

BIOBANKS EUROPE Newsletter
Issue No. 1 / 2015



BBMRI-ERIC

Biobanking and
BioMolecular resources
Research Infrastructure

EDITORIAL

As Chair of BBMRI-ERIC's Assembly of Members, I am very pleased reflecting in the **first issue of "Biobanks Europe"**. The mission of BBMRI-ERIC tells us that this pan-European distributed research infrastructure increases efficacy and excellence of European biomedical research by facilitating access to quality human biological resources, by harmonisation of procedures and implementation of common standards and by capacity building.

Let me confront you with some quotes from a not so long past. One is "they build a wall around all biosamples and now you have to see if you can get a hold on them". Another is "except from a well informed in-crowd no one knows about BBMRI and how to get there".

Let me reassure you, these quotes are not taken from any structured survey or questionnaire, but are captured from individuals during coffee-break small talks. Still, we take these comments seriously.

That's why the Work Programme 2015 of BBMRI-ERIC is **all about access, to both samples and data**. Just to make BBM-



Edvard Beem, Chair of BBMRI-ERIC's Assembly of Members

RI-ERIC operational, **building on the particular strengths, capacities and needs of the individual National Nodes**.

First achievements have been produced after an incredibly short year 2014 of only eight months. This period was amazingly short compared to the preceding Preparatory and Interim Phases that had taken several years. I had the opportunity to visit the BBMRI-ERIC Headquarter recently in Graz, Austria. I was impressed by the small but highly dedicated and professional team that is working very hard to transform all our previous paper plans into reality.

Consider **BBMRI-ERIC's Common Services**. Launched for ELSI and in preparation for IT, they form a key element for the infrastructure as they provide the biobanking community and biobank users with **dedicated**

expertise, services and tools.

You can read about the Common Service ELSI (p.8) elsewhere in this newsletter.

In the same respect of gaining visibility and trust, I find it extremely important that BBMRI-ERIC works closely together with other ESFRI biomedical research infrastructures, also in sharing funds from EC sources. Just by collaboration, we can establish a sustainable framework of shared services. This will help to transform biomedical research in Europe, from discovery through translation towards delivery of customised health care. We will be able to provide strong ethical and legal support, joint data stewardship and fair access as well as coordinated user access to advanced research samples, cohorts, instruments and facilities.

Let's have a look at how we already benefit from our co-operation! Read the thrilling story of the Italian National Node, recent developments and Marialuisa Lavitrano's personal views on biobanking (p.3-7). Consider her invitation to come to Milan during World EXPO this summer for the HOBBS 2015 conference (p.10). An invitation you cannot refuse!

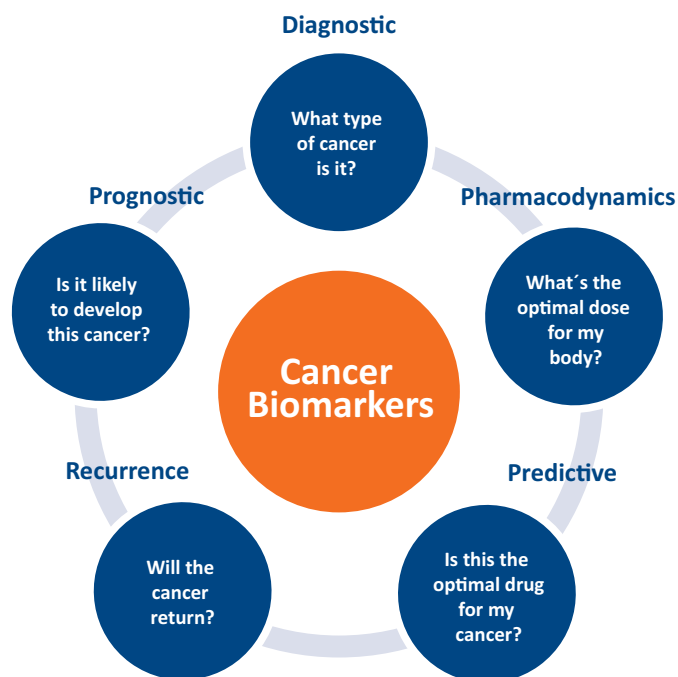
Edvard Beem

INTRODUCING THE ITALIAN NATIONAL NODE



Facts & Figures

90 Biobanks/Partners of BBMRI.it, **68** Biobanks have a quality system compatible with the requirements of the Partner Charter, **16** Biobanks are improving their quality systems and are assisted by the Quality Common Service of the Italian Node, **43%** have more than 10.000 cases collected, **66%** collect at least 3 different types of samples per subject (frozen samples, formalin-fixed, paraffin-embedded tissue, blood derivatives, nucleic acids, cell lines), **77%** participate in regional, national and/or international networks. The majority of Italian biobanks are disease-oriented (about half cancer and genetic diseases). **80.000** new cases every year for clinical biobanks and **12M** new cases every year for archived tissue biobanks.



Prof. Lavitrano, you are the National Node Director of BBMRI.it. Why is biobanking important to you personally and what can be achieved by it that otherwise would not be possible?

Biobanking is important to me personally because I have a longstanding interest in biobanking as an academic “user”. For me, biobank resources are essential tools for R&D, specifically for translational medicine applications in both academia and industry. Thus, I have a deep conviction that high quality biobanks are essential for high quality translational biomedical research, which ultimately applies to both individual patients’ welfare and the advancement of public health.

According to the US National Research Council to the Committee on a Framework for Developing a New Taxonomy of Disease, for instance, the full promise of precision medicine requires that researchers and health-care providers have access to a large set of samples as well as to have health and disease-related data linked to individual patients. Ultimately, the goal is to provide the best

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available care for each individual. Moreover, biobanks are important tools and instruments for helping to drive this change in healthcare delivery. They are increasingly recognised as crucial infrastructures and strategic partners for biomedical research.

Preserved tissue, for instance, is an indispensable tool for the identification of molecular markers of response to specific innovative therapies already available or that will be available in the future; they provide clinically useful information for the individual patient/citizen or for his/her family. Think of the identification of markers of disease risk for relatives as an example.

Could you be more specific?

Consider -omics studies. Over the last 20 years, -omics studies

identified some hundreds of potential biomarkers. Very few have been validated with clinical trials on biological samples. The major limitation to the identification and validation is the availability of samples of both tumour and normal tissue associated with an accurate clinical documentation. The innovative aspect of biobanks is the possibility to immediately gain access to biological samples from people affected by specific diseases or exhibiting variability in response to drugs, in comparison to matched control groups, apparently healthy subjects.

What are, in your opinion, the biggest roadblocks for biobanks?

The potential wealth of information, development and economic impact enclosed in bio-resources preserved in Ita-

ly and across Europe is at present under-used because of the fragmentation and heterogeneity in purpose, conservation, quality of samples of the collections and the lack of standardisation of methods in preservation and access to the samples.

What is a specific strength of Italian biobanks?

Italy is proud of its many quality-oriented biobanks, large archived tissue repositories [250M samples], the the Scientific Institute for Research, Hospitalisation and Health Care [IRCCS], and research hospitals where clinical practice and research are highly interconnected. Through a matrix architecture, each biobank is included in a specific thematic network as well as in the Italian regional network.

HandsOn: Biobanks (HOBB) is a yearly event of BBMRI-ERIC since 2012. The next HOBB is taking place in Italy and is linked to EXPO. Please tell us more.

This years HOBB is entitled "The EXPOnential relevance of Biobanking. Clinical Biobanks for personalized medicine". From 29 to 31 July 2015, HOBB is held in Milan, my home town



BBMRI.it: Fondazione Banca degli Occhi del Veneto

in the context of EXPO and under the esteemed patronage of the European Commission. The conference is hosted by the University Milano-Bicocca, one of the most prestigious Italian institutions. HOBBS 2015 discusses the growing relevance of clinical biobanks that provide the essential infrastructure for the development of personalised medicine. [read more on p.11]

In your opinion, what are the current key challenges on the European level?

There are three key challenges:

(1) To ensure fair and regulated access to biological resources through appropriate management both from the viewpoint of ethics and technology.

(2) To promote public-private partnerships [Expert Centre] as health care needs Pharma to contribute to the improved health of an individual. Industry, in return, needs access to samples, data and scientific/medical expertise for the development of therapeutics.

(3) To contribute to the discussion on the proposed General Data Protection Regulation, in order to ensure the proper

balance of protecting individual data as well as ensuring the benefits of research results for the public.

Where do you see the particular benefits of BBMRI-ERIC?

I believe that the emerging challenge of precision medicine can only be addressed by innovative solutions developed in an international, interdisciplinary, collaborative and scientific effort. This is what BBMRI-ERIC provides. Ultimately, the possibility to access very large, high quality collections of samples through simple and standardised procedures has implications for both academic and industrial research. This, not only for the definition of the molecular determinants of disease but also for the identification of diagnostic markers or therapeutic targets.

What do you see as the next key priorities for BBMRI-ERIC in general and BBMRI.it in particular?

Actually, there are many. Our key priorities are to:

- Implement research databases,
- Harmonise SOPs and elaborate appropriate

tools,

- Implement quality management criteria,
- Develop conditions to ensure sustainability of biobanks,
- Ensure the governmental support in the implementation of Research Infrastructures by putting them high on the research agendas.



BBMRI.it: Fondazione Banca degli Occhi del Veneto Onlus

BIOSKETCH

My greatest achievement is my daughter Elena, a beautiful young lady of 17 years, who is now at high school and wishes to become a scientist. She makes my life continuously happy and stimulates me to enjoy life in a way that I could not have imagined before. My own scientific career started in 1985, 12 years before giving birth to Elena. I left the family, the city where I was born, my friends as well as my boyfriend to follow the flame of research. My aim was to study the etio-pathogenetic dynamics of diseases, in particular of cancer at the molecular level. While studying the role of oncogenes in early embryo development, I suddenly stumbled on an accidental discovery related to sperm cells. The traditional view was that mature spermat-



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ozoa are metabolically inert cells, incapable of any other function than transferring the male genome into oocyte at fertilization; we discovered that sperm cells are able to bind, internalise and transfer exogenous genetic material into eggs at fertilisation, eventually generating a transgenic progeny. This top-notch research revolutionised the Darwinian dogma on the un-permeability of gametes to protect the genetic identity of a species. The

paper was published in „Cell“ in 1989. Henceforth, it has been defined as a „milestone in science“, deserving the cover of the journal and representing the beginning of a new field of research and technology. The Sperm Mediated Gene Transfer is still cited in laboratory manuals today. This discovery altered the course of my research for many years. I returned to oncology only in 2001. I have been involved in Molecular and Translational Medicine for almost my entire career. I was involved in cutting edge research projects that through biotechnological and translational approaches transferred research results from bench to bedside and vice-versa, also with the benefits of engaging in international collaborations. Apart from science, I also have a genuine interest in the related ethical issues and partici-

INTRODUCING BBMRI-ERIC COMMON SERVICES

A Common Service is a key facility providing expertise, services and tools relevant for the pursuance of the tasks and activities of BBMRI-ERIC.

pated in many international working groups contributing to the compilation of guidelines. Currently, I am Professor of Pathology and Director of the School of Oncology at the Milano-Bicocca University. As Pro-Rector for International Affairs [2006-2013], I was responsible for international curricula and research activities. I coordinated the training and mobility of faculty, staff and students. In particular, I am proud that as Deputy Director of the Surgical Science Department I was responsible to set up the MS course in Medical Biotechnology and the international PhD programme in Molecular and Translational Medicine [DIMET]. Over the years, I also had the privilege to contribute to the strategic planning of research and to the development of international strategies of the Ministries of Research and

of Health by participating to the Inter-ministerial Commission for International Research – JPI, ESFRI roadmap, EraNet, IMI, BioMedical Science sector, and coordinating the Italian participation in the BioMedical Sciences ESFRI roadmap. I participated in the Preparatory Phase of BBMRI, ECRIN and EATRIS as the Italian Member State representative. In 2013, I have been appointed as the BBMRI.it National Node Coordinator, in order to set up the Italian Node of BBMRI-ERIC. While the regency of my current appointments could have prevented me to accept, I seized the opportunity of contributing to the goal of personalised medicine through biobanking as public servant, my career-long commitment to promote transnational and transcultural scientific endeavors, the desire to apply the skills and experiences gained

throughout my career in academia and SME, and my involvement in many public sector activities. All this induced me to accept this challenging role. I can offer to BBMRI a deep understanding of the needs of academic and industrial users as well as other stakeholders, the understanding of the biomedical landscape, with regard to both clinical and basic research, regulatory aspects, health economics, as well as ethical, legal, and societal implications in life science research, including more than 25 years of experience in leading small and large groups in having developed skills to influence without using authority.



COMMON SERVICE ELSI LAUNCHED

The Common Service ELSI aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices.



COMMON SERVICE ELSI LAUNCHED

As the proper consideration of ethical, legal and social issues (ELSI) is key to any biobanking activity, the Common Service ELSI is considered a key asset of BBMRI-ERIC.

The Common Service ELSI aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices. Following a preparatory meeting, a call for tender and selection process in 2014, the Common Service ELSI was established in February 2015.

Contact

The Common Service ELSI is led by a Board of Co-Directors: Anne Cambon-Thomsen, Marialuisa Lavitrano, Jasper Bovenberg and Mats Hansson.

cs.elsi@lists.bbmri-eric.eu

Responsibilities

- Advise on a sound scientific/academic basis and experience in ethical reviews of European/international projects;
- Provide solid monitoring of ELSI issues related to biobanks and biobanking based on state of the art and deep knowledge of relevant ethical and legal frameworks in application;
- Provide an ethics check of compliance for research proposals submitted to BBMRI-ERIC in compliance with the BBMRI Business Plan and Statutes and with the European Commission research ethics framework;
- Follow up relevant evolution in legislations/regulations at the European level and organise coordinated answers to relevant public consultations and other possible intervention to address joint matters for the biobanking community on the European level;
- Provide updated background information and practical guidance to biobankers to respond to ELSI issues, especially in relation to the exchange of human samples and data for research use in Europe („Help-Desk“);
- Ensure the dissemination of results of relevant surveys and studies toward the various audiences;
- Organise tools and services to address ELSI issues related to biobanks and biobanking by building on already available tools and generating new ones if necessary;
- Organise experience sharing and exchanges regarding ELSI aspects between BBMRI-ERIC members;
- Set up training and education on ELSI issues related to biobanks and biobanking.



DATA FOR HEALTH AND SCIENCE DAY OF ACTION

16 June 2015

Brussels/Belgium

On 16 June 2015, BBMRI-ERIC invites research and patient organisations, academics and pharma as well as other stakeholders to participate in the Data for Health and Science Day of Action, which aims to communicate the expectations and concerns of the scientific community with respect to the General Data Protection Regulation to EU policy-makers and citizens. BBMRI-ERIC has been pushing for a balance between the protection of personal data and facilitating scientific research to enable innovation in our data driven knowledge economy.

REGISTER NOW:

<http://www.iscintelligence.com/event.php?id=262>

In a Nutshell

„In a bottom-up approach the Common Service ELSI will bring ELSI experts from Europe together in order to attain harmonised ethical regulatory frameworks that may be conducive to efficient biomedical research across borders while at the same time protect privacy and sharing. The efficiency of a distributed team to jointly provide ELSI advice and timely update adapted to each project using BBMRI resources in multiple member countries of BBMRI is now at hand.“

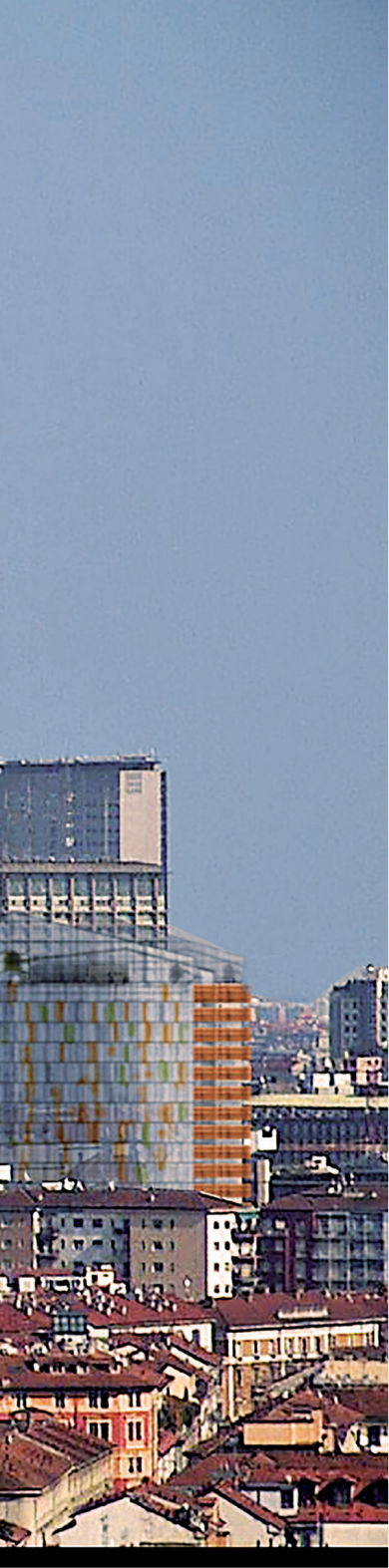
„A first flavour of what such a service could achieve was the organisation of a coordinated answer to the public consultation of the Council of Europe on the revised recommendation on research use of biological materials of human origin; the same spirit will underpin future actions of the Common Service ELSI. Being a platform for exchanging experiences, preoccupations and solutions to ELSI concerns in all the BBMRI member countries is a unique role that will help building the ERA in biobanking embedded in society. A chorus where each voice can be heard: diversity in harmony.“



HANDSON: BIOBANKS „THE EXPONENTIAL RELEVANCE OF BIOBANKING. CLINICAL BIOBANKS FOR PERSONALIZED MEDICINE“

29-31 July 2015, Milan/Italy

Speakers include: Marialuisa Lavitrano, Jan-Eric Litton, Jim Vaught, Niklas Blomberg, Pier Giuseppe Pelicci, Mika Ala-Korpela, Claudio Luchinat, Georges Dagher, Amedeo Santosuosso, Andrea Wutte, Barbara Parodi, Michaela Th. Mayrhofer, Anne Cambon-Thomsen, Elena Bravo, Michael Hummel, Jim Dowling, Gianluigi Zanetti, Kurt Zaltoukal, Alberto Bardelli, Maria Grazia Daidone ...



The HandsOn: Biobanks (HOBB) 2015

is entitled „The EXPOntial relevance of Biobanking. Clinical Biobanks for personalized medicine“ and will take place in Milan from 29 to 31 July 2015 in the context of EXPO and under esteemed patronage of the European Commission.

The conference will be hosted by the University Milan-Bicocca, one of the most prestigious Italian institutions. HOBB 2015 will discuss the growing relevance of clinical biobanks, essential infrastructure for the development of personalised medicine. The programme will include sessions on quality in all aspects of the biobanking process, pre-analytical conditions, international outreach, partnership between academia and industry. The scienti-

fic programme will cover the major topics with plenary and parallel sessions; keynote lectures; posters; ethics café discussions and interactive idea labs. Also, with the help of our sponsors, the participants will follow „The Route“, an interactive exhibition where practical aspects of collection, storage and use of liquid biopsies and archive tissues will be presented.

The event will be a chance for people from all over the world to share ideas and to build on international collaborations. The audience will represent academia, industry, medical doctors, patient groups, policy makers, public representatives and legislators to discuss the future issues for biobanking. Hoping to welcome you in Milan!

EARLY BIRD REGISTRATION & CALL FOR ABSTRACTS ENDS 30 APRIL 2015

REGISTER NOW: <http://handsonbiobanks.org/>



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„Biobanks Europe“ is the newsletter of BBMRI-ERIC, 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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