

BIOBANKS EUROPE
Issue No. 4/2016



BBMRI-ERIC

Biobanking and
BioMolecular resources
Research Infrastructure

EDITORIAL QUALITY AND NUMBERS MATTER!

The evolution of healthcare, regulatory and medical practice – and lately precision medicine – is not an arbitrary choice of the academic and industrial researchers or policy and decision makers. It is driven by science and the availability of new tools and knowledge originating from different sectors. Cutting-edge research as well as further innovations in the biomedical industry will strongly depend on implementing efficient and secure transnational access to high-quality human biological samples and associated medical information for both academia and industry. BBMRI-ERIC's associated Expert Centres can be organisations that represent a novel pu-

blic-private partnership model. In order to guarantee the excellence of transnational research collaborations, the aim of BBMRI-ERIC is to evaluate the mentioned above high-quality Expert Centres. For evaluation purposes, it is necessary to define certain criteria in a transparent manner. Hence, to be listed as a BBMRI-ERIC Expert Centre and trusted partner a set of criteria must be met that is defined in a BBMRI-ERIC document about Expert Centre.

During this year we have started the work on the H2020 project ADOPT BBMRI-ERIC, for which colon cancer was chosen as one of the main use cases as this cancer is one of the most commonly diagnosed cancers worldwide; 447.136 cases/year (2012), make it the 2nd most diagnosed cancer in the

EU. In the context of the project ADOPT BBMRI-ERIC, we will develop the most globally advanced and most comprehensive cohort of colon cancer cases including biosamples and detailed medical information. Such a high quality cohort of 10.000 colorectal cancer cases has so far never been established. This cohort will allow addressing key unsolved medical problems, such as individual risk assessment of stage II colon cancer, which is critically needed to optimise therapy. Furthermore, the experience generated will allow detailed calculation of timelines and costs to establish similar high quality cohorts for any other disease, therewith demonstrating the capabilities of such an effort such as BBMRI-ERIC. For rare diseases we have chosen the use case of osteogenesis imperfecta.

For all these efforts, quality is key. Consequently, the BBMRI-community is focusing on an ambitious programme regarding the improvement of the biobank quality Management System and the quality of the sample to foster scientific excellence and safeguard interoperability.



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

71 technical experts and researchers of universities, biobanks and laboratory infrastructures of 15 Member countries are contributing to an unprecedented pan-European joint harmonisation effort, aiming to improve the quality output of biobanks to safeguard biobank processes such as acquisition, reception, labelling, tracking, access, processing, replication, storage, packaging, distribution and transportation of samples, along with measurement, analysis, quality control and risk

management aspects in compliance and respect to ethical, legal and societal aspects, in particular data protection requirements. BBMRI-ERIC's goal is to interlink these valuable resources across Europe in order to foster co-operation and research on a pan-European level and beyond.

While writing this editorial, I received a letter from Robert-Jan Smith, Director General for Research & Innovation at the European Commission

and I quote: " The work that BBMRI-ERIC is carrying out is impressive and its contribution to the biomedical field is remarkable, bringing coherence and efficiency and enabling better access for researchers to biological samples and data across Europe. I would also like to congratulate you on the efforts that BBMRI-ERIC is making with respect to international outreach, reflecting the value of this infrastructure and its potential global impact."

I would also like to welcome Norway as a full member.

Jan-Eric Litton

INTRODUCING THE NORWEGIAN NATIONAL NODE



Facts & Figures

How many biobanks and samples do you have?

Two hundred and twenty-eight clinical biobanks are listed in the Norwegian Biobank registry. Since population based/research biobanks are only reported to the Regional Ethics Committees, the total number is presently not known, but the main ones are; the Mother and Child biobank (300.000) donors, the Janus biobank (300.000), the HUNT biobank (90.000), the Tromsø Study (50.000) and the HUSK Study (36.000). In addition, there are large collections of tissue samples (> 10 million donors) available through the clinical biobank network.

How many partners are there in BBMRI.no?

BBMRI.no has 11 partners, the Regional Health Authorities in

South-Eastern, Western, Central and Northern Norway, the National Institute of Public Health, the University of Oslo, the University of Bergen, Norwegian University of Science and Technology (NTNU), the University of Tromsø and The Cancer Registry of Norway.

Funding:

The Research Council of Norway has so far awarded two grants from its infrastructure program, a total of 19 MEUR (10 MEUR for 2011-2015 and 9 MEUR for 2016-2018). In addition, there is a significant in-kind contribution from all partners.

Website:

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

Professor Kristian Hveem, MD, PhD, why is biobanking important to you personally and what can be achieved by it that otherwise would not be possible?

I have been involved in population based research since 1995 (the HUNT 2 study). Being a clinically trained physician and epidemiologist, I took special interest in the recruitment of biological samples, and the

scientific opportunities in combining analyses from well-annotated biobank samples with health data and clinical endpoints. Subsequently I was engaged in the construction of the HUNT biobank, which I have led since 2003. Modern biobanking is a crucial factor in the development of precision medicine and a major prerequisite for being successful within medical research, including better drug development and biomarker validation. We need large biobanks for sufficient statistical power in studies of gene-environmental relations of both complex and common diseases and rare genetic variants. To be especially effective, they should be organised as strong, sustainable and competent biobank infrastructures on a national and international level.

What is the particular or specific strength of BBMRI.no biobanking activities?

BBMRI.no builds upon a strong Norwegian tradition of population based health surveys ongoing since the early 1970ies including collection and storage of biospecimen. A national network of all population biobanks (Biohealth Norway) administered by the National Institute of Public Health, the Univer-



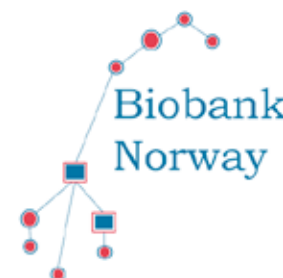
Norway - HUNT - Biobank liquid nitrogen storage

sity of Oslo, the University of Bergen, the Norwegian University of Science and Technology (NTNU) and the University of Tromsø was organised already in 2002. In 2010, when BBMRI.no/Biobank Norway, was established and funded as a national research infrastructure by the Research Council of Norway (RCN), all the clinical biobanks and the serum biobank of the Norwegian Cancer Registry were also included as partners in BBMRI.no. To have both clinical and population based biobanks onboard since 2010 has been a special strength and has promoted the establishment of a lar-

ge group of active, dedicated „biobankers“ throughout the entire country, organised in a structured network. ELSI has been a strong component in the BBMRI.no network, presently with special attention to the ethics involved in genetic studies and Next Generation Sequencing. In the recent year, almost 150.000 samples from the largest population biobanks have been genotyped and imputed, soon to be available for researchers on a national and international level.

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

From 2010-2013, I was also engaged as the first director of the Danish National Biobank which opened in new facilities at SSI/Copenhagen in 2012 as one of the largest and most advanced biobanks in Europe. Danish legislation allows for a more extensive linkage to registry data than any other country in Europe, resulting in excellent studies and publications in genetic epidemiology and pharmaco-epidemiology. Since 2014, BBMRI.no has led the Nordic Biobank Network.



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Coordinator

Norway is full member of BBMRI-ERIC since 1st January 2016. What was your motivation for becoming full member now (Norway was observer since 2014).

It has always been our intention to be a full member of BBMRI-ERIC. Since we are not a member state of the European Union, a modification of Norwegian law was required before we could be a full member, which has taken almost two years to pass through all the necessary legislative bodies.

In your view, what is the next challenge for BBMRI-ERIC in general and BBMRI.no in particular?

BBMRI-ERIC has been very successful in its first two years, with an almost exponential increase in activities, initiatives and establishment of Common Services for both ELSI and IT. It is essential to consolidate both the organisation, the new activities as well as involvement of new member states along the way, to maintain a strong and unified research infrastructure.

For BBMRI.no, our major priorities are to develop common Standard Operating Procedures for prospective, clinical bio-

banks, to establish a real-time, online Biobank Registry/Inventory and to develop one portal for access to biobank sample collections as well as to Electronic Health Records and national registries. In 2015/16, we have organised a Common Service for ELSI and a Common Service for biobanking on a national level. One work package focuses solely on strengthening the collaboration between the biobank community and industry.

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

The main objective is to be the major driving force in building up a European biobank network and facilitate access to sample collections from partner biobanks, their services and technical and scientific expertise. An area of special importance is to agree upon



Automated storage NIPH-Biobank Oslo

explicit quality standards for all biobanks.

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

Over the last years, there has been a prolonged and difficult discussion around the new Data Protection Act, which has temporarily landed with an acceptable solution for the research community. I will give credit to the BBMRI-ERIC secretariat for their significant involvement in the final face of this process. We have, however, two challenging years ahead of us to make sure the new act is properly implemented.

Building a successful European biobank network requires both diplomatic skills and a strong commitment amongst the member states to collaborate. I sincerely hope we will succeed in following up these positive achievements

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

After years of building biobank infrastructures, IT-networks, harmonising data and developing common Standard Operating Procedures and quality standards, the time has come

to demonstrate that these efforts will pay off scientifically. In addition to a better understanding of common, complex diseases, both rare disease and population genetics are areas where a comprehensive European biobank network can really make a difference.



Kristian Hveem, MD, PhD
*Professor in Clinical Epidemiology,
Department of Public Health,
Faculty of Medicine, NTNU*

I graduated from medical school in 1980 and have later specialised in internal medicine and gastroenterology. As a professor in clinical epidemiology, I have been the PI of a number of large-scale research projects based on biobanks and population cohorts, most recently as Norwegian PI on the ongoing NIH/NTNU/Research Council of Norway collaboration on CVD, “HUNTING for MI-genes”. I have been responsible for the construction and scientific design of the HUNT biobank

and the national CONOR biobank (COhort of NORway). From 2003-2012, I served as the deputy director of the Norwegian functional genomics platform (FUGE) for population biobanks, and since 2010, leading the national Biobank Infrastructure, Biobank Norway/BBMRI.no, funded by the Research Council of Norway. From 2010-2013, I was engaged as a “designer” and first director of the Danish National Biobank at SSI/Copenhagen. For 2016-2020, our research group, “HUNT-genes”, has been awarded as a K.G. Jebsen Center for Genetic Epidemiology, a national program for translational research, funded by the K.G. Jebsen Foundation.



Kristian Hveem and the Minister of Health Bent Høie visiting HUNT biobank

BOOSTING AND ACCELERATING THE OPERATIONS OF BBMRI-ERIC: ADOPT PROJECT MEETING COMMENCES IN VALLETTA



ADOPT BBMRI-ERIC team of academics on the rooftop of the Valletta Campus building, University of Malta

The first six months of ADOPT BBMRI-ERIC has now passed since the start of the project in October 2015 and the sleeves have been rolled up for the hard work to come. A team of 36 academics from 16 different Member States gathered in beautiful Valletta in mid March to discuss and update each other on the progress of the project. The ADOPT team also had a chance to meet with the accomplished members of the International Advisory Committee who observed the project work, and gave strategic advice on the course and future of ADOPT BBMRI-ERIC. While the meeting in Valletta started as any other EU-project gathering with Work Packages presenting their achievements, highlights

and future plans, the day ended with an ad hoc workshop on colon cancer variables and their definitions. The workshop demonstrated the necessity of seamless collaboration of the experts from various fields, and illustrated the practical next steps that are critical for the success of ADOPT. By taking a deep dive into the colon cancer variables, the ADOPT team made the collection of 10.000 colon cancer cases for future studies from various biobanks in Europe one step closer to reality.

The achievements of ADOPT BBMRI-ERIC

The Biobank 'yellow pages' known as the BBMRI-ERIC Directory 2.0 was released in

December 2015 to capture the 508 biobanks hosted by it, allowing the biobanks to describe more in detail their sample and data sets. The current Directory version also makes it possible to capture the various networks of biobanks. The ELSI team has taken steps towards piloting the Common Service (CS) ELSI tools and providing a booklet for the users, which describes the processes and tools available through CS ELSI. Biomarker team has progressed in terms of identifying suitable candidates for Biomarker Expert Centers. The efforts continue towards positioning BBMRI-ERIC as the key infrastructure for biomarkers. Last but not the least, important work is underway in connec-



Outi Törnwall, PhD
EU Project Manager,
BBMRI-ERIC

ting the rare disease community, defining the BBMRI-ERIC access procedure and costs, and creating a map of countries for future membership of BBMRI-ERIC.

Addressing the challenges

The International Advisory Committee was present at the meeting providing firm and pertinent advice for the ADOPT team. The Work Packages were recommended to interact with each other more, and monitor any relevant results from other EU projects that would benefit the project. The ADOPT team was also encouraged to take additional steps to maintain the good outset and momentum of the activities. The committee underlined the importance of the project and its results to BBMRI-ERIC community. Through ADOPT, the team will be able to show what is achievable through a fully operational Research Infrastructure.

Food for the body and soul

The ADOPT project meeting hosts professor Alex Felice and Joanna Vella from the University of Malta ensured, that the ADOPT team, while working hard, had a chance to taste the traditional Maltese cuisine delicacies, and experience the beauty of the magnificent

fortress city that rises steeply from two deep harbors. We were offered a private tour to St John's co-Cathedral, the adorned church, which is the home of the world famous artistic masterpieces by Caravaggio and Mattia Preti. We also visited the restored Brucellosis museum at the Department of Health building in Castellania Palace, that commemorates the work of the Mediterranean Fever Commission and Sir Temi Zammit, Malta's most famous medical doctor. Sir Zammit, a bacteriologist, left his marks in the history by discovering that contaminated milk was the source of transmission of human *Brucella melitensis* (Malta fever) in 1905.

To be continued

The team of ADOPT academics and their task forces gather again on the 10-11th of October 2016 in Prague for the ADOPT BBMRI-ERIC Annual Meeting. By that time, the project will undoubtedly take many significant moves forward and have several outcomes to present. Hence, I thank the ADOPT team and our hosts in Valletta, and look ahead towards an eventful second half year of ADOPT.

Outi Törnwall, PhD
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About ADOPT

ADOPT BBMRI-ERIC is a three year EU project involving 21 partners from 17 BBMRI-ERIC member countries that aims to boost and accelerate BBMRI-ERIC's key duties in providing better IT and ELSI services for users, and access to the biobanks. The cornerstone of the project is the collection of 10.000 colon cancer cases from various biobanks in Europe thereby establishing the first BBMRI-ERIC-wide disease cohort, something unique to the research field as such. The work of ADOPT allows the connection between the European biobanks information with the anonymised clinical IT systems enabling the pan-European studies based on biobank data and the disease specific patient electronic health record information. Other work of ADOPT focuses on rare diseases, biomarker development and enlarging the BBMRI-ERIC membership within and beyond the European Union. **The ADOPT BBMRI-ERIC project is funded by the EU Horizon 2020 programme.**



Europe Biobank Week

Biobanking for Health Innovation

September 13-16, 2016 | Vienna, Austria



REGISTER NOW

www.europebiobankweek.eu



WELCOME TO THE EUROPE BIOBANK WEEK - "BIOBANKING FOR HEALTH INNOVATION"

According to the OECD, biobanks are an essential part of the infrastructure underpinning the life sciences and biotechnology. They have the potential for a substantial impact on the economic growth and improvement of healthcare. Tomorrow's biobank challenges call for a transition to a new innovative and integrated approach. A step forward that will require fundamental changes in both thinking and acting, including ideas that go beyond an individual organization, but affect the full chain of people involved.

With this in mind BBMRI-ERIC and ESBB are pleased to announce that a result of their strategic alliance is a jointly organized conference: The Europe Biobank Week. Central theme for the first event that will take place from September 13–16, 2016 in Vienna, Austria, is "Biobanking for Health Innovation".

The meeting will be organized in association with the International Biobank Summit and the BBMRI-LPC Forum Meeting 2016. BBMRI.at will serve as local organizer.

The Europe Biobank Week is the new platform for a strong debate and collaboration on activities related to biobanking and biopreservation of samples and data for research and development. Biobanking is a specific European strength having become a fundamental component in addressing the ongoing and future requirements particularly of Europe's health service frameworks including competitiveness and innovativeness of health-related industries. The conference offers keynote lectures, educational sessions and a knowledge-sharing programme. This conference gives a great opportunity to meet biobanking experts from all around the world and to discuss these future issues for biobanking.

We welcome you to Vienna and the Europe Biobank Week,

Jan-Eric Litton
General Director BBMRI-ERIC

Erik Steinfeldt
President ESBB

Important Dates

Online registration opens: **March 31st**

Online abstract submission opens: **March 31st**

Preliminary programme : **April 15th**

Early-Bird Registration Fees

Until 20th June

Regular delegates : **500€**

ESBB members : **400€**

Delegates from middle income countries : **250€**

Representatives of patient organisations
and regulatory bodies : **200€**

Students and delegates from low
income countries : **90€**

For further information, visit :

www.europebiobankweek.eu

Location

Messe Wien Congress Center
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AUSTRIA
www.messecongress.at

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Front picture: YLOG paraffin tissue archive of BioBank Graz and immunofluorescence staining of HepG2 cells (both Medical University of Graz)

HOW TO BECOME A MEMBER OR OBSERVER OF BBMRI-ERIC

According to BBMRI-ERIC Statutes only countries and/or Intergovernmental organisations can become Members. Such a request needs a formal letter signed by a national competent authority (e.g. a Ministry) and includes also the nomination of a person, who shall act as National Coordinator. In principal every country can become a Member. However, as the majority of votes in any ERIC need to stay within the EU, the limitation derives from voting rights. Observers have no voting rights and therefore could be accepted as many as requested.

Who then is granting membership?

The Assembly of Members delegates are nominated by the competent authorities of the countries. BBMRI-ERIC as of today has 14 Members (1 non EU Member State, Norway) and 4 Observers. There is substantial hope that three or even four new countries will apply for membership this year.

What is the difference between Member and Observer?

Again I have to quote our Statutes: in the AoM only Members have voting rights, i.e. Observer delegates can participate in the discussions, but are excluded from making decisions.



Markus Pasterk
Administrative Director, BBMRI-ERIC
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What kind of decisions is the Assembly responsible for?

Among others the AoM adopts the annual Work Programme and budget, Internal Rules, appoints the Director General and approves hiring of other high-level staff. Becoming a Member also brings along responsibilities. Namely to provide access to their biobanks, establish a National Node, ensure coordination, make investments in infrastructure, contribute to capacity building and support the primary purpose of BBMRI-ERIC. BBMRI-ERIC has published a Guidance Booklet on how to join which provides not only full details on the process and financial figures but contains also letter templates for the formal requests. This booklet can be requested at the HQs and is also downloadable from our website: <http://bbmri-eric.eu/bbmri-eric-publications>



B3AFRICA: BRIDGING BIOBANKING AND BIOMEDICAL RESEARCH ACROSS EUROPE AND AFRICA



The development of biobank research collaborations within and across continents in high income countries indicates a “strong bias toward the Northern hemisphere” with regards to most actively publishing institutions¹. The B3Africa project (www.b3africa.org) proposes innovating solutions to close the research cycle, so that all the data generated by a research study can be consistently associated with original samples and be reused in other studies. B3Africa strategic aims are:

1. Create a harmonised ethical and legal framework between European and African partner institutions.

2. Provide an “out-of-the-box” informatics solution (the eB-3Kit) that facilitates sample and data management, processing and sharing, and that can be used under challenging networking conditions in Africa and Europe.

B3Africa partners are:

Sveriges Lantbruksuniversitet, Sweden; Biobanking and Bio-Molecular resources Research Infrastructure Consortium, Austria; Karolinska Institutet, Sweden; Centre for Research Ethics & Bioethics at Uppsala University, Sweden; University of the Western Cape, South Africa; Makerere University, Uganda;

Stellenbosch University, South Africa; International Agency for Research on Cancer, France; International Livestock Research Institute, Kenya; Medizinische Universität Graz, Austria; and Institute of Human Virology, Nigeria.

The initiative is supported by the EU Horizon 2020 work programme.

The B3Africa Consortium

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¹ Astrin J. J. and Betsou F. (2016). *Trends in Biobanking: A Bibliometric Overview*. Biopreservation and Biobanking. February 2016, 14(1): 65-74. doi:10.1089/bio.2015.0019.

QUALITY MANAGEMENT IN GERMAN BIOBANKS AND REQUIREMENTS FOR A QM MANUAL

In a series of three QM workshops organised by GBN (German Biobank Node) the participating biobanks reached a common understanding of their needs and defined parameters in order to lay the grounds for a QM manual with generic templates. After the first workshop last summer in Heidelberg the participating biobanks had given their feedback to different questionnaires concerning the core processes and related SOPs.

A detailed analysis of the questionnaire results have been discussed during the second workshop in December 2015 in Berlin.

After intense and fruitful discussions the group of quality managers successfully reached a mutual consent: the goal of

this GBN work package is to create a process-oriented quality manual - including harmonised SOPs that predominantly describe general requirements for efficient quality control and assurance - rather than specifying pre-analytical parameters in detail.

Nevertheless, a set of minimum standards needs to be established and the respective parameters have to be documented - at least for the core processes in the context of sample acquisition, transport, entry, processing and storage. These harmonised SOPs can then be used as a blueprint with local adaptations in all German biobanks.

For the preparation of generic SOPs, the responsible persons of the QM work package from

Heidelberg, Jena and Munich will now meet monthly to finalise these documents. In summer of 2016, a draft version of a GBN-QM Manual will be available to the community.

To link these national activities with ongoing international efforts, a close collaboration with the BBMRI-ERIC quality work plan has been established. Recently, European technical specifications concerning pre-analytical workflows influencing sample quality have been published (DIN CEN/TS). Comparative analysis and implementation of these specifications and other already existing standards (DIN EN ISO 17025, DIN EN ISO 15189) will be the next step in the GBN work package in close exchange with BBMRI.

BBMRI.nl

ONE NATIONAL RESEARCH INFRASTRUCTURE FOR PREVENTION, PERSONALISED TREATMENT AND HEALTH



BBMRI-NL, EATRIS-NL, and DTL/ELIXIR-NL have developed a common vision and roadmap on how The Netherlands can set course for a collective Personalised Medicine & Health Research infrastructure.

The goal is to bundle and connect a wide range of resources, including biobanks, IT-technologies, facilities and data collections, into one large-scale research infrastructure named Health-RI.

Health-RI will stimulate and facilitate collaboration through sharing of data and biomaterials among researchers, medical practitioners, and the general population (patients and healthy citizens) at a national level. This will facilitate the

development of a continuously growing knowledge base available for research and data mining, with the ultimate goal of improving prevention, diagnosis and prognosis of diseases. Moreover, it will bring innovations to patients faster.

A crucial factor to the success of Health-RI is the common commitment to invest in research and sharing resources. In addition, a national (e-) health system needs to be developed. This will give citizens full control over their personal data, while ensuring privacy protection. The Health-RI roadmap provides an important step in the right direction.

Health-RI is a response to the 'call for dreams' on large infrastructures of the Royal Academy of Sciences (KNAW). It is based on the input of many colleagues in the field, the P4 medicine and health research field in 2025, and has strong roots in programs of today.

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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