, Araceli Diez-Fraile, Jean-Paul Ebejer, Niina Eklund, Kaisa Silander, Klaus Kuhn, Juha Knuutila, Florian Kohlmayer, Lefteris Koumakis, Ines Leeb, Nicolas Malservet, Kostas Marias, Sebastian Mate, Roxana Merino Martinez, Kristjan Metsalu, Timo Miettinen, Luciano Milanesi, Heimo Müller, Luca Pireddu, Romyana Proynova, Philip Quinlan, Hans-Ulrich Prokosch, Cornelia Rufenach, Morris A. Swertz, Frank Ückert, David van Enckevort, Ondřej Vojtíšek, Gianluigi Zanetti



## Communication and Dissemination



Figure 25.: 2016 Key Facts & Figures on Communication Activities by the Headquarters

In 2016, BBMRI-ERIC issued two Biobank Europe magazines (newsletters), introducing BBMRI.at and BBMRI.no retrospectively to a wider audience. Also, we disseminated news on key achievements of BBMRI-ERIC (esp. quality, projects, IT, ELSI).

**BBMRI-ERIC Headquarters as well as the Common Service ELSI and IT published together 20 publications including papers in peer reviewed journals, the 2016 Work Programme, the 2015 Annual and Financial Report, and the FAQs on the GDPR. The annual report highlights especially the achievements of National Nodes.**

On the web, 77 news postings were issued which disseminated news on meetings and achievements from both BBMRI-ERIC and the National Nodes. Tweets, re-tweets and linkedin updates amount to a total number of 156. The majority concerned exchanges on services and workshop results with other research infrastructures (esp. via twitter) and biobankers as well as researchers (esp. via linkedin).

A total of 4,445 people were subscribed to the BBMRI-ERIC e-Newsflash at the beginning of 2016. By the end of the year, the number of subscribers had increased to 4,567. The opening rate increased from 24.3% to 24.9% over the year. The click rate saw an even more significant rise, increasing from 3.8% to 4.4%. Both the opening and the click rate were above average.

In 2016, a total of 24,051 users visited the BBMRI-ERIC website, which is a 24% increase compared to 2015.

In a nutshell, our 2016 communication and dissemination activities lead to an increase in both quality and quantity of news-reporting and readers.

## Publications by BBMRI-ERIC and the Common Services

1. Mayrhofer, MT, Holub, P, Wutte, A & Litton, JE: BBMRI-ERIC: the novel gateway to biobanks. *Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz* **59**, 379–384 (2016).
2. BBMRI-ERIC: *Work Programme 2016* 2016.
3. BBMRI-ERIC: *Annual and Financial Report 2015* 2016.
4. Bovenberg, J, Boeckhout, M, Chassang, G, Schlünder, I, Tzortzatou, O & Falzon, RV: *The EU General Data Protection Regulation - Answers to Frequently Asked Questions 1.0* 2016. doi:10.5281/zenodo.164631.
5. Holub, P, Litton, JE, Wutte, A, Törnwall, O, Mayrhofer, MT & Management Committee of BBMRI-ERIC: *Performance Indicators for BBMRI-ERIC* 2016. doi:10.5281/zenodo.159416.
6. Wutte, A & Litton, JE: *BBMRI-ERIC-Associated Expert Centres/Trusted Partners V2.0* 2015. doi:10.5281/zenodo.164634.
7. Merino-Martinez, R, Loreana Norlin, DvE, Anton, G *et al.*: Towards Global Biobank Integration by Implementation of the Minimum Information About Biobank data Sharing (MIABIS 2.0 Core). *Biopreservation and Biobanking* **14** (4 2016).
8. Holub, P, Swertz, M, Reihls, R, van Enckevort, D, Müller, H & Litton, JE: BBMRI-ERIC Directory: 515 Biobanks with Over 60 Million Biological Samples. *Biopreservation and Biobanking* **14**, 559–562 (2016).
9. Doucet, M, Becker, KF, Björkman, J *et al.*: Quality Matters: 2016 Annual Conference of the National Infrastructures for Biobanking. *Biopreservation and biobanking*. doi:10.1089/bio.2016.0053 (2016).
10. Spjuth, O, Krestyaninova, M, Hastings, J *et al.*: Harmonising and linking biomedical and clinical data across disparate data archives to enable integrative cross-biobank research. *European Journal of Human Genetics (EJHG)* **24**, 521–528 (2016).
11. Gholami, A, Lind, AS, Reichel, J, Litton, JE, Edlund, A & Laure, E: Design and implementation of the advanced cloud privacy threat modeling. *International Journal of Network Security & Its Applications* **8**, 103–122 (2016).
12. Holub, P, Dowling, J, Muhammad, S, Niazi, K, Hakimzadeh, K & Parák, B: *Security and privacy requirements and secure storage architecture* Delivered as Milestone M6.2 document of EGI- Engage. 2016. doi:10.5281/zenodo.161551.
13. Dowling, J & Hakimzadeh, K: *Security toolset release for BBMRI-ERIC* 2016. doi:10.5281/zenodo.273860.
14. Swertz, M, Neerincx, P, Vojtíšek, O & Holub, P: *Analysis of requirements on biobank and study workflows* 2016. doi:10.5281/zenodo.273901.
15. *Workshop Report: Ethics Review of European Biobank Research: Towards Mutual RECOgnition?* 2016.
16. Holub, P, van Enckevort, D, Reihls, R *et al.*: *Consolidated Registry of BBMRI-ERIC Biobanks* 2016. doi:10.5281/zenodo.273550.
17. Alexandre, D, Lablans, M, Ückert, F *et al.*: *Implementation of the BBMRI-ERIC architecture and database* 2016. doi:10.5281/zenodo.273766.
18. Eklund, N, Mate, S, Schüttler, C *et al.*: *D8.1 Requirements specification for data harmonisation and terminology mapping tools* 2016. doi:10.5281/zenodo.164398.
19. Mate, S, Leb, I, Schüttler, C *et al.*: *D8.2 Overview Document on Already Existing Data Harmonisation Tools* 2016. doi:10.5281/zenodo.165775.
20. Hansson, MG, Dahlin, MK & Howard, HC: *Sharing and access to data and human biospecimens for the benefit of patients – Towards a BBMRI-ERIC Policy* 2016.

## Conferences and Meetings by BBMRI-ERIC

In 2016, BBMRI-ERIC was represented at more than 100 events. The largest share consists of conferences and workshops with a total of 22 different events including key note lectures, talks, and poster presentations (e.g., the Europe Biobank Week in Vienna, the IARC 50th Anniversary Conference in Lyon, the DACH Symposium für Klinische Studien in Freiburg, and the TERENA Networking Conference in Amsterdam).

The second largest category is 'Projects', with a total of 18 meetings, including work-package-related working sessions. Activities related to education and training, management and administration as well as Expert Centres and biomolecular resources were grouped in the 'Other' category, totalling 12.

Additionally, there were seven meetings related to the EU (e.g., DG RESEARCH or DG JUSTICE) and ESFRI as well as seven meetings within BBMRI-ERIC governing bodies, i.e., the Assembly of Members, the Management Committee, the Finance Committee, and the Steering Committee. Another six meetings were dedicated to the Common Service ELSI on the one hand and societies, associations and agencies, such as the European Society of Radiology, on the other hand. Five meetings were related to workshops at the National Nodes, while the Common Service IT and Quality had four meetings each. Last but not least, three meetings concerning the Stakeholder Forum and three meetings regarding potential new Members took place.

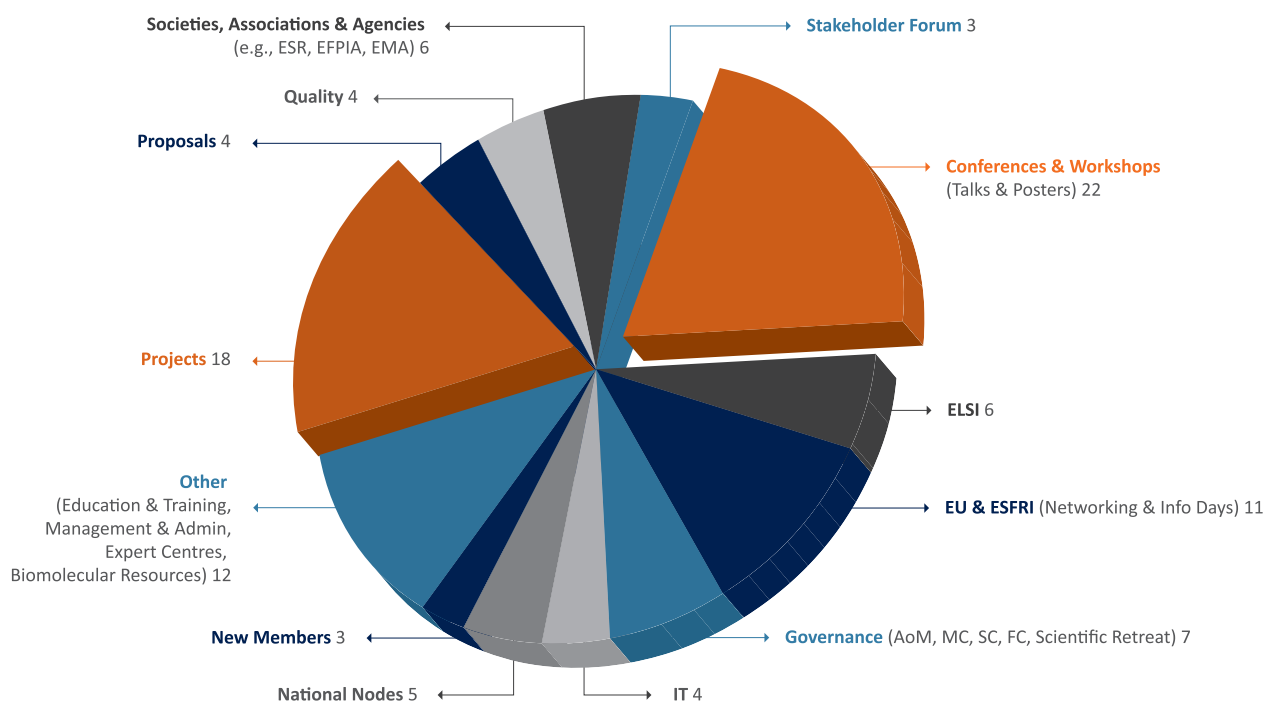


Figure 26.: 2016 Meetings: Purpose and Scope

## Scientific Articles by the BBMRI community: Headquarters, National Nodes, Common Services

### Journal Publications

1. Aarem, J, Brunborg, G, Aas, KK *et al.*: Comparison of blood RNA isolation methods from samples stabilized in Tempus tubes and stored at a large human biobank. *BMC Res Notes* **9**, 430 (2016).
2. Abubakar, M, Howat, WJ, Daley, F *et al.*: High-throughput automated scoring of Ki67 in breast cancer tissue microarrays from the Breast Cancer Association Consortium. *J Pathol Clin Res* **2**, 138–153 (2016).
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- Cordis, BBMRI-ERIC at the ECR 2016 on integrating biobanking with imaging data: bringing added value to diagnostics and research (March 2016)
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- IBBL, A new plasma quality control assay for metabolomics (June 2016)
- CORDIS, 2016 *Europe Biobank Week*: Bringing the European biobanking community together to discuss health innovation; 13<sup>th</sup> – 16<sup>th</sup> September 2016 (July 2016)
- ISC, A big step towards personalised medicine: CBmed appointed first Expert Centre of European Biobanks; (July 2016)

## Collaboration Agreements

To date, BBMRI-ERIC has signed agreements and Memoranda of Understandings with



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## Glossary

- AAI** Authentication and Authorisation Infrastructure. 23, 25, 26, 129
- AARC** Authentication and Authorisation for Research and Collaboration. See <https://aarc-project.eu/> and GÉANT, 25
- Assembly of Members** Assembly of representatives of the member countries of BBMRI-ERIC. 166
- BBMRI-ERIC Associated Expert Centre/Trusted Partner** Non-profit public-private partnership organisations, see Workstream 10.8 – Expert Centres. 31, 34, 46, 53
- BBMRI-ERIC Directory** Information service by BBMRI-ERIC, providing highly aggregated data about the biobanks and their collections of biological material and data. Previously also known as BBMRI Catalogue. 17, 21, 22, 24, 27, 28, 33, 45, 58, 90
- BBMRI-ERIC Negotiator** A service for facilitating access to BBMRI-ERIC partner biobanks, by orchestrating and simplifying the communications between researchers (requesters) and biobankers. 4, 21–24
- BIBBOX** ‘Biobank in a Box’ (BIBBOX) is an integrated software toolset as a part of reference information technology tools for biobanks. 21, 24, 40, 58
- CEN** European Committee for Standardization (Comité Européen de Normalisation), <http://www.cen.eu/>. 27, 118, 186
- CEN/TS** Technical Specification by CEN, <https://www.cen.eu/work/products/TS/Pages/default.aspx>. 27, 28, 58, 62, 90
- Common Service** A Common Service means a facility of BBMRI-ERIC according to Article 15(1) according to the Statutes.. 53, 160
- Common Service IT** Common Service on Information Technologies (IT). 24, 25, 37, 39, 40, 58, 62, 74, 75, 83, 89, 90, 100, 102, 125, 130, 132, 160, 163, 185, *see* Common Service
- Common Service ELSI** Common Service on Ethical, Legal, and Societal Issues. 24, 37–39, 59, 62, 73, 74, 76, 83, 88–91, 102, 130–132, 134, 160, 162, 166, 183, 185, *see* Common Service
- DG JUSTICE** The European Commission Directorate-General for Justice and Consumers, <http://ec.europa.eu/justice/>, [http://ec.europa.eu/justice/mission/index\\_en.htm](http://ec.europa.eu/justice/mission/index_en.htm). 166
- DG RESEARCH** The European Commission Directorate-General for Research and Innovation, <http://ec.europa.eu/research/>. 166
- Director General** The Director General is responsible for management of BBMRI-ERIC. 5, 6, 39, 42, 49, 51, 53, 142, 160, 187
- EFPIA** European Federation of Pharmaceutical Industries and Associations, <http://www.efpia.eu/>. 55
- ELSI** ethical, legal, and societal issues. 37–39, 52, 76, 80, 85, 88, 118, 131
- ESBB** European, Middle Eastern & African Society for Biopreservation and Biobanking, <http://esbb.org/>. 49
- ESR** European Society of Radiology. 45, 55
- EUDAT** European data infrastructure, <https://www.eudat.eu/>. 26

**Finance Committee** The Finance Committee is an advisory and preparatory committee of the Assembly of Members to: (a) advise the Assembly of Members and the Director General on matters relating to the management and preparation of the budget of BBMRI-ERIC, its expenditure and accounts, and its future financial planning; (b) provide the Assembly of Members and the Director General with advice on the financial implications of the other BBMRI-ERIC bodies' recommendations; (c) upon request, provide advice on other financial matters relating to the management and administration of BBMRI-ERIC; (d) submit a proposal concerning the appointment of external auditors to the Assembly of Members. (Statutes Article 12.1). 160, 166, 185

**FTE** Full Time Equivalent. 57, 61, 64, 67, 71, 74, 78, 79, 82, 84, 87, 89, 93, 96, 100, 108, 114, 117, 121, 124

**GDPR** General Data Protection Regulation. 39, 74, 76, 85, 88, 91, 100

**GEDE** Group of European Data Experts in RDA, <https://rd-alliance.org/groups/ge-de-group-european-data-experts-rda>. 26, *see* RDA

**Global Biobank Week** Annual biobanking conference, continuation of HandsOn Biobanks and Europe Biobank Week. It is planned 13<sup>th</sup> – 15<sup>th</sup> September 2017 in Stockholm, Sweden. 49

**GÉANT** The GÉANT Association, <http://www.geant.net/>. 186

**Headquarters** also called Central Executive Management Office of BBMRI-ERIC. It is located in Graz and supports the Director General in performing the managerial functions. 51, 140, 160, 185

**ISBER** International Society for Biological and Environmental Repositories, <http://www.isber.org/>. 49

**ISO** International Organization for Standardization (ISO), <http://www.iso.org/>. 28, 58, 90, 118, 187

**ISO/CD** Committee Draft of ISO. *see* ISO

**ISO/TC** Technical Committee of ISO. 26, 28, 42–44, 58, *see* ISO

**Management Committee** The Management Committee (MC) consists of the National/Organisational Coordinator. Observer countries may be invited to participate. The MC is chaired by the Director General. (Statutes, Article 14.2). 30, 31, 53, 74, 160, 166, 185

**Member** EU Member States, third countries as well as intergovernmental organisations may become Members BBMRI-ERIC. 5, 166, 186, 187

**MTA** Material Transfer Agreement. 58

**National/Organisational Node** National Nodes 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. Organisational Node means an entity, not necessarily with legal capacity, designated by an intergovernmental organisation that coordinates the Biobank(s) and Biomolecular Resources of the organisation, and links its activities with those of the pan-European infrastructure, BBMRI-ERIC. 31–33, 49, 53, 54, 56, 160, 161, 184

**Observer** EU Member States, third countries as well as intergovernmental organisations may become Observers BBMRI-ERIC. 5, 187

**P<sup>3</sup>G** Public Population Project in Genomics and Society, <http://www.p3g.org/>. 38

**PWI** Preliminary Work Item. 44, *see* ISO

**QMS** Quality Management System. 65

**RDA** Research Data Alliance, <https://rd-alliance.org/>. 26, 187

**SEAB** Scientific and Ethical Advisory Board. 6, 7, 54, 161, 185

**SOP** Standard Operating Procedure. 32, 33, 40, 123, *see* QMS

**Stakeholder Forum** Stakeholder Forum provides a platform for stakeholder of BBMRI-ERIC, e.g., patient advocacy groups, learned societies, and industry. Stakeholder Forum is distinct from BBMRI-LPC Forum. 54

**Steering Committee** The Steering Committee is responsible for supporting and monitoring the performance of the Director General of BBMRI-ERIC between the sessions of the Assembly of Members in implementing the decisions of the Assembly of Members, including the Strategic Plan, the Work Programme and the budget and shall report thereof to the Assembly of Members. Members of the Steering Committee do not represent a Member or any other organisation to which they belong; they are acting in the best interest of BBMRI-ERIC, within the powers mandated by and according to the decisions taken in the Assembly of Members. (Rules and Procedures). 160, 166, 185



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