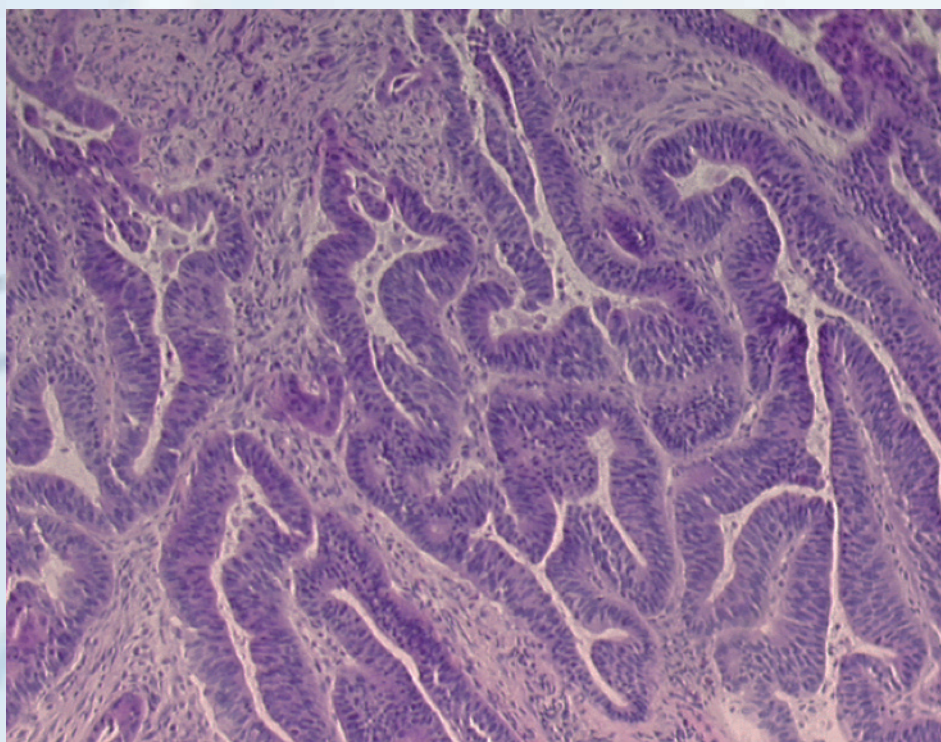


# BIOBANKS EUROPE



**BBMRI-ERIC®**

Biobanking and  
BioMolecular resources  
Research Infrastructure



**Issue No. 7/2017**

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## EDITORIAL CITUS, ALTUS, FORTIUS

The above is an Olympic expression of excellence, rather than a glorification of performance or victory. It is about giving one's best, improving and striving for perfection on a daily basis, both in the arena and life. I think this motto applies well to BBMRI-ERIC and the devoted work done by the many people involved.

Between May 16 and 19 this year, representatives from the BBMRI-ERIC Members States, the National Nodes and the Headquarters gathered at the Olympic Museum in Lausanne for a meeting hosted by BBMRI.ch. Participants spent several days working intensely on the **ADOPT BBMRI-ERIC** project, followed by the National Nodes representatives' meeting with the Management Committee, a joint meeting including

Headquarter representatives, National Node Directors and the Assembly, and last but not least, an Assembly of Members meeting. The joint meeting will result in a report that I shall provide, and that will be disseminated among our ever-growing community at a later stage.

As for the **ADOPT BBMRI-ERIC** project mentioned above, the overall concept is to accelerate the next steps towards imple-



*Capturing a moment on the stairs of the Olympic Museum in Lausanne: the 2017 BBMRI-ERIC family portrait*

menting BBMRI-ERIC and its services. The deliverables of **ADOPT** are tailored towards this goal. In particular, they address the issues described by ESFRI in a document titled 'Prioritisation of Support to ESFRI Projects for Implementation' dated 7 April 2014.

The project will increase the efficacy and excellence of European biomedical research by:

- Facilitating access to quality-defined human health/disease-relevant biological resources, including associated data, in an efficient and ethically and legally compliant manner;
- Reducing the fragmentation of the biomedical research landscape by harmonising procedures, implementing common standards and fostering high-level collaboration;
- Building capacities in countries with lesser developed biobanking communities, thus contributing to Europe's cohesion policy and strengthening the European Research Area (ERA). ADOPT BBMRI-ERIC is an acronym from the phrase:

*implementAtion anD OPeration of the gaTeway for health into the Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium.* The work package leaders come from different Member States in order to reflect the pan-European nature of BBMRI-ERIC. Building on the outco-

goal is to be reached, plans on how to set up such a valuable cohort have to be made now (read more on pages 14-17).

On a more personal note, I am proud to announce that we have reached one of my secret goals: the BBMRI-ERIC Directory 3.1 has reached 100M samples – and counting (page 27).

'ADOPT is an intriguing project which I am happy to be part of. If we are successful, I believe that we have really done something to help the patients with colorectal cancer'

**Outi Törnwall, PhD**  
EU Project Manager BBMRI-ERIC

mes of **ADOPT BBMRI-ERIC**, BBMRI-ERIC will provide the European research community with gateway access, expertise and services. The goal is for BBMRI-ERIC to build a large European colorectal cancer cohort for its Member States. If that

This figure is set to continue to grow significantly in the coming years. Having recently been upgraded to version 3.1, the BBMRI-ERIC Directory is a great step forward in improving the findability and accessibility of biobanking resources

in Europe, and possibly even beyond. It is connected to the Negotiator 1.0, a brand-new service that substantially simplifies the communication steps necessary to obtain information on the availability of relevant samples and data. Here, I would like to thank Petr Holub and the Common Service IT for their excellent work. The BBMRI-ERIC Directory will have a major impact on health and health-related research by providing access to quality-controlled human biological samples and associated medical and molecular data, all key resources for investigating the basic mechanisms underlying diseases.

**ADOPT BBMRI-ERIC** will directly accelerate the implementation of BBMRI-ERIC by introducing one-stop-shop access to the collections of the European research community. Additionally, ADOPT BBMRI-ERIC is expected to have a major impact on reducing the fragmentation of the biomedical research landscape through standards of procedures. The current European standard for samples was outlined in the last magazine (Biobanks

Europe No. 6). The CEN Technical Specifications (CEN/TS) published were presented as a basis for standardised sample processing in the BBMRI-ERIC community in order to improve sample-handling processes.

So far, nine self-assessment surveys have been developed. As a result, biobanks can now carry out self-evaluation to check the quality of human samples with respect to the applicable standards. These biobanks or the biobank samples and collections can then be reviewed by BBMRI-ERIC, after which steps may be taken to increase their visibility in the Directory. What is more, some first steps towards a BBMRI-ERIC audit programme will be taken later this year.

The 1912 Summer Olympics in Stockholm were the first games that had five continents participating. It was also the first time the tug of war competition took place. At the 2017 Global Biobank Week, participants from five continents will once again gather in Stockholm. The overarching theme will be quite different, however: *Towards Harmony in Bioban-*

*king*. That is not to say that we haven't already set a record for this event, receiving a total of 340 abstracts.

**See you at the Global Biobank Week in Stockholm in September!**

[www.globalbiobankweek.org](http://www.globalbiobankweek.org)



**Prof. Jan-Eric Litton, PhD**  
Director General BBMRI-ERIC

## 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 advise 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 scientists or experts in their own right, not as representatives of their respective background orga-

nisations 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:*



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

‘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 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.’



**SEAB Chair Alastair Kent**  
*Genetic Alliance, United Kingdom*

‘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.’

## WORDS FROM THE STAKEHOLDERS

*The following statements are a reprint from the 2016 BBMRI-ERIC Annual and Financial Report:*

‘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.’

**Dr. Brendan Barnes**  
EFPIA

‘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.’

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



## INTRODUCING THE CZECH NATIONAL NODE

### Facts and Figures

*How many biobanks and samples do you have?*

BBMRI.cz has five main biobanks and the amount of samples is increasing every year.

*How many partners in BBMRI.cz?*

BBMRI.cz has four partners: 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

#### Funding:

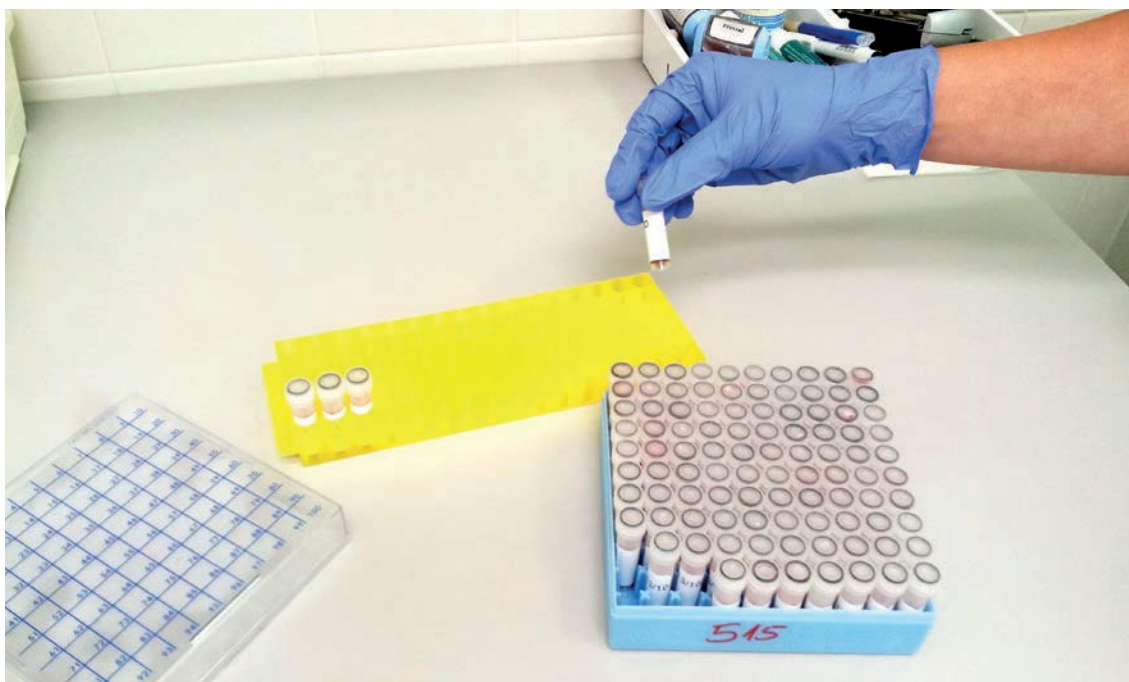
BBMRI.cz is funded with €5 million for the period 2010-2016.

#### Website:

<http://www.bbmri.cz>

Indicator	2014	2015	2016
Number of archived specimens de novo in LTS (all categories)	20588	37077	72983
Number of archived specimens de novo in STS (serum)	45080	47022	48000





*Preservation of whole blood samples in cryo-tubes*

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 RECAMO Centre for Basic and Translational Cancer Research.

In 2000, the 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 activity was com-

plemented by the hospital-integrated IT Bank of Biological Material (BBM) module linking clinical and laboratory data to biobanking aliquots in 2004. Since then, the institutional development continued until 2009, when MMCI applied in the first call of Research Infrastructure funding with the project 'Bank of Clinical Specimens', focused on cancer (BBMRI.cz), that was granted and initiated in October 2010.

The aims of the BBMRI.cz infrastructure were to operate a network of medical research biobanks that preserve biolo-

gical samples from cancer patients in a long-term manner under **secured, standardised and accredited conditions – unless done, such material will be permanently lost for future biological and medical research** – this process led to the establishment of a network of cancer research biobanks comprising BBM MMCI, the BBM of the 1<sup>st</sup> Faculty of Medicine 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 are operating as [BBMRI.cz](http://BBMRI.cz), organised as a research infrastructure.

The constructed system of biobanks at [BBMRI.cz](http://BBMRI.cz) consists of two types of storage for patient samples – a long-term storage (LTS) repository, and a short-term storage (STS) repository. The LTS repository collects various types of tissues (tumour, metastases, non-tumour) classified by diagnosis, serum at surgery, genomic DNA and RNA. This part of the biobank is filled with low frequency, typically at the moment of the patient's primary surgery.

The STS repository contains sera only and is iteratively updated at each patient's visit to the hospital when a blood specimen is taken for the determination of tumour markers. The STS serum repository presently stores leftovers of tumour marker patient material for a period of up to one year. However, the aim is to expand this peri-

od to up to 5 years. The unique design, i.e. the fact that not only the tissue material but also longitudinal strings of sera are stored, enables access to patient-derived material during the course of the complex patient treatment, thus reflecting pathophysiological and treatment-induced changes in the course of the disease.

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**Interview** with [Dalibor Valik, M.D, Ph.D, Director \[BBMRI.cz\]\(http://BBMRI.cz\)](#)

*Why is biobanking important to you personally and what can be achieved by it that otherwise would not be possible?*

The whole process of biobanking has its inherent strength in the simple fact that whatever material is taken from a patient can be preserved for use by next generations of investigators. Importantly, this is not meant to be a flow-through system of what you put in you have to retrieve from, but instead, people involved in building biorepositories are creating a kind of specific library to store

unique biological elements for future research.

In this way material that would be lost may be kept if biobanking facilities are in operation at the major academic medical centres.

*What is the particular or specific strength of [BBMRI.cz](http://BBMRI.cz) biobanking activities?*

The specific strengths of [BBMRI.cz](http://BBMRI.cz) are described in general on the relevant website – [www.bbMRI.cz](http://www.bbMRI.cz).

Here you can explore the specific features of the network, some of them being described in the paper retrievable from the webpage. For the purpose of a cancer centre, we operate what we call the long-term and short-term modules, the purpose being to preserve as much biological material from a given patient as possible. Such material is obviously linked to the full set of clinical data and as such, the whole operating loop is embedded in the hospital information system.

Another specific feature is the fact that the source elements,

i.e. source laboratories, being organisational parts of the participating hospitals, are covered by accreditation ISO 15189.

BBMRI.cz's development ambitions comprise taking 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 inno-

vative industrial activities to enhance introduction of new potential medicinal products to better serve the patient community in the Czech Republic.

Direct socio-economic impacts of BBMRI.cz pertain 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 through the use of collected

biological material connected to clinical data and tested through a comprehensive system of clinical trials. The search for relevant biomarkers specific for certain disease using archived human tissues is a critical component in the design of innovative medicinal products and diagnostic procedures in human diseases.

BBMRI.cz was built through bottom-up activity by research-oriented clinicians in leading cancer centres (oncologists, pathologists, laboratory physicians and cancer



*Long-term storage repository of samples at Masaryk Memorial Cancer Institute*

researchers) based on diagnostic services – those people wisely realised that the material of human origin obtained in healthcare institutions on a daily basis is in fact a gold source of knowledge for future research, provided that it is not wasted. BBMRI.cz exemplifies a developed research infrastructure encompassing and interlinking key hospital areas such as surgery departments, clinical laboratories, IT services and ethical/legal services responsible for collection release mechanism. Nowadays, the BBMRI.cz system is well-prepared to address current bio/medical challenges such as i) the need for quality-defined material and data, ii) the use of material and data for meaningful research, iii) compliance with ELSI (ethical, legal and social implications) requirements and iv) sustainability.

*In your view, what is the next challenge for BBMRI-ERIC in general and BBMRI.cz in particular?*

The next challenge for BBMRI-ERIC and obviously for the national networks is mostly to convince relevant entities about

the practical contributions of a research infrastructure of this type. I think that in fact, a lot of work was done, specifically at the IT level, and the tools that are prepared for implementation are one of the necessary steps to increase visibility and functionality of the BBMRI-ERIC system.

It is, however, my opinion that BBMRI-ERIC is the most advanced one and furthermore, that future integration of research infrastructures pertaining to human medicine will follow in the near future; this would be of benefit to all involved and mostly to the end-users, who are our patients.

*What in your opinion can be achieved through BBMRI-ERIC that cannot be achieved otherwise?*

Mostly, everything mentioned above, but in brief, the 'landscape analysis' and description of what is available and where, was one of the most important assets. The prime topic that has been brought up by members of our BBMRI-ERIC group was however, the overall emphasis on quality and tra-

ceability in clinical research. You may observe that BBMRI was the only research infrastructure operating in the field of medical research that raised this element as a key measure that has to be addressed if we (i.e. the scientific and medical community and financing bodies) are going to succeed in moving ahead.

*What are in your opinion the current challenges at the European level?*

Again, essentially what we have been discussing throughout, but in brief, the key challenge is where research money goes. One only has to think about the so-called wasted research costs to realise that something has to be done about this.

*What specific topic would you like to share with the broader biobanking community?*

These are definitely issues of quality, issues of research relevance and issues of relevant biomodelling. Clearly, in personalised medicine, we have moved beyond oversimplified rodent models and we need to come up with something

## BIOSKETCH

Dalibor Valik graduated from medical school in 1985 and subsequently specialised in paediatrics and clinical biochemistry. From 1994 until 1996, he worked at the Department of Clinical Chemistry and Immunology at Mayo Clinic, Rochester, USA. It was then that he developed an interest in metabolic disorders and biochemical genetics. In 1997, he was appointed Head of the Department of Laboratory



**Dalibor Valik, M.D, Ph.D**  
*National Node Director BBMRI.cz  
 and Chairman of the BBMRI-ERIC  
 Financial Committee*

Medicine at Masaryk Memorial Cancer Institute (MMCI) in Brno, CZ, before becoming associate professor in oncology in 2009. The year after, he was appointed both Executive Director of the newly established

Regional Centre of Applied Molecular Oncology MMCI (RECAMO) and National Coordinator of BBMRI.cz. In his function as National Node Coordinator, he has been responsible for constructing and designing the national network of research biobanks for cancer research. In 2011, he became Head of the Advanced Cell Immunotherapy Unit of the Department of Pharmacology at Masaryk University. This year, he was elected chairman of the BBMRI-ERIC Financial Committee.

better, reflecting the needs of human disease modelling. This is a very difficult and non-trivial issue, but the sooner this happens, the better the results available for the future use in patients in the form of diagnostic/theranostic procedures or treatments will be.

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## ADOPT BBMRI-ERIC: BUILDING A GATEWAY ACCESS TO EUROPEAN BIOBANKS



funded by  
the Horizon 2020  
programme of  
the European Union



### *How It All Started*

In 2015, a special call called INFRADEV-3-2015 was launched within H2020: Individual implementation and operation of ESFRI projects. ESFRI had approved the final selection of priority projects at its plenary meeting on 1st April 2014 and a report titled 'Prioritisation of Support to ESFRI Projects for Implementation' was forwarded to the Greek Presidency six days later. Based on the ESFRI

report, the Competitiveness Council had taken the following steps by 26<sup>th</sup> May:

- identify three priority projects (EPOS, ELIXIR, ESS);
- identify nine further projects ready for implementation by 2015-2016 (ECCSEL, EISCAT-3D, EMSO, BBMRI, ELI, CTA, SKA, CLARIN, DARIAH);
- recognise three projects under implementation which need further support for sustainability and European coverage (CESSDA, SHARE, ESS ERIC).

In the context of the call, BBMRI-ERIC was the only strictly health-related research infrastructure to receive

the grant. Therefore, deciding on a particular disease was of utmost importance. For common diseases, colorectal cancer was chosen as a use case, as it is one of the most frequently diagnosed cancers worldwide. 447,136 cases per year (2012) make it the second most frequently diagnosed cancer in the European Union.

### *About ADOPT*

The ADOPT BBMRI-ERIC project (GA no 676550) was launched in autumn 2015 for a 36-month period in order to boost and expedite the implementation and development of services within BBMRI-ERIC. The project has hence given BBMRI-ERIC and its wider community an opportunity to

accelerate the cooperative efforts that integrate biological repository resources through the National Nodes and their expertise into an operational, distributed, research infrastructure. Building on the outcomes of ADOPT, BBMRI-ERIC will provide the European research community with gateway access, expertise and services. By autumn 2018, ADOPT aims to deliver:

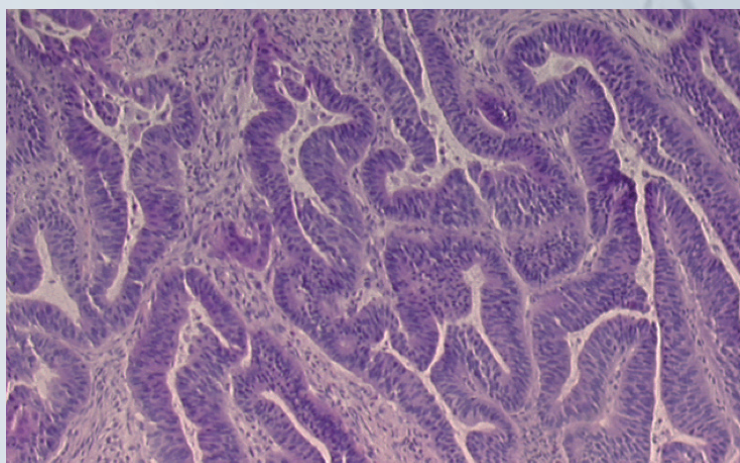
- a European map of biobanks (Directory), linked to BBMRI-ERIC and with proper tools in place to facilitate access to samples and data whilst protecting privacy (IT Gateway);
- services for the research community in the form of IT tools, ELSI guidance (e.g., Help-

desk) and Stakeholder engagement as well as services in the field of rare diseases;

- enhanced connection between basic research and clinics through biomarker use cases.

The common thread in ADOPT is the colorectal cancer use case. It means that we are working toward establishing the

first BBMRI-ERIC-wide disease cohort with 10,000 colorectal cancer cases, including samples and detailed medical information, by simply pooling together cases from the National Nodes and their associated biobanks. The expected benefits of ADOPT will not only consist of contributions to high-quality research through building a gateway access to European



*Hematoxylin and eosin-stained histological section of a colon cancer*

biobanks, but also result in a more uniform biomedical landscape by way of harmonisation, implementing common standards and fostering scientific excellence in research collaborations.

ADOPT BBMRI-ERIC has now been running for 20 months.

### *Gateway to Biobanks*

Facilitating access to samples and associated data is one of the major purposes of BBMRI-ERIC. The work on the IT infrastructure, the IT Gateway as we call it in ADOPT, aims at enabling a privacy-preserving connection between European biobanks and central BBMRI-ERIC facilities, enabling pan-European studies based on biobank data and disease-specific patient electronic health record information.

Key achievements towards the IT Gateway are the establishment and development of the **BBMRI-ERIC Directory** and the **BBMRI-ERIC Negotiator**, both biobank-based. The Directory currently consists of 626 biobanks, 1,363 collections and an estimated 100+ million samples across the BBMRI-ERIC Member States. While the Directory puts the biobanks on the map, the Negotiator simplifies communication between the biobank material requestor and the respective biobanks. Indeed a useful tool when communicating with multiple biobanks at the same time.

The real 'acid test' for the IT Gateway comes with the colorectal cancer collection, which entails collecting medical data on 10,000 cancer cases either by means of fully/semi-automated processing of hospital

documents (7,000 cases) or manually via user interface. For hosting the colorectal cancer data, a data model, database and user interface have been developed and are currently ready for the collection to start. Here, the focal point are BBMRI-ERIC-linked, well-established biobanks in Europe which are willing to provide their data and samples for the benefit of colorectal cancer research. Within the last year, the colorectal cancer collection process within ADOPT successfully attracted the attention of a total 80 biobanks in 16 different countries in Europe, 25 of which are already willing to take part in the joint collection. These biobanks, located in Austria, Belgium, Cyprus, the Czech Republic, Finland, France, Germany, Italy, the Netherlands, Sweden and the UK, are willing to provide more than 8,000 ca-



ses. While further cases from biobanks are being identified, the work towards solving the data protection principles of ADOPT is on-going. It is crucial for the principles to be flexible enough to comply with the national regulations.

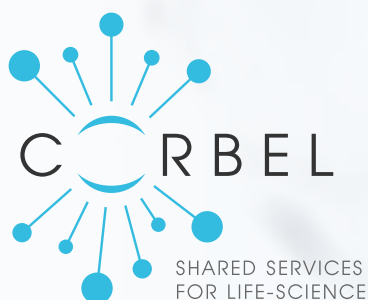
monstrating the capabilities of an effort such as BBMRI-ERIC.

### *Looking Beyond*

This is the first time ever that such a high-quality cohort of colorectal cancer cases is being established. In the long run, this cohort will allow addressing unsolved medical problems, such as individual risk assessment of stage II colorectal cancer, which is critically needed to optimise therapies. Furthermore, the experience gained through the work will allow detailed calculation of timelines and costs to establish similar high-quality cohorts for other diseases, therewith de-



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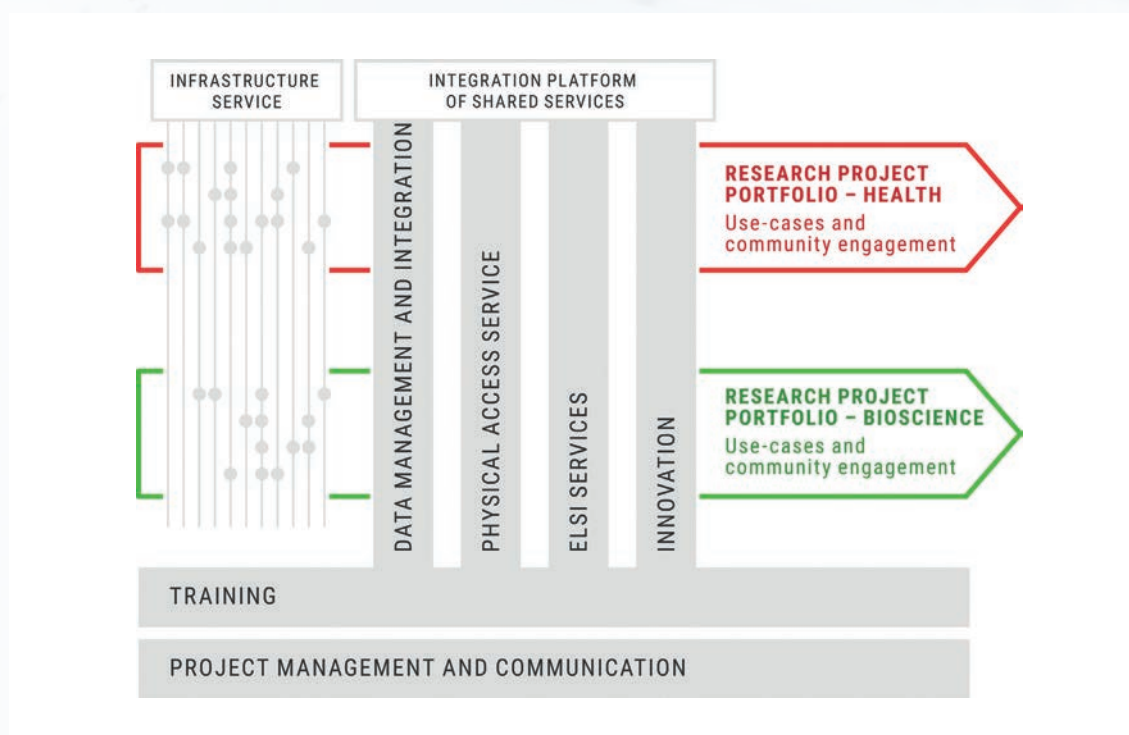
funded by the Horizon 2020  
programme of the European Union



The CORBEL project is a four-year Research and Innovation Action set up by the European Commission in 2015 to establish a framework of shared services between ESFRI Biological and Medical Research Infrastructures (BMS RI). It aims at enhancing the efficiency, productivity and impact of European biomedical research and its translation into medicine on a global level. CORBEL ([www.corbel-project.eu](http://www.corbel-project.eu)) is co-coordinated by ELIXIR (N. Blomberg) and BBMRI-ERIC (J.-E. Litton). The core purpose

of CORBEL is to drive BMS RI interoperability, aiming to operationalise interfaces, access protocols, data management, and ELSI support so that users can seamlessly access the rich landscape of European biological and medical research infrastructure services. Based on a user-led approach and guided by open calls, CORBEL is developing the tools, services and kind of data management that are required in cutting-edge European research projects: BMS RIs are collectively establishing a sustained foundation of colla-

borative scientific services for biomedical research in Europe, embedding the combined infrastructure capabilities into the scientific workflow of advanced users. Currently, more than 20 interdisciplinary research projects that were identified during the 1<sup>st</sup> Open CORBEL Call are pioneering research across at least two different RIs. Furthermore, CORBEL enables BMS RIs to support users throughout the entire implementation process of a scientific project: from planning and applying for grants through to



long-term sustainable management and exploitation of research data. By harmonising user access, unifying data management, creating common ethical and legal services, and offering joint innovation support, CORBEL will establish and support a new model for biological and medical research in Europe. The BMS RI joint platform will visibly reduce redundancy while at the same time simplifying project management and transforming the ability of users in order to deliver advanced, cross-disciplinary research. Researchers are highly encouraged to make use of the tools that are already available, such as the CORBEL Innovation Helpdesk and the CORBEL webinars. The Helpdesk offers assistance regarding collaboration with industry and technology transfer, while the CORBEL webinars aim at addressing common challenges and sharing best practices.

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## A GDPR CODE OF CONDUCT FOR HEALTH RESEARCH

The General Data Protection Regulation (GDPR) provides for general rules for the handling of personal data in various fields and contexts, be they commercial or non-commercial, be they economic or scientific etc. Specific needs of research, however, are not sufficiently reflected. In addition, health data are considered a special category of data needing a higher level of protection. Research on the basis of such data therefore needs a sector-specific tailoring. The GDPR encourages the development of such a specification via code of conducts 'for the purpose of specifying the application of this regulation' (see Art. 40 GDPR).

This is especially important, as legal texts are not easily accessible for non-lawyers. A Code of Conduct shall thus be understandable, clear, transparent, guiding, practical and non-legalistic. Providing such guidance for researchers and administrative staff would help to reduce unnecessary fear of diffe-

rent data protection standards in EU Member States and thus enhance data sharing for the sake of progress in research. A Code of Conduct would not only serve as a basis for further best practices. Those best practices will ensure compliance, but also reduce bureaucratic hurdles and thus save money, which can then be used for research purposes. Ultimately, they can help in avoiding reluctance to share data due to unnecessary fears of law infringements. Believing in the power of such a Code of Conduct and its joint development, BBMRI-ERIC started the process for its development. Join us and read more at <http://www.bbmri-eric.eu/BBMRI-ERIC/gdpr-code-of-conduct/>.

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## TOWARDS NEW HORIZONS A FAREWELL MESSAGE FROM ANNE CAMBON-THOMSEN

FORMER COORDINATING DIRECTOR (2015-2017) - COMMON SERVICE ELSI

I recently joined the new European Group on Ethics of Science and New Technologies (EGE), meaning that I am now one of the 15 experts who will advise the European Commission on all areas of policy where ethical, societal and fundamental rights issues intersect with the development of science and new technologies. However, this new position has also led me to step down from as Director of the Common Service ELSI. I have to say that this is a very emotional 'au revoir', it feels like becoming a part of BBMR-ERIC's history! While I am looking ahead, I cannot refrain from evoking memories of the many steps taken and the many friends made, the sharing of visions and the questioning, as well as the setting up of operational activities anchored in passionate discussions. After 10 years of shaping the preparatory phase, running the ELSI

work package, celebrating the birth of BBMRI-ERIC and conceiving and running the first



**Dr. Anne Cambon-Thomsen**  
*Former Coordinating Director  
(2015-2017) - Common Service ELSI*

BBMRI-ERIC Common Service, together with the very inspiring Service Co-Directors, with Michaela Mayrhofer's invaluable input and competence and Director General Jan-Eric Litton's confidence and support, I can only say thank you - it has been a privilege. My thanks also go to the entire ELSI team, an amazing construction of motivated and competent people

that are aware of the central role of this Service, and to the members of the Management Committee and the Assembly of Members, who were so important in launching and accompanying the first years of the Common Service ELSI. Having such a competent and hard-working team behind it, its future is on good tracks, and I am confident that the support given to the community will be at the highest level, something that is essential in this challenging domain in which ELSI is a central preoccupation.

I wish Mats Hansson, who accepted the responsibility to lead the Service in this interim period of 2017, all the best. I am sure that the Common Service ELSI will continue to be as creative and efficient with the support from the other co-leaders and the whole team.

## INTRODUCING THE NEW DIRECTOR OF THE COMMON SERVICE ELSI



**Prof. Mats G. Hansson**  
*Interim Director  
of the Common Service ELSI*

Mats G. Hansson is Director of the Centre for Research Ethics & Bioethics. He has extensive experience working as a biomedical ethics researcher and principal investigator in several multi-disciplinary research projects. His work mainly focusses on ethical, social and legal aspects regarding the implementation of genetic diagnosis in clinical practice and the use of human tissue materials in research, as well as clinical and medical ethics. He holds an undergraduate degree in biology (1974) and a doctoral degree in theology (1991).

Mats Hansson is Professor of Biomedical Ethics, a position that is jointly funded by Uppsala University and the Uppsala County Council. He also works as a clinical consultant at Akademiska sjukhuset (Uppsala University Hospital). He will be leading the Common Service ELSI as Interim Coordinating Director from May to December 2017.

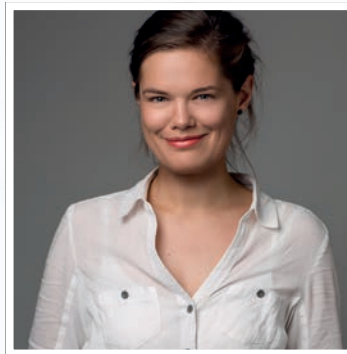
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## STARTING A DIALOGUE WITH STAKEHOLDERS STAKEHOLDERS CAN AFFECT OR BE AFFECTED BY AN ORGANISATION'S ACTIONS, OBJECTIVES AND POLICIES

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 its mission to facilitate the access to resources and support high quality biomolecular and medical research, BBMRI-ERIC aims to involve key stakeholders in its work to ensure their voice is heard and represented in European biomolecular and health research. As donations of valuable human biological samples and the corresponding data, stored by the biobanks, are essential for understanding human diseases and corresponding prevention programmes, BBMRI-ERIC is dedicated to consulting the biobanking stakeholder community in this process.

Identifying 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 disea-



**Michaela Th. Mayrhofer**  
*Senior Project Manager*  
*BBMRI-ERIC*

ses on 19 April 2016, therewith relaunching its stakeholder engagement (funded by ADOPT BBMRI-ERIC). The participating patient group stakeholders included the European Institute of Women's Health, European Cancer Patient Coalition, EURORDIS – Rare Diseases Europe, Genetic Alliance UK, Alzheimer Europe, and the Dutch VSOP. The meeting, chaired by Alastair Kent of Genetic Alliance UK, marked the beginning of a transparent consultation

and participatory stakeholder engagement process, which will be enlarged by chapters on industry representatives and other organisations and learned societies (e.g., EFPIA, EMA, etc.). Since then, several meetings have taken place focusing on informing on the latest achievements of BBMRI-ERIC and involving patient organisations in the discussions on a GDPR Code of Conduct. The overall aim is to address key issues for a continuous constructive dialogue to ensure stakeholders' needs are well represented in the activities of BBMRI-ERIC.

As outlined in BBMRI-ERIC's Work Programme, the Stakeholder Forum is designed as a timely and dynamic platform of exchange building on a participatory governance. The thematic topics in question will determine if one, some or all organisational chapters of the Stakeholder Forum will meet in smaller, topic-specific workshops. In 2016, the focus was on setting up the patient chap-

ter. The interest of industry and learned societies was explored and allowed the launch of these respective chapters in 2017. The chairperson of the Stakeholder Forum shall be a patient

advocacy group representative and by this function by default a member of the BBMRI-ERIC Scientific and Ethical Advisory Board. The chair will be supported by the BBMRI-ERIC En-

agement Officer, who starts in September 2017.

**Michaela Th. Mayrhofer, PhD**  
*Senior Project Manager BBMRI-ERIC  
 Chief Policy Officer of the Common Service ELSI  
 michaela.th.mayrhofer@bbmri-eric.eu*



## CONCLUSIONS FROM THE PATIENT STAKEHOLDER CHAPTER

Patients and families with life limiting conditions do believe in the crucial role of scientific research to make new and better treatment available. Patients therefore accept donating their data and samples to be shared amongst legitimate users for the purpose of advancing understanding and contributing to the realisation of the potential for health gain providing there is an appropriate framework in place. For these reasons, the patient stakeholder group believes it would be appropriate to establish a framework to support legitimate uses of data and samples, and reduce the risk of misuse or abuse of patient data to an acceptable level, bearing in mind that the elimination of all risk of misuse will probably only be achievable through the creation of a governance framework that is so tight that desirable applications are likely to be impeded to an unacceptable extent.

## APPLICATIONS SUBMITTED FOR THE EXECUTIVE MASTERS IN MANAGEMENT OF RESEARCH INFRASTRUCTURES



**Prof. Marialuisa Lavitrano**  
*National Node Director BBMRI.it  
University of Milano-Bicocca*

Applications for the Executive Masters in Management of Research Infrastructures closed on May 31<sup>st</sup>. A total of 110 applications were submitted, highlighting that this new programme will certainly fill a gap. Offering a mix of face-to-face and online modules, the degree is tailored towards the needs

of busy executives looking to acquire additional skills and competences required to successfully manage research infrastructures.

The Masters programme was developed within Rltrain, an EU-funded Horizon 2020 project aimed at improving and professionalising training for research infrastructure managers and leaders.

The vision behind the project is to train a new generation of executives for national and international research infrastructures and equip them with state-of-the-art managerial and leadership skills tailored to the needs of scientific service providers.



**Markus Pasterk, MSc**  
*Administrative Director  
BBMRI-ERIC*

See the official website at <http://emmri.unimib.it/en/> for more information.

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## EMA FRAMEWORK FOR REINFORCED COLLABORATION WITH ACADEMIA INCLUDES RESEARCH INFRASTRUCTURES

In March 2017, the European Medicines Agency (EMA) Management Board adopted the framework of collaboration with academia, which is intended to formalise, structure and further develop interactions with the academic community, including Biomedical Science Biological and Medical Sciences (BMS) research infrastructures. EMA's Executive Director Guido Rasi explains: *'The framework will allow us to integrate cutting-edge scientific knowledge more tightly into our activities. It will also help academic start-ups benefit from advice from the EU regulatory network to translate their discoveries into patient-focused medicines.'*

### The framework's overall objectives are:

- raising awareness of the mandate and work of the European medicines regulatory network to increase academia's trust in and engagement with the regulatory system;
- fostering the translation of academic research into novel methodologies and medicines which meet regulatory standards and address needs of public and animal health;
- ensuring that the best scientific expertise and academic research are available on time to support effective evidence generation, regulatory advice and guidance, as well as decision-making in regulatory processes;
- working with academia to develop regulatory science that embraces scientific progress in medicines development without compromising patient safety, such as for example, the use of novel endpoints or novel methodologies.

BBMRI-ERIC is excited to be part of this dialogue. Further information can be found at <https://goo.gl/dxDMdT>.



## DATA IN QUESTION – SURVEY ON CURRENT CHALLENGES IN BIOBANK-BASED RESEARCH

BBMRI-ERIC will be launching a survey related to collections of biological samples among biobankers and professionals experienced in research. The key focus of the enquiry will be to identify challenges arising from legal, ethical or social developments that impact established practices related to samples and health-related data handling and sharing. It will also explore the effects of the growing demand for engaging with third parties such as industry representatives,

patients or citizens. The major topics covered by the online questionnaire are professional experiences and opinions about: (1) the secondary use of data, (2) informing and/or re-contacting participants, (3) sharing data with third parties from industry, (4) participant engagement, and 5) collaboration with industrial partners. The study will be a collaborative effort between BBMRI-ERIC and COST Action CHIP ME, RD-Connect, IMI DO-IT and Biobank Norway. By participating

in the survey, you will help to gain new knowledge about how informed consent practices could be better adapted to the requirements of different stakeholders in the context of new legislation such as the EU General Data Protection Regulation. Access to the online survey will be provided across the BBMRI network and via newsletters. If you have any questions related to the survey or would like to participate, please send an email to Melanie Goisaufl at [melanie.goisaufl@univie.ac.at](mailto:melanie.goisaufl@univie.ac.at).

## NEW TOOLS TO FACILITATE FINDABILITY AND ACCESSIBILITY OF BIOBANKING RESOURCES

### BBMRI-ERIC DIRECTORY 3.1 REACHES 100M SAMPLES

BBMRI-ERIC is proud to announce that two new tools aiming to improve the findability and accessibility of biobanking resources in Europe, and possibly even beyond Europe, are now available.


The BBMRI-ERIC Negotiator is a brand-new service that provides an efficient communication platform for biobankers and researchers requesting samples and/or data. It substantially simplifies the communication steps that are necessary to obtain information on the availability of relevant samples/data, particularly if the researchers need to communicate with multiple candidate biobanks. The Negotiator 1.0 is connected to the already established BBMRI-ERIC Directory, the largest biobanking catalogue on the globe. Having recently been upgraded to version 3.1, the Directory reached 100 million samples in May this year. The reactions from within the community after the news started spreading showed once again how valuable the tools BBMRI-ERIC provides to its community are.

The BBMRI-ERIC Negotiator 1.0 is available at <https://negotiator.bbmri-eric.eu>

The BBMRI-ERIC Directory 3.1 is available at <https://directory.bbmri-eric.eu>

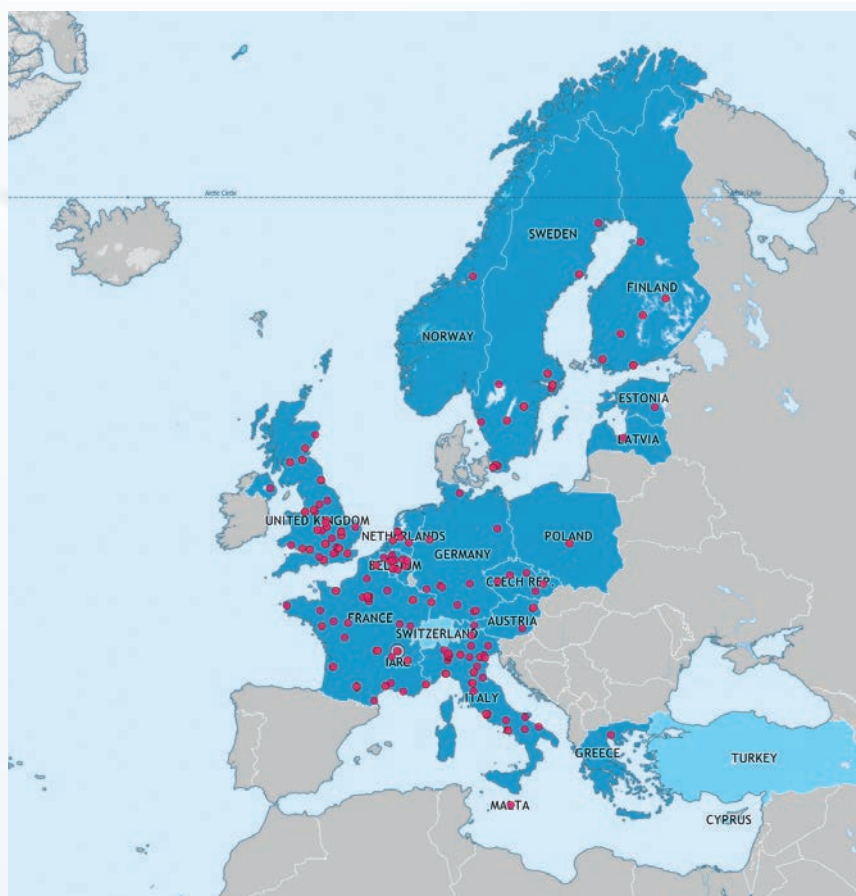
**Assoc. Prof. Petr Holub, PhD**  
*IT/Data Protection Manager and Chief Policy Officer  
of the Common Service IT BBMRI-ERIC, petr.holub@bbmri-eric.eu*

#### Tweet Activity



**BBMRI-ERIC @BBMRIERIC**  
BBMRI-ERIC DIRECTORY REACHES 100M SAMPLES, MAKING IT THE LARGEST #BIOBANKING CATALOGUE ON THE GLOBE!!!  
<https://goo.gl/g6zZQ2> #research  
pic.twitter.com/GrTHmRIGuR

Impressions	<b>615</b>
Total engagements	<b>31</b>
Link clicks	11
Likes	9
Retweets	6
Detail expands	3
Media engagements	2



## 2016 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

- Biomolecular Resources Workshop, Uppsala

- Stakeholder Forum Patient Chapter Kick-off meeting, Brussels

- AoM #7 Vienna

- Working Groups established for disease-oriented biobanks, liquid biopsies and immortalised cell lines

JANUARY

FEBRUARY

MARCH

APRIL

MAY

JUNE

JULY



- 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

If you want to learn more, see our 2016 Annual and Financial Report at <http://www.bbMRI-ERIC.eu/publications/>

- 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

## NATIONAL SYSTEM ACTION TO SHARE AND IMPLEMENT INNOVATIVE GOOD PRACTICES REGARDING INFORMED CONSENT AND ETHICAL EVALUATION IN BIOBANK-BASED RESEARCH



Since Regulation (EU) No 536/2014 has been implemented over the past few years and with the GDPR set to enter into force in May next year, this year has been decisive in shaping a new ethical, legal and societal horizon for both biobank-based research and research as a whole. BBMRI-ERIC's Italian Node thinks of this great challenge as an excellent opportunity in terms of good practice development, community building, public awareness and patient/citizen as well as researcher/clinician engagement towards infrastructures.

BBMRI.it decided to follow a participatory approach in order to identify cross needs and ethical, legal and societal priorities. To that end, a national survey was conducted among

BBMRI.it partner biobanks. 33 out of 65 biobanks participated in the survey. In addition, there were four deliberative workshops during the BBMRI.it 2016 Day, one aiming at biobankers and ELSI experts, the others intended for all relevant players, including patients/citizens and industry. Thanks to these activities, three national ELSI workshops could take place, bringing together biobanks, research ethics committees, patient organisations, and ELSI experts. Each of the 104 individuals joining the workshops was asked to obtain their home institutions support (institutional endorsement of the activity). Three specific focuses, including cross-cutting issues, as well as a common participatory approach for national action were agreed on. Since April, two peer working groups have been working with the rare disease and the cancer community, focusing on ELSI requirements regarding informed consent as good practice

based on understanding, awareness, and participation. A third peer group with research ethics committees (REC) has shared a dynamic matrix defining the status of biobanks as well as biobanking. Handling the genetic/genomic dimension, public-private partnership and the re-use of global data are the central, cross-cutting issues. The working method applied is a deliberative one. It is based on collaborative tools, the joint analysis of practices already in use and the generation of knowledge both to share ELSI requirements and to validate a participatory approach that can be applied in highly complex, scientific contexts.

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## QUALITY MANAGEMENT CROSS AUDITS IN BBMRI.AT BIOBANKS A SIGN OF MUTUAL TRUST



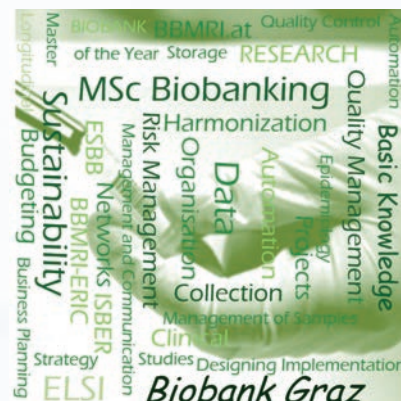
Anticipated with great excitement, partner biobanks of BBMRI.at recently performed their first intra-consortial cross audit, which can be considered as one of the crucial milestones of the National Node's work package on quality management (work package leaders: O. Wagner, H. Haslacher, both Medical University of Vienna). For this purpose, representatives of the MedUni Wien Biobank, the Biobank Innsbruck, the VetBio-Bank Vienna and the BBMRI.at

Coordination Office paid a visit to Biobank Graz, which maintains a vital and dynamic quality management system. The audit scope involved chapters 7 and 8 of ISO 9001:2008, covering realisation, control, prevention and improvement processes. Both auditors and auditees reported to have gained valuable experience from the visit, which is planned to be the first in a row of mutual quality management system audits within the consortium. In a next step, an audit programme covering

all relevant aspects of the standard and including all partner biobanks will be elaborated. The main goals of this internal audit programme on the basis of equality and mutual benefit are on one hand to offer a subject-specific review of one's own processes, and on the other hand to provide insight into existing approaches to common problems for the reviewers, which at their home institutes might sometimes maintain more recently established QM systems.



## MSc IN BIOBANKING AT BBMRI.AT PARTNER BIOBANK GRAZ AT MEDICAL UNIVERSITY OF GRAZ, AUSTRIA



'The distance learning master course 'MSc in Biobanking' will start a second time this autumn (September 2017) at Biobank Graz, Medical University of Graz, Austria'

### **Target group:**

This university course is open for graduates with a bachelor degree in medicine, technical specialists and graduates in natural sciences (biology, pharmacy, biotech etc.), who have interest in the field of biobanking or wish to specialise or broaden their professional

knowledge in biobanking. Also people with a respective expertise working in biobanks may apply.

### **Duration:**

The degree 'Master of Science in Biobanking' requires a master thesis that should be completed within the four semesters of the study (90 ECTS).

### **Structure:**

This university course is a part-time postgraduate programme offered as a distance learning course. It is an international

University course in the field of biobanking in English. The curriculum comprises 12 modules, of which modules 1 to 11 are mandatory modules and module 12 is an optional mandatory module. Each semester a compulsory face-to-face course (approximately one week) for all participants will take place in Graz.

**Next start:** September 2017

**Information & Registration:**  
[mscbiobanking@medunigraz.at](mailto:mscbiobanking@medunigraz.at)





# ESOF 2018

## EUROSCIENCE OPEN FORUM

# TOULOUSE

### AN INVITATION TO ACTIVELY PARTICIPATE IN ESOF 2018, THE EUROSCIENCE OPEN FORUM, IN TOULOUSE, FRANCE, 9-14 JULY 2018

The 8<sup>th</sup> edition of the **Euro-Science Open Forum (ESOF)** will take place in Toulouse, France, from 9<sup>th</sup> to 14<sup>th</sup> July 2018. Dedicated to science, innovation and how they intertwine with society, ESOF 2018 will offer scientists from all over the world, business people, policy makers, science communicators, and the general public a unique framework for interaction and debate. Under the motto Sharing Science: Towards New Horizons, knowledge sharing will be the main focus of the event, especially through the science program-

me, which will include numerous seminars, workshops and debates on the latest breakthroughs in research led by globally renowned scientists. Special attention will also be given to research infrastructures by dedicating different streams to different topics such as science policy and transformation of research practice, including an entire stream dedicated to health in our societies. As part of the ESOF 2018 science programme, the call for proposals for the scientific session will be open until the 23<sup>rd</sup> June 2017. Proposals can be submitted

at [www.esof.eu](http://www.esof.eu). Any person or institution can propose topics for sessions as long as they are consistent with the main topics of ESOF while also complying with the ESOF requirements, i.e. interdisciplinarity, high scientific value and a European nature.

As Champion of this event, I shall be especially happy to welcome you to Toulouse, the 2018 European City of Science.

**Dr. Anne Cambon-Thomsen**  
ESOF 2018 Champion / EuroScience  
Open Forum  
[office@toulouse2018.esof.eu](mailto:office@toulouse2018.esof.eu)

Stockholm, Sweden | September 13-15, 2017

# GLOBAL BIOBANK WEEK

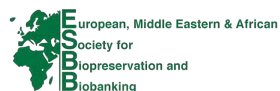
Towards Harmony  
in Biobanking



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JULY 15, 2017, TO TAKE ADVANTAGE  
OF THE EARLY BIRD RATE

[www.globalbiobankweek.org](http://www.globalbiobankweek.org)

 #GBWstockholm





BBMRI-ERIC, ESBB and ISBER are joining forces for the first-ever Global Biobank Week!

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- High-level plenary talks
- **More than 100** posters

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 Panasonic  
 TTP Labtech

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#### SOCIAL PROGRAMME:

The Global Biobank Week Social Programme will give you the opportunity to meet your peers during the congress and discover Stockholm. Please join us!

#### LOCATION:

The Brewery, one of the most characteristic elements in the skyline of Stockholm – located in the heart of the city!

**The Brewery – Conference Centre Stockholm**  
**Torkel Knutssonsgatan 2**  
**104 62 Stockholm, Sweden**

Please visit the website for more information  
[www.globalbiobankweek.org](http://www.globalbiobankweek.org)

# IMPRINT

## ***PHILOSOPHY, NATURE AND PURPOSE OF BUSINESS***

'Biobanks Europe' is the magazine of BBMRI-ERIC, which is designed to facilitate the joint establishment and operation of research infrastructures of European interest and beyond. The ERIC status allows pulling together biobanks and biomolecular resources into a pan-European facility and providing access to collections of partner biobanks and biomolecular resources, their expertise and services on a non-economic basis. BBMRI-ERIC is established for an unlimited period of time.

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