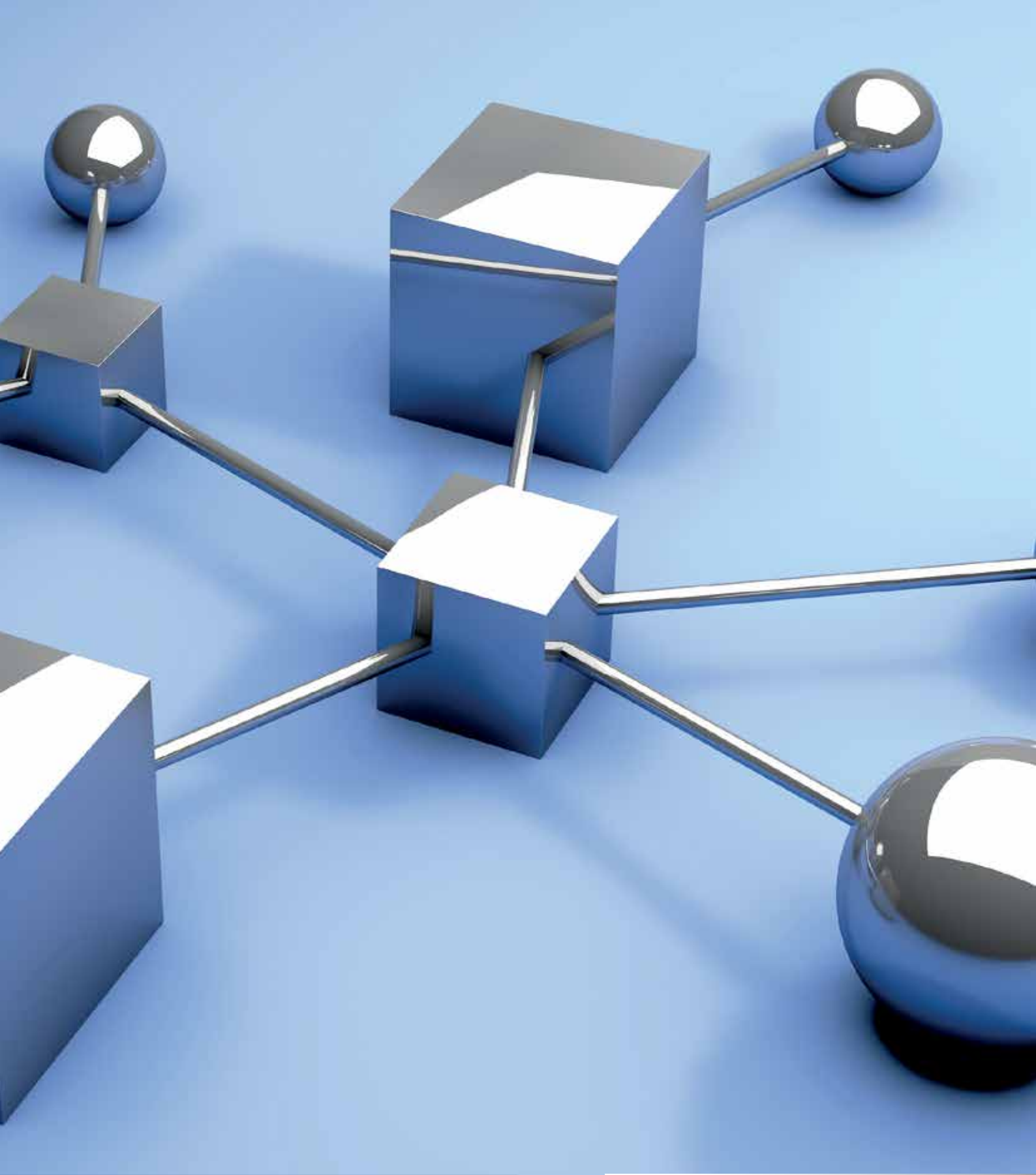

BIOBANKS EUROPE

Issue No. 5/2016

BBMRI-ERIC®
Biobanking and
BioMolecular resources
Research Infrastructure

EDITORIAL
PERSONALISED MEDICINE

The implementation of personalised (PM) medicine in healthcare is slow. One reason is the lack of evidence that is needed to demonstrate the benefits of PM to citizens and healthcare systems. Another problem is the quality of the biological samples. To address the challenges in PM, several public health research funders and policy-making organisations, together with the European Commission, presented 1 May 2016 a new initiative called the International Consortium for Personalised Medicine, or „IC PerMed". BBMRI-ERIC was invited to join this initative. Several challenges were identified by ICPerMed addressing:

1) ***Citizens and Patients:*** public engagement and involvement of citizens/ patients in science,

2) ***Data and ICT:*** integrating Big Data and ICT solutions to generate the required knowledge,

3) ***Research Efforts:*** translation of discoveries into clinical research,

4) ***Market Access:*** bringing new PM innovations to the market,

5) ***Health Systems:*** shaping up the healthcare into a knowledgeable system that is able to adapt fast to new approaches.

In the framework of the H2020 project CORBEL[1] (Coordinated Research Infrastructures Building Enduring Life-Science Services); seven of the eleven partnering European research infrastructures (BBMRI, EATRIS, ECRIN, ELIXIR, EU-OPENSCREEN, INFRAFRONTIER, and ISBE) have come together to formulate views how the European research infrastructures can contribute to the Agenda of ICPerMed. For BBMRI-ERIC we have identified our contribution to the defined challenges.

1. BBMRI-ERIC and many of the most important Patient Organizations in EU have joined forces since April 20, 2016 for an Engagement Process. The stakeholders include the European Institute of Women's Health, European Cancer Patient Coalition, EURORDIS - Rare Diseases Europe, Genetic Alliance UK, Alzheimer Europe, and Dutch Genetic Alliance VSOP. Among the most pressing challenges identified by the Patient Organizations were data (over) protection and the issue of informed consent, reciprocity and re-contacting the patients, as well as PM.

2. BBMRI-ERIC is currently formulating a strategic vision and guideline of how large privacy-sensitive data sets can be made available within the wide research community. Particular focus is towards an approach that not only maximizes material sharing but the actual reuse of data for the benefit of PM.
An open-source software platform that covers security, ethics and regulations for per-

sonal data protection, storage and analysis of big data have been developed in the FP7 project Biobank Cloud[2].
BBMRI-ERIC is involved in creating the legislation to support the big data use such as GDPR (General Data Protection Regulation) and providing its translation and interpretation for the research community.

3. Quality matters and it is a one of the paramount factors dictating the reproducibility of research results. Since April 2015, BBMRI-ERIC has been actively contributing to the process of international standards development as Observer Liaison of ISO/TC 276 Biotechnology as well as of ISO/TC 212 Clinical Laboratory Testing and In Vitro Diagnostic Test Systems. The latest exiting development in the field of quality is BBMRI-ERIC's involvement in the future work of the H2020 project SPiDIA4P, towards providing new pre-analytical standard documents that will address the main missing clinical sample types and their molecular bioanalyties for PM. The new key sample types include liquid biopsies and microbiomes that already have started to revolutionize the field of PM.

4. BBMRI-ERIC actively works towards facilitating efficient access to biomolecular resources and expertise for both academic and industrial partners. As an alternative for the large pharmaceutical and biotechnology companies to build up their own biobanks, they can establish collaboration with BBMRI-ERIC that can facilitate access to millions of biological samples that are available in biobanks across Europe. For this purpose, BBMRI-ERIC has developed a concept of Expert Centres that are established outside of BBMRI-ERIC as public-private-partnerships in the pre-competitive, not-for-profit field.

5. BBMRI-ERIC has established a contact with EMA (European Medicines Agency) in order to raise awareness of the importance of diagnostics that comply with the existing and upcoming quality standards. EMA and BBMRI-ERIC are also seeking opportunities to advocate more active involvement of healthcare professionals in regulatory activities via the enhancement of educational programs, participation in scientific events and collaborative regularity science research projects.

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

[1] http://www.corbel-project.eu/ | [2] http://www.biobankcloud.com

INTRODUCING THE AUSTRIAN NATIONAL NODE

BBMRI.at
Biobanking and BioMolecular resources Research Infrastructure Austria

Facts & Figures

How many biobanks and samples do you have?

BBMRI.at has a focus on healthcare integrated biobanks and covers basically all diseases. Currently four biobanks and their various collections with more than 12 million specimens (human and animal) are members of BBMRI.at, i.e.

- Biobank Graz, Medical University of Graz (7.5 million samples)
- MedUniWien Biobank, Medical University of Vienna (4 million samples)
- Biobank Innsbruck, Medical University of Innsbruck (425.000 samples registered in the BBMRI.at Catalogue)
- VetBiobank, University of Veterinary Medicine (20.000 animal samples)

How many partners are there in BBMRI.at?

BBMRI.at has seven consortium partners and comprises all Medical Universities of Austria (i.e. the Medical University of Graz, Medical University of Vienna, Medical University of Innsbruck, Paracelsus Medical Private University Salzburg), the University of Veterinary Medicine with their biobanks and two further partners (Alpen Adria University Klagenfurt, Life Science Governance Institute).

Funding:

BBMRI.at is funded with EUR 3.5 million by the Austrian BMWFW (GZ 10.470/0016-II/3/2013) for 5 years. In addition, there is in-kind contribution from all consortium partners.

Website: www.bbmri.at

Key activities of BBMRI.at:

Ovrall objectives of BBMRI.at are to establish a national biobanking research infrastructure and to link it to BBMRI-ERIC as a competent partner.

Examples of BBMRI.at's current main activities are:

(1) Implementation of common quality management to provide access to quality-defined samples: All BBMRI.at biobanks have committed themselves to establish pre-analytical sample management according to the Technical Specifications of the European Committee for Standardization (CEN/TS). To achieve this BBMRI.at developed a self-assessment-tool for evaluating the conformity to the CEN/TS. The tool is provided to the BBMRI-ERIC community and will be developed further jointly.

YLOG semi-automated storage system for FFPE samples at Biobank Graz. Biobank Graz currently has 7.5 million samples of which the vast majority is FFPE samples.

The BBMRI.at team at the Med Uni Innsbruck in 2013.

To facilitate the implementation of CEN/TS and the building of biobanks, BBMRI.at offers hands-on training courses.

(2) Activities in stakeholder and user engagement to increase public acceptance and utilisation of biobanks, such as i) citizen-expert-panels to engage with the public, ii) initiating the first BBMRI-ERIC Expert Center for biomarkers, and iii) establishing of a Translational Science Forum to better understand user needs from industry.

(3) Activities in data management, such as i) the feasibility show case "Austrian-Digital-Liver-Project" that brings together pathologists, clinicians and surgeons to build an advanced Liver-Specimen/Data-Platform, ii) establishment of a digital Clinical-Patient-Phenotyping-Tool for bedside documentation of bio-specimen and patient phenotypes, and iii) upgrade of BBMRI.at by complementing tissue samples with digital histological images and establishing a high security national medical research data infrastructure.

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

Biobanking has evolved from an activity that, in the past, essentially every scientist in biomedical research had to manage individually to a highly professional field today.

Increasing demands on quality of biosamples have to be addressed in order to exploit the analytical capacities of modern –omics technologies and guarantee reliability of molecular data generated. Furthermore, data management is becoming more and more relevant in biobanking, and biobanks are developing from repositories of biosamples (containing finite raw material) to data- and knowledge- banks providing a reusable resource.

These developments go hand in hand with an increasingly more complex ethical and legal environment which requires professional expertise to support scientists in performing research compliant with ELSI requirements.

Tell us more about your engagement in the field of biobanking.

We started with biobanking in 1993 to improve the utilisation of tissue samples collected in the context of histopathological diagnosis for research. In the last 10 years focus has shifted from sample collection, which is now performed by the Biobank Graz, to developing technologies to improve biobanking and the use of biosamples. Participating in several national and EU-funded programmes, we were involved in the development and evaluation of novel fixatives for biosamples, development of standards for sample pre-analytics, which are already published as CEN technical specifications and

Public engagement activities at BBMRI citizen panel in Graz. BBMRI.at conducts 3 citizen expert panels per year in Graz, Vienna and Innsbruck.

currently being developed to ISO standards, explored new sample types for biobanking, such as stem cells or saliva for metabolome analysis, and developed technologies for biobanking of samples containing high risk pathogens. A more recent activity is to complement tissue samples with detailed medical data including digital images. I also had the privilege to coordinate the preparatory phase of BBMRI and I am currently national node director of BBMRI.at.

In your view, what is the next challenge for BBMRI-ERIC in general and, as host country of BBMRI-ERIC, of BBMRI.at in particular?

One of the big challenges for BBMRI-ERIC is to help national biobanks to become sustainable in the longterm. In this context improving efficiency by coordination of activities, and increasing the quality, visibility and use of biobanks will be of central importance. Furthermore, it is important that BBMRI-ERIC is recognised and acts as a common biobanking infrastructure for all European member states. For Austria ,as the hosting country, I see an important role in providing an outstanding environment for further development of BBMRI-ERIC (i.e. the central executive management office of BBMRI-ERIC is located in a brand new research campus and Styria is a leading innovation region in Europe, spending 4.8% of its GDP on R&D). For BBMRI.at it is important to increase collaboration with other national nodes to enhance the engagement with local biobanks and user communities.

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

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

Snap-freezing of tissue samples in Isopentane pre-cooled liquid nitrogen is one of the best methods of tissue conservation for molecular analysis

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, contribution to the development of ISO standards, and BBMRI-ERIC's recognition as a key research infrastructure for ELSI issues in biomedical research.

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

The biomedical research community is highly fragmented and this has to be overcome to properly address the great societal challenges. BBMRI-ERIC could provide an outstanding framework to enable large-scale collaborative research and to facilitate a cultural change in the biomedical sciences. But there is still a long way to go until collaboration and sharing of resources become commonly recognised.

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

Biobanking should recognise the increasing role of data associated with samples and become more actively involved in developing data management solutions and data infrastructure. Another important aspect is the stronger consideration of user needs in terms of required quality of bio samples, as well as costs and efficiency of access to samples and data.

BBMRI.at public engagement at the Long Science Night 2016. At the booth of Biobank Graz and BBMRI.at Coordination children and their parents enjoyed to look at tissue under the microscope and learn about the work of a biobank.

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BIOSKETCH

Univ.-Prof. Dr. Kurt Zatloukal is a Professor of pathology at the Medical University of Graz, Austria and the director of the Christian Doppler Laboratory for Biospecimen Research and Biobanking Technologies. His research focusses on molecular pathology of diseases as well as the development of biobanking related technologies.

He coordinated the preparatory phase of the European Biobanking and Biomolecular Research Infrastructure (BBMRI) and is now the director of the Austrian national node of BBMRI-ERIC.

He contributed to the development of new European standards and norms for pre-analytical processing of tissue samples for molecular diagnostics.

He is involved in developing the ethical and legal framework for Austrian medical research and healthcare.

He is member of the Austrian Arzneimittelbeirat (Pharmaceutical Advisory Board) and the scientific board for genetic testing and human gene therapy at the Austrian Ministry of Health, and member of the Austrian Standards Institute. He is a member of the Academia Europaea, a corresponding member of the Austrian Academy of Sciences, has published 200 scientific papers, and was co-inventor of 25 patents.

Univ.-Prof. Dr. Kurt Zatloukal
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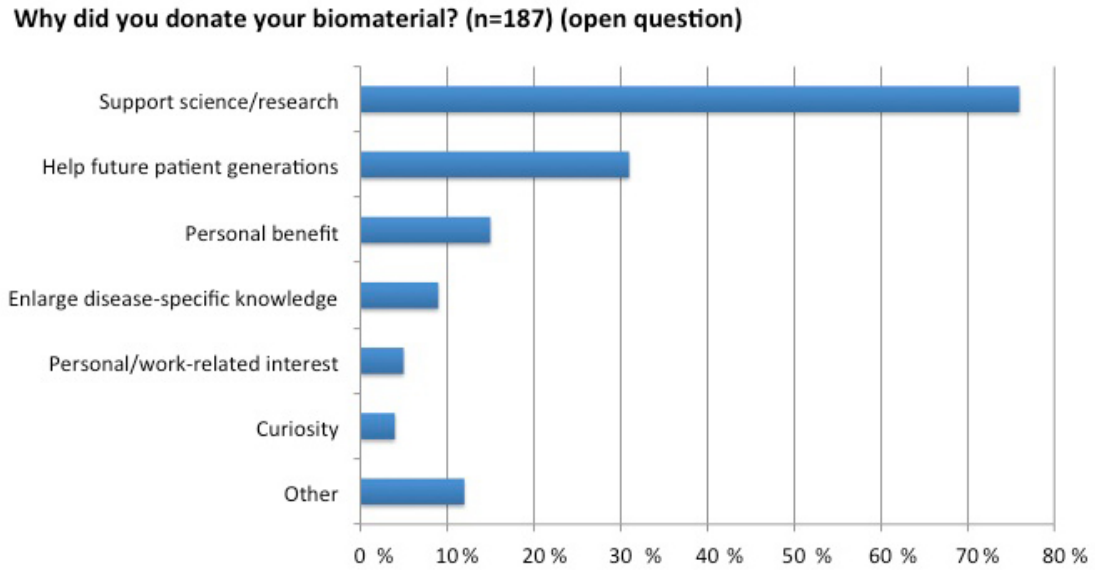
ENGAGING WITH BIOBANK STAKEHOLDERS

BBMRI.de
Biobanking and BioMolecular resources Research Infrastructure Germany

Biobanks are mostly unknown among patients and the public. Even employees of medical hospitals have difficulties in describing what biobanks are used for medically or scientifically. The most frequent association among laypeople is “blood” or “sperm donation”, and some people might even think of this as a proper biobank. To address this communication gap, the German Biobank Node (GBN) is working on public engagement concepts for biobanks. The goal is to help people understand why biobanking is essential for the future of medical research and health innovation and how they can be involved. “We think it is very important to convey a positive image of biobanking in Germany, including its social and ethical aspects, in order to achieve broad acceptance of biobanks in the public”, explains Prof. Roland Jahns, who is the work package leader for public outreach in GBN.



In 2015, GBN started a careful analysis of different stakeholder groups with a special focus on donors, biobank managers and scientists. About 200 donors were asked about their attitudes towards biobanks and their understanding of biobanks. The evaluation of the patient surveys shows that the willingness to donate biomaterials is high and the attitude towards donation is mostly positive. Participants want to support research and help advance medicine. However, most of them cannot recall what a biobank is, although they were previously informed about the use of their donated biomaterials. Currently, a communications campaign is developed by GBN that biobanks can use for their local public outreach activities.

Communication gaps seem to be a problem in other stakeholder groups too: qualitative interviews with biobank managers underline that they recognise a pressing need to engage with internal target groups (researchers, clinicians), in order to foster collaboration and create confidence among all involved parties. With the increased centralisation of biobank structures, it appears very important to provide information on governance structures, procedures, and ethical issues helping motivate clinicians to get involved in biobanking. Many scientists still lack the knowledge regarding the collection/access processes, specific uses, governance structures and individual benefits of a centralised biobank. Activities like training and information events could reduce such hurdles. Essentially, more research in additional stakeholder groups is planned in the future.

UK'S TISSUE DIRECTORY LAUNCHED

BBMRI.uk
Biobanking and BioMolecular resources Research Infrastructure United Kingdom

Following the successful registration of over 50 biobanks, the UKCRC Tissue Coordination Centre has launched an online directory of biobanks. It is possible to search the Directory by viewing the list of diseases or you can search the directory of biobanks directly via disease term. This UK-wide resource, led by Dr Philip Quinlan, Director of the Centre, represents the first step in seeking to integrate UK biobanking infrastructure into a searchable resource to support research activity. The group of UKCRC funders anticipate that the projects they award funding, make use of the Directory, as they are keen to optimise the use of existing human tissue collections and associated clinical and sample handling data whilst minimising duplication of effort. To register or search for samples visit www.biobankinguk.org. We are dedicated to making the process as straight forward as possible so if you have any feedback or questions please get in touch at *contact@biobankinguk.org*

IN SEARCH OF SOLUTIONS FOR FACILITATED TRANSNATIONAL ACCESS

THE BBMRI-LPC PROJECT

bbmri-lpc
BBMRI – Large Prospective Cohorts

ABOUT BBMRI-LPC

An EU-funded (FP7) BBMRI-LPC project (http://bbmri-lpc.org/) was initiated in 2013 to explore facilitated transnational access to samples and data in European large prospective cohorts (LPC). This project was the first focused extension for the EU biobanking program BBMRI, operational from 2008 to 2011.

Participants of the 2nd annual BBMRI-LPC consortium meeting at IARC in Lyon, France

BBMRI-LPC involves 33 partners from 18 countries, including universities, research institutes and private companies, offering their expertise in science, technology, ethical and legal aspects. As the 4-year funding period is soon coming to end, it is a good moment to have a look on the achievements and challenges encountered within BBMRI-LPC.

THE BBMRI-LPC ACHIEVEMENTS

Framework for Access

One key goal of BBMRI-LPC is to itemize the access process, to highlight any stumbling blocks and to contribute in developing 'best practices' for transnational access. During the second and third year of BBMRI-LPC, the road for transnational access was truly initiated. Three pan-European scientific calls were set up to support concrete research projects involving multiple large prospective cohorts. The calls raised a lot of interest and 26 applications of high scientific quality were received, of which 12 were awarded. **The fourth and last call for BBMRI-LPC, this time for access to whole exome sequencing in biobanked samples, was finalised in the summer of 2016 and more than 20 applications are currently under review for access.**

Dissemination and Training

Establishment of the BBMRI Biobank Forum with representatives from all European countries has greatly contributed to the entry of new biobank initiatives in the European biobanking field, particularly entries from Eastern European countries. The aim of the Forum is to serve as a platform for information exchange between countries with advanced population-based cohorts, biobanks and registries and those that are planning to initiate large population-based biobanks. The Forum organising group has made a major effort to reach both ministerial and scientific representatives from emerging biobanks across Europe.

As a result, we now have contacts in essentially all European countries, including information from more than 100 emerging biobanks. Three Biobank Forum meetings have been organised: in Graz (2013), in Tallinn (2014) and in Budapest (2015). The 4th Biobank Forum meeting is organized in Vienna as part of the Europe Biobank Week 2016. To further facilitate transfer of information and expertise from the established biobanks to the new biobanking initiatives, several courses on practical biobanking and numerous site visits have also been organised in the frame of BBMRI-LPC. A collection of useful information for the early-stage biobanks has been compiled in a "Handbook for Practical Biobanking" accessible on the project website. The "Biobanking article of the week", regularly published on the social media and project website, has received positive feedback from the field.

ELSI Issues

BBMRI-LPC and the BBMRI-ERIC Common Service ELSI have made close collaboration during the project. The general ethical concerns for the future developments of biobanking have been addressed through presentations in international congresses. In particular, the issue of data sharing has been worked out in the context of the development of Big Data. Also, the challenge of intellectual and biological property has been addressed to contribute in identifying the current roadblocks for data sharing.

Public-Private Interactions

Although establishment of academic-industrial interactions has been hampered by the international crisis, many of the BBMRI-LPC parties have managed to establish regional, often bilateral public-private interactions (PPI). To get a better view on these PPI dynamics, an inventory of the existing and emerging interactions between the BBMRI-LPC related biobanks and/or academic centres

and the private sector has been created through a series of interviews with the key opinion leaders. New academic-industry interactions are delivered by the transnational access projects and through the quality management development. In parallel, the same activities are advancing multi-omics approaches to yield systems-level insights.

Biobank Research

Research on sample management and analysis within BBMRI-LPC aims to provide a scientific evidence base for high-performance instrumentation, methodologies and protocols in biobanking. To achieve real-life interoperability of services, the processes used by the service providers (biobankers) need to be balanced with the customers' (researchers) demands on costs, speed, versatility, and sample quality.

Precipitated DNA - FIMM/University of Helsinki, Finland

Liquid nitrogen storage tanks - FIMM/University of Helsinki, Finland

Sample collection in Meilahti Integrated Biobank Infrastructure (MIBI), Finland

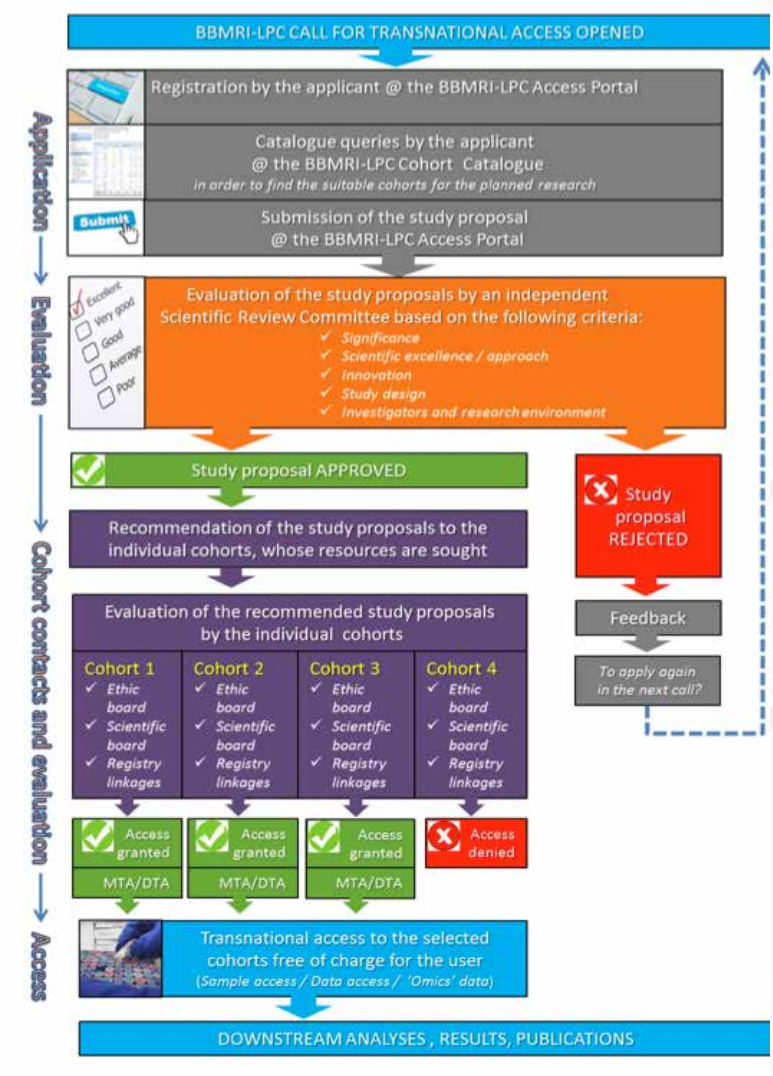
Evidence-based protocols for joint use have been launched and tested at the participating core facilities.

ADDRESSING THE CHALLENGES

Whilst the BBMRI-LPC calls for the scientific projects and their review process were accomplished in a very short time and were highly effective per se, the duration of the subsequent access provision has been unexpectedly long: despite the selection of the first four access projects in Q2 2014, the samples started crossing European borders only in Q4 2015.

The transnational access process includes several obligatory logistic, administrative and regulatory steps, which variably include the individual cohort approval, confirmation of the endpoints, the local ethics approval, the registry linkage issues, confirmation of availability of the samples, negotiation of MTA, sample retrieval and preparation, and organising the sample shipment. As all of these steps require a certain time frame, the process subsequent-

PROCESS OF ACCESS IN BBMRI-LPC



ly ends up excessively long. Itemising the various stages of the process and recording the country- and cohort-specific variations is expected to produce one of the most essential deliverables of the BBMRI-LPC project: future recommendations for an improved transnational access.

LOOKING TO THE FUTURE

BBMRI-LPC has worked in close collaboration with BBMRI-ERIC to build up a European infrastructure for a better use of biobanked samples and data. The aim of this joint effort has been to promote synergies and to maximise the benefits of European infrastructure projects. When BBMRI-LPC ends, several components of the project will continue their life as essential parts of the BBMRI-ERIC work.

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LEARN „HOW TO BUILD A BIOBANK“
AT THE BBMRI.AT PARTNER BIOBANK GRAZ

This interactive 3-day-course has been designed for all those who are involved in setting up a new biobank, who look to collaborate with a biobank or research institute, who face the challenges of a growing biobank or who try to overcome the challenges of maintaining a large biobank. The format of this course is a mixture of presentations and discussion sessions allowing participants to learn from the expert advice and the specific experience of their peers. Bring your questions with you for discussion!

DATE: 23-25 NOVEMBER 2016, Graz

LOCATION: Biobank Graz, Medical University of Graz, Austria
COSTS: €450.00 Euro (including scripts, meals, social event)

For more information and questions about registration please contact *biobank@medunigraz.at*

UK BIOBANKING SHOWCASE AGENDA

DATE: 16 NOVEMBER 2016, Oval, London

UK Biobanking Showcase is the flagship event of the UKCRC Tissue Directory and Coordination Centre. The event will bring together researchers, Biobanks, Industry and the public to celebrate UK biobanking. There will be debates, discussion panels, workshops, talks, including “Why we need to change the culture of Biobanking” research perspectives and “Providing standardised access for pharmaceuticals” as well as lots of chances to feedback on the future development of the Centre. Held on **16 November at the Oval, London,** the event is a unique chance to drive the future of UK biobanking.

www.biobankinguk.org

QUALITY MANAGEMENT SERVICES

WHAT IS THE QM SERVICE ABOUT?

BBMRI-ERIC provides tools and expertise, as well as knowledge and experience sharing on quality management for biobanks and research on biomolecular resources.

WHO IS THIS SERVICE FOR?

The service offers support on quality management related to biobanking activities. It is primarily intended for users located in Member Countries of BBMRI-ERIC.

HOW CAN I ENGAGE?

Sign up for the e-Newsflash! Sign up to our QM expert Working Groups. See QM info&experts at a glance!
http://bbmri-eric.eu

KEY QM SERVICES

✓ **QM consultancy programmes**
(for Guidelines and Standards)

- OECD Best Practice Guidelines for Biological Resource Centres
- Common Minimum Technical Standards and Protocols for Biological Resource Centres dedicated to Cancer Research
- Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs)
- ISO* Standards of Series 9001, 15189, 15190, 17025, 19011
- CEN**/Technical Specifications (TS) 16826-1/2; CEN/TS 16827-1/2/3; CEN/TS 16835-1/2/3; CEN/TS 16945:2016

Others to be forthcoming

✓ **QM monitoring and audit programmes**
on demand

✓ **QM training and education formats**
Expert working groups, webinars, web-conferences

✓ **QM documentation and assessment**
Documents and tools for biobanks

* ISO (International Organization for Standardization),
**CEN (European Committee for Standardization)

WHO TO CONTACT?

Andrea Wutte, BBMRI-ERIC Quality Manager, *andrea.wutte@bbmri-eric.eu*

ELSI SERVICES

WHAT IS THE ELSI ABOUT?

BBMRI-ERIC provides tools and expertise, as well as knowledge and experience sharing on ethical, legal and societal issues for the biobanking community through its Common Service ELSI.

WHO IS THIS SERVICE FOR?

The service offers support on ethical, legal and societal issues related to biobanking activities. It is primarily intended for users located in Member Countries of BBMRI-ERIC.

HOW CAN I ENGAGE?

Sign up for the e-Newsflash!
Sign up in our ELSI expert database!

KEY ELSI SERVICES

- ✓ Offering practical interpretation of new legislations (e.g. FAQ on GDPR)
- ✓ Monitoring of relevant ethical and legal frameworks in development (e.g. Safe Harbour)
- ✓ Coordinating replies to relevant public consultations on the European level (e.g., Council of Europe Recommendation CM/REC(2016)6)
- ✓ Developing tools to support biobankers in their daily work, especially when addressing legal matters (e.g. WIKI legal & hSERN)
- ✓ Informing about publications & research results, surveys, and relevant meetings
- ✓ Providing an ethics check of ELSI compliance for research proposals
- ✓ Organising experience sharing and exchanges regarding ELSI aspects (www.europebiobankweek.eu)

Sets up a Help Desk on ELSI issues (forthcoming in 4Q 2016)

WHO TO CONTACT?

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BBMRI-ERIC Chief Policy Officer CS ELSI, *michaela.th.mayrhofer@bbmri-eric.eu*

IT SERVICES

WHAT IS THE IT SERVICE ABOUT?

BBMRI-ERIC provides tools and expertise, as well as knowledge and experience sharing on information technologies (IT) for biobanks and research on biomolecular resources.

WHO IS THIS SERVICE FOR?

IT services are intended for researchers looking for for samples and data, for biobankers promoting their biobanks and searching fellow biobanks, for funding organisations to provide overview of infrastructure, as well as other users. It is primarily intended for users located in Member Countries of BBMRI-ERIC.

HOW CAN I ENGAGE?

Sign up for the e-Newsflash! Join the IT community of BBMRI-ERIC.

KEY IT SERVICES

- ✓ **Directory** - intended for all different types of users, providing aggregate information about biobanks and their sample/data collections, http://www.bbmri-eric.eu
- ✓ **Locator** - a tool for researchers looking for sample/data, enabling them to query available sample/data sets on the level of individual samples and/or data items, under development
- ✓ **Negotiator** - facilitating communication between researchers searching for samples/data and biobanks, allowing refinement of their queries and once the search is done, to request the samples, under development

In order to provide these main services, a number of other components are under development, ranging from data harmonisation services and extraction of structured data from unstructured clinical records, to operating infrastructure to deploy and support all the IT services. CS IT will also operate selected IT services to support other activities of BBMRI-ERIC, such as providing help-desk for Common Service ELSI and for activities related to rare diseases.

WHO TO CONTACT?

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HIGHLIGHTS OF THE ANNUAL REPORT 2015

By Jan-Eric Litton

BBMRI-ERIC has managed to reduce the start-up phase of BBMRI-ERIC (which was calculated in the Business Plan for a period of 36 months) to 18 months only. This means that the ‚Work Programme 2015' paved the way for the implementation of our services in our Member States.

Of mutual benefit was certainly the decision of the **United Kingdom** (new member) and Norway (previously Observer) respectively to apply for full membership to BBMRI-ERIC, an application that was enthusiastically welcomed and approved by BBMRI-ERIC's Assembly of Members. With their joining, BBMRI-ERIC comprised of 17 countries and one international organisation (IARC) by the end of 2015.

Quality above quantity is a key word for BBMRI-ERIC. In this respect, BBMRI-ERIC actively contributes to the process of international standard developments as **Observer Liaison of ISO/TC 276** Biotechnology as well **as of ISO/TC 212** Clinical laboratory testing and in vitro diagnostic test systems. As Observer Liaison, BBMRI-ERIC has been asked to contribute to the drafting process by addressing comments and references as well to as share the developments of the ISO Working Groups with the BBMRI community. This allows BBMRI-ERIC to fulfill its mandate as an international organisation in the interest of the European biobanks. To date, 75 technical experts and researchers at universities, biobanks and laboratory infrastructures are contributing to this unprecedented pan-European joint harmonisation effort. This work will have a direct impact on research and healthcare to reproduce data and save a lot of money for our members and help sustain biobanks.

According to the BBMRI-ERIC Statutes (Art. 3, paragraph 4) 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. As the first Common Service of BBMRI-ERIC, the **Common Service ELSI** started according to these values in February 2015, which today comprises 21 experts in the field of law, ethics and social science from across Europe. Just to take one example, the ELSI group has been instrumental in writing a Position Paper on the General Data Protection Regulation and helped to translate complex issues into a lay language for the general public and policy makers alike.
In July 2015, the first upgrade of the **BBMRI-ERIC Catalogue -**

the Directory 1.0 was launched. It allowed users to explore the infrastructure of BBMRI-ERIC, put biobanks on the map, communicate with biobanks, identify the biobank's samples and data of interest, and facilitate the negotiatiation for access with the respective sample/data custodians. During late 2015, the Directory 2.0 was released encompassing 60 millions biobank samples from our member states' biobanks. Ultimately, the setup of the BBMRI-ERIC **Common Service IT** has been a critical activity and was approved by the Assembly of Members in October. In the coming years, it will act as a sustainable development and operations platform for IT services of BBMRI-ERIC.

A major part of development during these years will be funded through the HORIZON 2020 project **ADOPT BBMRI-ERIC**, which aims at boosting and accelerating implementation of BBMRI-ERIC and its services throughout the member states. ADOPT BBMRI-ERIC is of particular strategic importance as it involves all National Nodes. However, all **project participation of BBMRI-ERIC proved rather successful;** all coordinated projects of BBMRI-ERIC were accepted and strategic partnerships could be formed. In total, BBMRI-ERIC has allocated **€6.6 million** through participation in research project proposals, of which €3.68 million fall under direct income in 2015 for activities of the Headquarters, Common Services and linked third parties. In less than two years, we could double the amount of the member states' contributions to the core budget of BBMRI-ERIC through successful participation in numerous grant applications.

Besides the obvious financial benefits, it enabled BBMRI-ERIC to boost and accelerate the implementation of BBMRI-ERIC (especially the Common Services) as well as to include the National Nodes (which are either linked third parties or project participants/beneficiaries represented by their National Node host institutions) in building on their respective strengths.

A major reform achievement was to better convey better the various **expertise, contributions and achievements** (both nationally and for the biobanking community) **of the National Nodes** in embracing the variety of their governance structures and funding streams which showcases the distributed nature of BBMRI-ERIC and highlights these in this year's report.

Once more, this Annual and Financial Report 2015 illustrates the vast productivity of the BBMRI family in 2015. The report is publicly available at **www.bbmri-eric.eu.**

1 **WORK PLAN**
e-INFRASTRUCTURE
Work Stream 1.1:
A New Gateway to European Biobanks

2 **WORK PLAN**
QUALITY
Work Stream 2.1: Quality Management System
Work Stream 2.2: Self-Evaluation
Work Stream 2.3: Implementation of the Bioresource Research Impact Factor (BRIF)
Work Stream 2.4: Development of a BBMRI-ERIC Approval Process

3 **WORK PLAN**
CLINICAL BIOBANKS
Work Stream 3.1: Clin Bio

4 **WORK PLAN**
POPULATION-BASED COHORTS
Work Stream 4.1: BBMRI-LPC

• NEW MEMBERS & GOVERNANCE MEETINGS & PROJECT STARTS

JANUARY

- • Invitation to Portugal (interested in joining BBMRI)

FEBRUARY

- 6 CS ELSI launched
- 2 BRIF/CoBRA guidelines
- 7 EXCEMET interested in becoming a BBMRI-ERIC Expert Centre/Trusted Partner
- • Accepted by EC as project participant of BioMedBridges (in effect as of October 2014)
- • Invitation to Qatar (interested in joining BBMRI)
- • MC #8, 11-12 February 2015, Munich
- • MC #9 26-27 February 2015, Milan

MARCH

- 6 BMS RIs meet with rare disease community under BBMRI-ERIC leadership
- 6 BBMRI-ERIC and EVAg publicised MoU

APRIL

- 1 CS IT tender published
- 6 BBMRI-ERIC Observer Liaison with ISO Technical Committees 276 and 212
- • United Kingdom welcomed as new Member by the AoM
- • Project Participant of RD-Connect (in effect)
- • FC #4, 23 April 2015 (teleconference)
- • AoM #4, 27 April 2015, Vienna ('Annual and Financial Report 2014' approved)
- • EGI-Engage project start

MAY

- 5 Identification of key priorities for the 'Work Programme 2016' with National Nodes/Common Service Directors
- 2 Self-assessment questionnaire provided by BBMRI.it
- • CY-Biobank project start
- • Visit to Moldova (interested in joining BBMRI)
- 6 General Data Protection Regulation Day of Action in the European Parliament
- 6 Comments to the draft WMA Declaration on ethical considerations regarding health databases and biobanks

JUNE

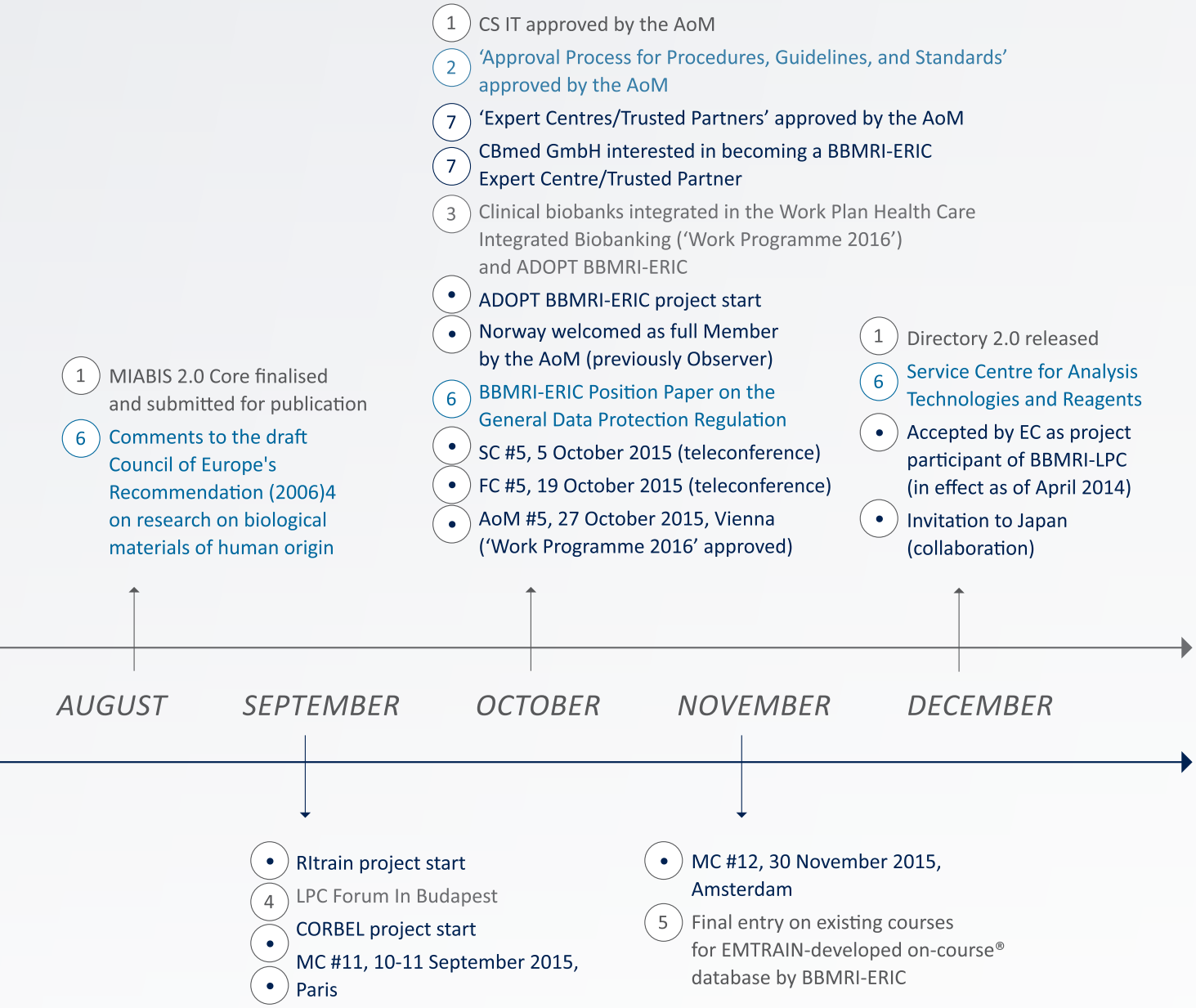
- 1 Directory 1.0 released
- 2 Quality Managers identified within National Nodes
- • B3Africa project start
- 5 HandsOn: Biobanks Conference in Milan during EXPO
- • MC #10 , 29 July 2015, Milan

JULY

5 **WORK PLAN**
BIOBANK OUTREACH
Work Stream 5.1: Scientific Retreat
Work Stream 5.2: HandsOn: Biobanks Conference
Work Stream 5.3: Education & Training Strategy

6 **WORK PLAN**
COMMON SERVICES
Work Stream 6.1: Working Group on Rare Diseases
Work Stream 6.2: Common Services for Biological Resources
Work Stream 6.3: Biobanking Infectious Materials
Work Stream 6.4: Common Service ELSI

7 **WORK PLAN**
EXPERT CENTRES
Work Stream 7.1: Planning for a Structure



IMPACT ASSESSMENT REQUIRES TIME AND QUALITY

SIS2016
1ST CONFERENCE ON SOCIAL IMPACT OF SCIENCE
Barcelona, 25-29th of July 2016

On 25-29th of July 2016, **the 1st Conference on Social Impact of Science (SIS2016)** took place in **Barcelona** as „analysing, communicating and improving social impact is one of the most pressing demands to all scientific fields", however „still very difficult due to the lack of indicators, repositories and experiences.

Nevertheless, there are some scientific domains where significant steps have been already taken. There are also some countries where universities and science agencies are very advanced in the construction of these indicators."

The conference stimulated with keynote lectures by three Nobel Prize laureates. Moreover, it provided a framework where research groups from diverse contexts and domains were able to discuss existing good practices, as well as the processes for further improvement. Furthermore, SIS2016 brought together researchers, scientific agencies, science stakeholders and civil society from several fields. BBMRI was the only ERIC and research infrastructure for health present and presenting.

Relevant for BBMRI-ERIC is that impact assessment of any infrastructure is fruitful only when looking back at the achievements on a 10+ years time span as the full impact on a specific field or the society is not and cannot be known from the start. The more complex a research infrastructure is, the harder it is to measure as it relies on case studies and in-depth analysis to account for the specific (national or scientific) context.

Michaela Th. Mayrhofer, PhD
BBMRI-ERIC Senior Project Manager
BBMRI-ERIC Chief Policy
Officer CS ELSI

Stockholm, Sweden | September 13-15, 2017

GLOBAL BIOBANK WEEK

Towards Harmony in Biobanking

www.globalbiobankweek.org

ABSTRACT SUBMISSIONS OPEN FROM FEB 1 - MAY 1, 2017

BBMRI-ERIC
gateway for health

European, Middle Eastern & African Society for Biopreservation & Biobanking

isber
INTERNATIONAL SOCIETY FOR BIOLOGICAL AND ENVIRONMENTAL REPOSITORIES

Photo: Elias Freiberger

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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