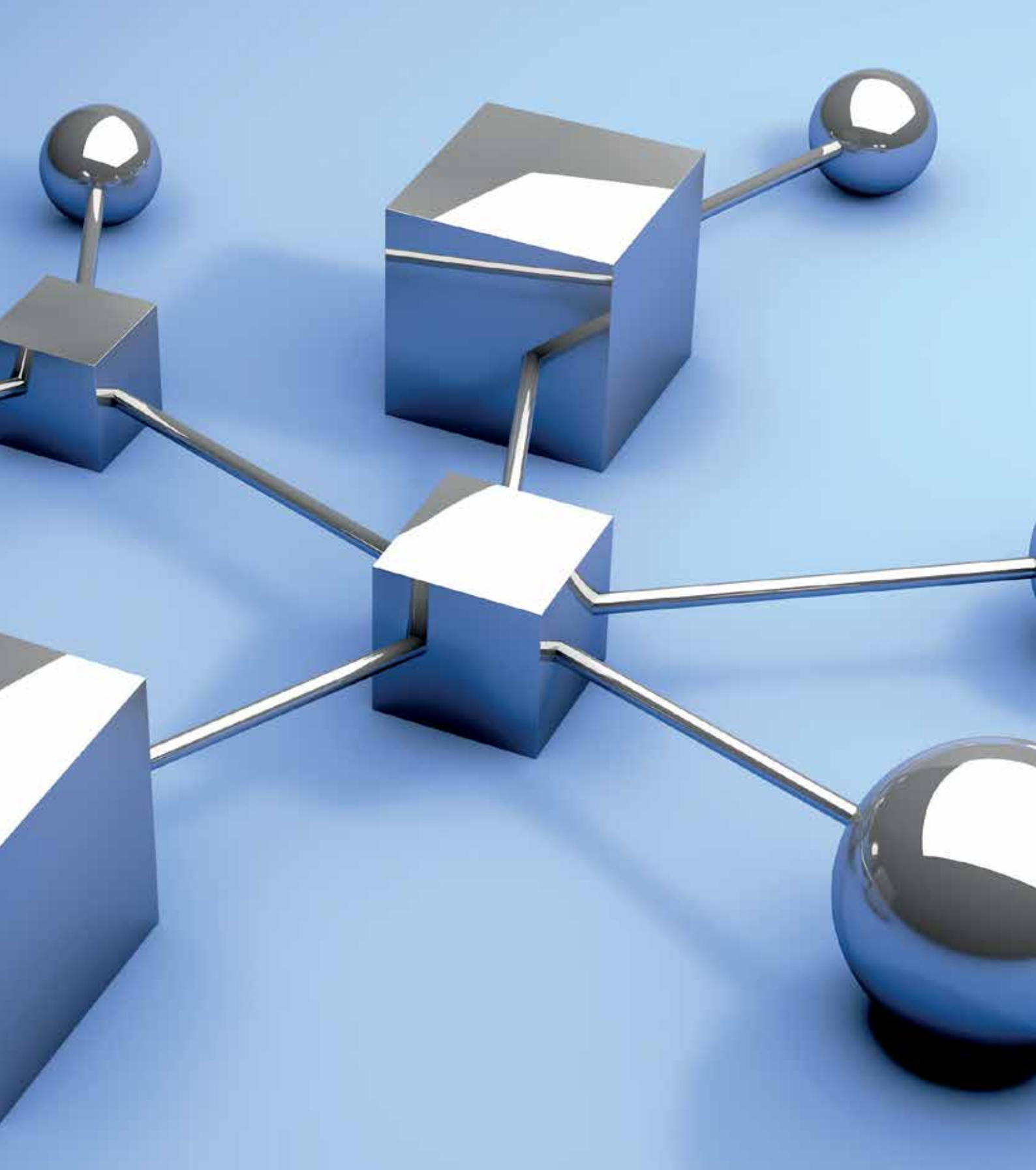


BIOBANKS EUROPE Newsletter

Issue No. 3 / 2015

BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

EDITORIAL
SO SIMILAR, SO DIFFERENT, SO EUROPEAN!

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

BBMRI-ERIC is set up to become an important source for partners in both academic and scientific institutions, as well as in the pharmaceutical and Life Science industries; thereby contributing directly to the Innovation Union concept. An enormous potential exists in BBMRI-ERIC for biomedical innovation, knowledge-generation and knowledge-transfer based on the population base of more than 500 million citizens. BBMRI-ERIC shows already a good geographic and regional coverage in Europe, involving countries from South, East, West, North and Central Europe. BBMRI-ERIC has developed a funding model that allows both large member states such as Germany and the United Kingdom as well as very small member states like Malta and Estonia to participate as equal members.

On 27 October 2015, the Member States of BBMRI-ERIC approved the core Work Programme and budget for 2016. The Work Programme 2016 will, in particular, concentrate on the improvement of quality management on one hand and developing a suitable e-infrastructure for biobanks in Europe on the other hand. For the latter, setting up the BBMRI-ERIC Common Service IT has been a critical activity and precondition in 2015.

BBMRI-ERIC Common Services form a key element of the infrastructure as they provide to the biobanking community and biobank users top-levels expertise, services and tools in specific areas of biobanking.

A major part of software development during these years will be funded through the H2020 project ADOPT BBMRI-ERIC (page 4), while remaining development and operations will be funded from the BBMRI-ERIC core budget. ADOPT BBMRI-ERIC aims to boost and accelerate the implementation of the BBMRI-ERIC and its services. These aims are in line

ADOPT BBMRI-ERIC

ADOPT BBMRI-ERIC gateway for health

TOPIC: H2020-INFRADEV-3-2015
TYPE OF ACTION: RIA
DURATION: 36 months
START DATE: 1 October 2015
TOTAL REQUESTED GRANT BY CONSORTIUM: € 4.950.860,00
PI: Jan-Eric Litton

with the objectives identified in the policy document on „Prioritisation of Support to European Strategy Forum on Research infrastructures (ESFRI) Projects for Implementation“ of 7 April 2014. In the context of ADOPT BBMRI-ERIC, cases (samples and data) of colorectal cancer patients have been selected for a pilot study because both genes and environmental factors are known to contribute to the etiology of colorectal cancer. It is also known that an early diagnosis of the disease improves the prognosis for the patient. Colon cancer is a sufficiently common cancer in Europe to constitute a significant public health problem. For rare disease patients, a pilot study on osteogenesis imperfecta has been chosen.

Computers and the Internet are among the most important inventions of our time. Questions on privacy and considerations what constitutes personal information become more pertinent in the information age when the immense possibilities of sharing information that come along with technical possibilities, which create chances, risks and expectations. On page 11, our Common Service ELSI experts enlarge on questions what the Safe Harbour agreement and the recent European court ruling mean for biobanking in practice, whereas on page 10, the results of a Workshop on access policy will be presented. Ultimately, on page 15, BBMRI-ERIC specifies its very important position on the General Data Protection Regulation.

Since April 2015, BBMRI-ERIC is officially an Observer Liaison of ISO/TC 276 „Biotechnology“ as well as of ISO/TC 212 „Clinical laboratory testing and in vitro diagnostic test systems“. The Work Programme 2016 is aligned with the developments of both technical committees TC 276 and TC 212 (page 18). Last but not least, I like to welcome Norway as full member of BBMRI-ERIC (page 13).

The BBMRI family is growing.

Jan-Eric Litton

TOTAL REQUESTED GRANT BY BBMRI-ERIC:

€ 3.786.840,00 (Common Service ELSI, Common Service IT)

BENEFIT/TASKS FOR BBMRI-ERIC:

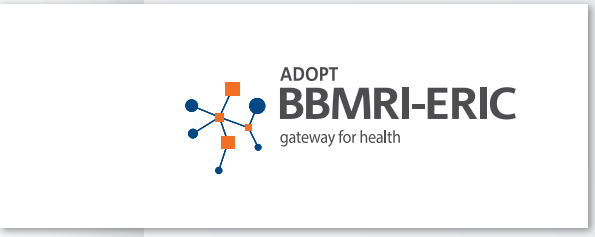
Coordinated by BBMRI-ERIC, funding for key activities

ASSIGNED LINKED 3rd PARTIES/BBMRI-ERIC FRAMEWORK AGREEMENT:

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

TURN THE PAGE TO LEARN MORE ...

ADOPT BBMRI-ERIC



ABSTRACT

BBMRI-ERIC: the Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium, aims to establish, operate and develop a Pan-European distributed research infrastructure in order to facilitate the access to biological resources as well as facilities and to support high quality biomolecular and biomedical research.

The ADOPT BBMRI-ERIC proposal aims at boosting and accelerating implementation of BBMRI-ERIC and its services. Its main deliverables are designed to complete or launch the construction of key Common Services of the Research Infrastructure as required for ESFRI-projects „under implementation", reflecting the targets of the European Research Area (ERA). One of the challenges in the post-genomic era is the research on common complex diseases, such as cancer, diabetes and Alzheimer's disease. Unlocking the secrets of these diseases will depend critically on the study of human biological samples and data from large numbers of patients and healthy individuals.

The EU's ageing population will result in an increase in many of those diseases and consequently an increased healthcare expenditure for senior citizens. BBMRI-ERIC is a specific European asset having become a fundamental component in addressing the ongoing and future requirements particularly of Europe's health service frameworks, including competitiveness and innovativeness of health related industries. Its implementation is essential for the understanding of the diversity of human diseases, biological samples and corresponding data, which are required for the development of any new drug or diagnostic assay and are, therefore, critical for the advancement in health research, ultimately leading to personalised medicine. BBMRI-ERIC will provide a gateway access to the collections of the European research community, expertise and services building on the outcome of ADOPT BBMRI-ERIC.

LIST OF PARTICIPANTS

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

INTRODUCING THE MALTESE NATIONAL NODE

BBMRI.mt
Biobanking and BioMolecular resources Research Infrastructure Malta

Facts & Figures

BBMRI.mt is the Malta BioBank. It emerged over the last few years from the Thalassaemia Testing and Haemoglobin Research Programme and the Neonatal Testing Programme conducted jointly by the Malta Department of Health, Sptar Mater Dei, and the University of Malta, (now) The Centre for Bio-Banking and Molecular Medicine.

The biobank now holds around 30,000 samples of blood or DNA, as described in *www.um.edu.mt/biobank.*

The Malta BioBank is funded by specific grants from the Government of Malta and institutional support of the University of Malta and the Sptar Mater Dei in addition to research funding from a variety of public and private sources.

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

I came late to biobanking. My earlier interest was in the genetics and haematology of haemoglobin disorders such as thalassaemia and the fundamental physiology of globin gene control in humans. In the course of this research, we built large collections of newborn and patient blood samples from our clinics and population testing programs. To a certain extent, we could be described as 'stamp collectors'. The haemoglobinopathies yield a number of molecular models that are useful to understand the genetics and pathogenesis of rare and common disorders.

The collections grew further when my laboratory also became responsible for the molecular genetics diagnostic services in the hospital. At some point we realised the value of standards and quality in maintaining these collections. That is when we joined EUROBIOBANK. The bank turned out to be valuable for developing service and research programmes. In fact, we like to speak of biobank-led research. Indeed, the bank also serves to re-evaluate samples from patients that may have been without a diagnosis. For instance, recently we discovered that mutations in transcription factors could account for a type of blood picture similar to that of thalassaemia. In fact, we found several of these in a retrospective review of banked samples.

What is the particular or specific strength of Maltese biobanking activities?

Small island populations have intrinsic value for genetics research and the same is true for Malta, which has a population of just under 450,000. In particular, Malta has good data on population origins that match the genealogical records of the Catholic Church and it is

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relatively easy to engage with families and the community. We now have an ‚averaged' Maltese genome. It is a robust reference dataset and filter in support of gene discovery research. In general, the people are co-operative when invited to participate in research. We are now looking into the prospects of ‚Research Co-Operatives' research cooperatives or ‚Social Enterprises' with which to organise social enterprises as vehicles for organising partners in biobanking and gene discovery research.

Tell us more about your engagement in the field of rare diseases.

My interest in haemoglobin disorders also introduced me to the field of rare diseases and their impact after joining Eurobiobank. The field is not as yet well-developed in Malta and we need to considerably raise awareness. We work closely with a private NGO (The Marigold Foundation) and the Ministry of Health to spread the word, build registries, organise services, and connect with research. Our paradigm, across Europe, must be that the best health services are conducted in the academic context of bio-medical science and research.

You and your team have great experience in science communication please tell us more about it.

Yes; for the last few years together with a number of colleagues both in the University and the Malta Chamber of Scientists, we organised a number of activities intended to communicate the value of science and scientific research with the public. A few weeks ago, we held the fourth edition of the event 'European Researchers' Night, Science in the City' that attracted over 20,000 people into Valletta, the capital city. Of course, the biobank was part of the display and earned considerable interest from the public. 'Science in the House' is one of the most significant activities because it is held in Parliament with the members of the House of Representatives to show off the research and have a frank discussion of science policy and of course spending; 10% of our MPs took part.

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

Undoubtedly, scientific excellence should be an immediate term objective of BBMRI-ERIC. Now that BBMRI has entered its operational phase and BBMRI.mt finds its proper place within its structure they have to create in harmony the procedures equired for achieving substantial long-term goals. We would really like to see the biobanks become engines of research. BBMRI.mt is now firmly embedded in the new Center for Biobanking and Molecular Medicine at the University of Malta and at Sptar Mater Dei.

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

BBMRI-ERIC bears on the strengths of all its members large and small. It has the capacity to harmonise quality and standards that might be otherwise difficult to achieve. It is a source of opportunity to promote significant discovery even with smaller biobanks from the smallest countries. The infrastructure could exert much influence at national and Pan-European levels with respect to the academic and health systems as well as the private sector. They could be further promoted to anchor important new directions for life science research. As stated before, we

like to speak of biobank-led research, by which the quality of the collection gives direction to life science and biotechnology. Integrating the biobanks into the health systems could increase the diversity of the collections. We like the idea of patient research cooperatives on the lines of social enterprises that are embedded in the community for long-term data collection. The establishment of distributed expert centres could be effective for engaging with the pharmaceutical and biotechnology sectors in different countries. We may need to overcome a degree of reticence among the clinical communities for BBMRI goals to succeed entirely.

A lit up ladder representing the structure of the DNA molecule on the streets of Valletta during the event European Researchers Night, Science in the City, September, 2013.

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

I am afraid Europe is passing through challenging times with fragmentation replacing the solidarity on which the Union was based. The large-scale migrations that we see could have a significant impact on demographics and epidemiology. The economic challenges are dangerous too. BBMRI-ERIC could be a role model in facing these challenges by united action between the National Nodes from the different geographies, sizes and economies. The diversity of the resources gives BBMRI-ERIC unique opportunities to explore alternate business models to promote discovery and translation to personalization of care by finding the correct balance between the public and private sectors.

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

Quite simply to think of scientific excellence, scientific excellence and scientific excellence; to turn biobanks into engines of life science research with the full participation of the community in giving, both samples and health information, a paradigm change in philanthropy.

BIOSKETCH

I am a graduate of the Medical School of the University of Malta and St. Luke's Hospital (MD 1971 & M.Phil. 1975) and the School of Graduate Studies of the Medical College of Georgia, Augusta GA, U.S.A. (Ph.D. 1981). I held academic positions on the Faculty at Augusta in both the School of Medicine and the School of Graduate Studies (Associate Professor; Cell & Molecular Biology & Pediatric Hematology) and on the Research Service of the Veterans' Administration Medical Center (Augusta, GA, U.S.A.) as Programme Director in Hemoglobin Research (Molecular Hematology). During this time, my research was supported by grants from the US, National Institutes of Health and the Veterans' Administration.

I have fond recollections of my mentors, two in particular. One of these was the late Joe Louis Grech; he was Clinical Pathologist at St. Luke's Hospital where I studied and had a special interest in the biochemical genetics of blood. The second, in Augusta, was the late Titus Huisman, originally from the Netherlands, who was a world leader in haemoglobin research. In 1992, I was appointed

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Professor (Biomedical Sciences) at the University of Malta where I teach courses in "Molecular Biology and Genetics" and the "Physiology of Blood and Body Defence Mechanisms" in the School of Medicine. Here, I directed the establishment of the Thalassaemia and Molecular Genetics services and the development of a Molecular Biotechnology Research Program including Human / Medical Genomics and the Malta BioBank. My research in Malta has been funded by institutional support of the University of Malta, The Malta Council for Science and Technology and the Sptar Mater Dei, together with competitive awards of the EU Framework and other R & D programmes. I have published numerous research articles mainly on the genetic disorders of haemoglobin gene control, including thalassaemia, and human molecular genetics, most with my former students and trainees who now develop programmes of their own, here and elsewhere.

I contribute to several international societies in science, haematology and human genetics as well as being Foundation President of the Malta Chamber of Scientists and Chairman of the consortium ‚European Researchers' Night, Science in the City' the city being Valletta, my home town. I represent Malta on the Management Committee and the Assembly of Members of the Biobanking and BioMolecular resources Research Infrastructure of the EU (BBMRI-ERIC).

In a Nutshell

***Common Services** shall consist of the facilities of BBMRI-ERIC that provide expertise, services and tools relevant for the pursuance of BBMRI-ERIC's tasks and activities, laid down in the Work Programme. (Statutes, Article 15.1)*

***Common Services** shall be established under BBMRI-ERIC and under the responsibility of the Director General. (Statutes, Article 15.2)*

***Common Services** shall be hosted in countries that are BBMRI-ERIC Members. The selection procedure for hosting Common Services shall follow the principles set out in Annex IV. (Statutes, Article 15.3)*

*Each of the **Common Services** shall be managed by a director, appointed by the Director General after consultation with the national delegates of the hosting Member State. (Statutes, Article 15.4)*

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

Find out more at: http://www.bbmri-eric.eu/common-services

SHARING AND ACCESS TO DATA AND HUMAN BIOSPECIMENS FOR THE BENEFIT OF PATIENTS – COMMON SERVICE ELSI WORKSHOP *by Mats Hansson*

Mats Hansson
Professor of Biomedical Ethics
Director of the Centre for
Research Ethics & Bioethics
at Uppsala University
Co-Director of CS ELSI

8-9 September 2015 the Common Service ELSI arranged its first workshop with the purpose of engaging a wide community of ELSI scholars associated with the National Nodes, making up the backbone of ELSI expertise supporting BBMRI-ERIC. 45 participants gathered in Paris to take the first steps towards a BBMRI-ERIC policy for sharing and access to data and samples. There is a growing international agreement on the need to provide greater access to research data and biospecimen collections to optimise their long-term value and exploit their potential for health discovery and validation. Currently, the rising value of data and biospecimen collections does not correspond with an equal increase in data/sample sharing and data/sample access. Ideally, data and biospecimens should be made widely available to the most inclusive and ethically responsible research community, but there is often resistance by institutions and individuals who fear that they will not receive recognition for their intellectual investments in building data and sample repositories. Sharing is essential for the advancement of biomedical science and innovation but from a patient perspective it is morally imperative. In order to promote sharing, patient consent forms may include the following requirement to scientists collecting data and samples: "You may have access to my data and samples only if you promise to share them with other scientists" – thus making scientists accountable to patients.

That the workshop was so successful is mainly thanks to the wide representation from ELSI experts from the different National Nodes of BBMRI-ERIC, including philosophers, lawyers, biomedical scientists, medical doctors, social scientists and bioethicists. A report is prepared based on the underlying structure of the workshop including: i) Philosophical underpinnings for sharing, ii) Legal conditions for sharing biospecimens and health data across European borders, iii) Information and consent procedures based on notions of broad consent for prospective sampling, iv) Respect for intellectual property rights involved in sharing agreements and, v) How to set up procedures and policies for sharing that are consistent with patient and public trust. The report is expected in December 2015.

THE COURT OF JUSTICE OF THE EUROPEAN UNION HAS DECLARED THE TRANSFER OF PERSONAL DATA TO THE US ON THE BASIS OF ‚SAFE HARBOUR' INVALID – WHAT IS THE IMPACT OF THIS RULING, IF ANY, ON EUROPEAN BIOBANKS?

by Jasper Bovenberg and Irene Schlünder

ON OCTOBER 6, 2015, THE COURT OF JUSTICE OF THE EUROPEAN UNION (CJEU) RULED THAT THE EUROPEAN COMMISSION'S DECISION (DECISION 2000/520) ESTABLISHING THE "US SAFE HARBOUR PRINCIPLES" (SHP) AS A LEGAL BASIS FOR THE TRANSFER OF PERSONAL DATA TO THE UNITED STATES IS INVALID[1]. WHAT DOES THIS MEAN FOR BIOBANKS IN THE EU?

What is „Safe Harbour"?

Data protection law in the EU has a common legal framework: the Data Protection Directive of 1995 [2]. Article 26 of the Directive allows the transfer of personal data to third countries "only if the third country in question ensures an adequate level of protection". The European Commission is the competent body to declare countries as ‚safe' countries in this sense. Among these are for example Switzerland and Argentina, not the United States. With respect to transfer of data to the US, the Commission took a more complex approach: the so-called ‚Safe Harbour' Decision states, in essence, that, if a US based organisation has committed itself to the "safe harbour privacy principles for the protection of personal data" agreed with the Government of the United States and laid down in the Commission's decision, then personal data transferred to such an organisation (a so-called 'Harborite') by an EU organisation is considered to be adequately protected and thus valid under the EU Directive.

What did the CJEU decide?

The CJEU declared the Commission's SHP decision invalid. The Court's ruling requires the Irish Data Protection authority to re-examine the complaint brought before it that the law and practices in force in the United States do not ensure an adequate level of protection of

[1] JUDGMENT OF THE COURT (Grand Chamber), 6 October 2015, in Case C-362/14, *http://curia.europa.eu/juris/document/document.jsf?text=&docid=169195&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=462865*

[2] DIRECTIVE 95/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

personal data of EU citizens. But the leeway for this re-examination is small, since the Irish Data Protection authority has to take into account the CJEU's opinion that „Legislation permitting the public authorities to have access on a generalised basis to the content of electronic communications must be regarded as compromising the essence of the fundamental right to respect for private life, as guaranteed by Article 7 of the Charter of Fundamental Rights of the European Union." The CJEU further held that Commission decisions regarding the adequacy of protection of personal data in third countries do not prevent a supervisory authority of a Member State from examining complaints from EU citizens that the law and practices in force in such a country do not ensure an adequate level of protection. As a result, EU Commission adequacy findings can always be challenged before the national data protection authority concerned, which could lead to fragmentation and delay where the data to be transferred to a third country comes from multiple Member States.

What is the impact for biobanks?

As a result of the CJEU's decision, EU biobanks, registries and researchers who transfer personal data (which under circumstances could include coded or pseudonymised data) of EU citizens to the United States can no longer validly do so on the basis of the SHP. BBMRI-ERIC suggests that the BBMRI National Nodes advise all associated biobanks and principal investigators whom this may concern, to check whether they operate under the SHP. If they do not so operate, they are unaffected by the ruling of the European Court. Those who do operate under the SHP can no longer validly do so and must base their transfers of personal data of EU citizens to the US on another legal ground, such as informed consent or the use of Standard Contractual Clauses. As to informed consent, this consent must explicitly relate to the transfer of the personal data to the United States. Notably, in view of the CJEU's ruling, for this 'consent to transfer' to be adequately informed, the information must make clear that the recipient country does not offer adequate protection of personal data. Arguably, if the data have been de-identified to the extent that they no longer qualify as personal data, then transfer of such data does not fall under the data protection legislation. BBMRI-ERIC Common Service ELSI is available for counselling, if needed.

Jasper Bovenberg, *Attorney at Law, Co-Director of CS ELSI, jabovenberg@xs4all.nl,*
Irene Schlünder, *German Expert of CS ELSI, irene.schluender@bbmri-eric.eu*

SAVE THE DATE

EUROPE BIOBANK WEEK, BIOBANKING FOR HEALTH INNOVATION

13-16 SEPTEMBER 2016 / VIENNA, AUSTRIA

NORWAY JOINS AS FULL MEMBER

The Assembly of Members of BBMRI-ERIC, in accordance with the provisions of Article 10 of the Statutes and the „request to become a Member of BBMRI-ERIC“ of the Medical Research Council, ADMITS the Kingdom of Norway, WELCOMES and CONGRATULATES Karianne Solaas as the head of the Norwegian delegation to the Assembly of Members.

Norway will be a full member as of 1 January 2016.

Learn more about BBMRI.no/ Biobank Norway: *http://www.ntnu.edu/biobanknorway*

ASSEMBLY OF MEMBERS APPROVES WORK PROGRAMME 2016

On 27 October 2015, the Assembly of Members of BBMRI-ERIC approved the Work Programme 2016, which focuses on the development of the e-infrastructure and quality development. You will find the Work Programme online at *http://bbmri-eric.eu/bbmri-eric-publications*

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European, Middle Eastern & African Society for Biopreservation & Biobanking

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MoU WITH THE EUROPEAN SOCIETY OF RADIOLOGY

In November 2015, BBMRI-ERIC and the European Society of Radiology signed a Memorandum of Understanding (‚MoU') to jointly promote the importance and visibility of imaging biobanks, to coordinate efforts to establish a European imaging biobank infrastructure and to ensure its annotation to existing biobanks.

Areas of Collaboration, among others:

- Establish a joint working group, whose primary focus is to work on the linking of MIABIS (Minimum Information About BIobank data Sharing) with DICOM (Digital Imaging and Communications in Medicine)
- Collaborate with regard to the BBMRI-ERIC Directory 2.0
- Collaborate to identify existing cohorts with imaging biobanks and to encourage them to link them to BBMRI-ERIC.
- Include information on this collaboration on the organisations' websites, social media etc.
- Publish a joint paper on imaging biobanks
- Develop joint press releases when appropriate to keep all stakeholders informed about progress of collaboration
- Hold face-to-face meetings at the respective congress/conference
- Lobby for European funding of imaging biobanks and consider joint project applications.
- Evaluate avenues for a more formal collaboration with ESR and integration of imaging biobank activities into BBMRI-ERIC.

ESBB & BBMRI-ERIC JOIN FORCES: ONE BIOBANK EVENT FOR EUROPE

On 30 September 2015, BBMRI-ERIC and ESBB (European, Middle Eastern and African Society for Biopreservation & Biobanking) have formed a strategic alliance for the benefit of European biobanking efforts. Starting in 2016, the two organisations will jointly organise the most important annual biobanking conference in Europe and facilitate collaboration on activities related to biobanking and biopreservation of samples for research and development. This agreement emphasises that biobanks are a European strength.

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BBMRI-ERIC'S POSITION ON THE GDPR

EXECUTIVE SUMMARY

Seventeen European Member States and one International Organisation (IARC) have joined forces in establishing the Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium (BBMRI-ERIC). As of 3 December 2013, BBMRI-ERIC is an international organisation established under EU law, facilitating access to biological resources as well as biomedical facilities. The specific legal form of an ERIC is designed to facilitate the joint establishment and operation of research infrastructures of European interest in the European Research Area (ERA).

BBMRI-ERIC acknowledges and embraces the dynamic potential of the General Data Protection Regulation for the ERA. At the same time, insufficiently thought-out provisions could seriously hamper Pan-European research as well. Building on the Day of Action led by BBMRI-ERIC on 16 June 2015, which led to a set of concise recommendations on the General Data Protection Regulation[3], this position paper further elucidates and illustrates these recommendations. BBMRI-ERIC urges that the following concerns of the European research community are taken into account in the ongoing legislative process and is prepared to enter into a dialogue with policymakers on the following issues:

[3] *http://bbmri-eric.eu/documents/10181/125935/Position+Paper+Day+of+Action+Data+for+Health+and+Science+Final.pdf/.*

- *Safeguard the Interests of Patients in Medical Research*

Patients have a legitimate expectation of an increase of knowledge, as recognised by Council and Parliament in Recital 88. For this reason, **the Regulation should safeguard the interests of patients in medical research.** Future research purposes are often impossible to predict. A legal requirement for patients to re-consent often for novel forms of research is therefore encumbering for both the researcher and the patients. While protecting the data from misuse and illegal disclosure, the Regulation should also ensure that samples and data do not go to waste. **Patients should therefore have a right to consent to the inclusion of their data and biomaterials to biobanks and databases for biomedical research,** even if potential research objectives cannot be stated as specifically as in a concrete clinical study.

We propose that the message of Recital 25 aa (Council version) must be maintained.

- *Maintain the Distinction Between Processing of Personal Data for Scientific Research Purposes and Other Forms of Processing*

Biomedical research aims at furthering our knowledge of human health and developing new treatments and therapies to counter disease. For this reason, **all biomedical research can be considered a substantive public interest.** Ensuring that this remains so requires drawing a line between processing for scientific research purposes and processing for other purposes, such as direct marketing and personal profiling of clients, as follows from Parliament's and Council's amendments to Recital 126. A number of parliamentary amendments go one step further however, raising the barriers for research too high through wordings such as 'high public interest' and allowing processing for research using non-anonymous health data only if that research 'cannot possibly be carried out otherwise'. We urge you to replace 'possibly' with 'reasonably'. Finally, we should note that **a number of novel data subject rights proposed in the GDPR are already routinely offered in research, such as the right to object.**

We approve of the amendments to Recital 126 (Parliamentary amendments and Council version). At the same time, we are concerned about the term 'high public interest' in Parliamentary amendments for Recital 123a and Article 81(2a) (and others) and urge a change to 'public interest'. We are also concerned that amendments to Articles 81(2a) and 83(1b) (Parliament version), stating that data processing involve pseudonymisation 'under the highest technical standards', will prove severely detrimental to research and urge a wording such as 'reasonably high' standards. We consider some of the derogations for processing data for scientific research purposes as envisaged by the Council in Article 83 to be more far reaching than strictly necessary. In particular, a derogation for Article 19 could be omitted.

- *Harmonised Rules Are Preferable to Promote Pan-European Research*

Consistent harmonised rules for research at EU level are needed to promote research collaboration Europe-wide. Harmonised data protection rules for research, which take the perspective of Pan-European research into account are urgently needed, particularly in rare disease research. The opportunity to develop sector-specific rules under the aegis of the GDPR is one way of furthering harmonisation. Given the ambitions of the European Union to strengthen the development of a European Research Area, **Pan-European organisations such as BBMRI-ERIC should also have a right to submit Codes of Conduct directly to the EU Data Protection Board.**

We appreciate the opportunity for associations and other bodies representing categories of controllers or processors to draw up codes of conduct (Art. 38) and envisage a future role for BBMRI-ERIC in this process. However, European organisations such as BBMRI-ERIC should also have the right to submit codes of conduct directly for approval to the EU Data Protection Board. Article 38 para 2 should therefore be amended as follows: ‚ERICS and other European research networks or organisations representing more than three Member States shall submit the draft code of conduct directly to the European Data Protection Board.'

- *Member State-Specific Derogations for Processing Personal Data for Scientific Research Purposes Remain Important*

Currently, many Member States' research and research infrastructures are operating on the basis of specific derogations and interpretations of the Data Protection Directive. **Such derogations should not be used by Member States or competent authorities such as funding agencies and ethics committees to block cross-border research and exchange of personal data for research purposes.** At the same time, achieving full harmonisation for health research through the General Data Protection Regulation would be too ambitious a goal.

The General Data Protection Regulation should leave sufficient leeway for Member State-specific approaches in the absence of harmonised health systems. Ideally, established national and international legislative frameworks, guidelines and codes of conduct relating to scientific research should be acknowledged specifically in Article 83.

Therefore, maintain specific exemptions for processing of special categories of personal data, including genetic data and data concerning health, for purposes of scientific research in Article 9 para 2(i) (Council version) and Article 83, including Member State-specific derogations for the requirement of consent. Make sure that Member State-specific derogations are not invoked to block, delay or otherwise unduly frustrate cross-border data exchange for research purposes. Therefore make the derogation clause consistent by introducing specific safeguards in Article 83, as indicated in Article 9 para 2 (i). In addition, established national and international legislative frameworks, guidelines and codes of conduct relating to scientific research should be acknowledged specifically in Article 83.

BBMRI-ERIC GAINS MOMENTUM WITHIN ISO AND ITS WORKING GROUPS *by Andrea Wutte & Petr Holub*

Since April 2015, BBMRI-ERIC is officially an Observer Liaison of ISO/TC 276 'Biotechnology' as well as of ISO/TC 212 'Clinical Laboratory Testing and In Vitro Diagnostic Test Systems'. It contributes actively to the process of international standard developments by addressing comments and by sharing developments of the ISO Working Groups with the BBMRI community.

Between 26 and 30 October 2015, the International Organisation for Standardisation (ISO) called for working group meetings within the TC 276 Biotechnology. The Mirror Committee of Japan welcomed more than 100 delegates, members and observers to Tokyo, Japan. The Forum for Innovative Regenerative Medicine (FIRM) excellently hosted meetings of all five Working Groups at the venue of the National Cancer Center (NCC) at Tsukiji Campus.

Deep, intense and constructive discussions were conducted in order to review created documents and all associated comments, received from the international mirror committees, liaisons and observers.

The *WORKING GROUP 01* 'Terminology' is acting as a hub for the working groups of TC276 regarding harmonisation of terms and definitions whenever these are found to conflict or overlap.

The *WORKING GROUP 02* "Biobank and Bioresources" has made major progress. The first draft of a manuscript reflecting basic requirements for biobanks was written and very thoroughly reviewed and commented. Many expectations for the content of a future standard for biobankers were expressed, creating fertile ground for the next steps in the development. There is no doubt that this working group faces a great challenge to meet the need for a standard or a package of international standards in the biobanking field, to be used by both the public and private sectors, and which will fill the gap between the material sources and the R&D laboratories using the samples and/or data. The working group is coordinating its work with relevant technical committees, including ISO/TC 212 'Clinical Laboratory Testing and In Vitro Diagnostic Test Systems'. **BBMRI-ERIC** is also contributing to the developments of the **ISO/TC 212 *WORKING GROUP 04* 'Microbiology and molecular methods'** as Observer Liaison.

The developments within this group will have a major impact on specific pre-analytical processes performed in human biobanks as ell as the interface to the WGs 'Terminology', 'Analytical Methods' and 'Data Processing and Integration'. These numerous interfaces are most obvious for human biobanks, and therefore the BBMRI-ERIC community is paying special attention to them and supporting them with expert knowledge. The BBMRI-ERIC Work Programme 2016 is aligned with the developments of both technical committees TC 276 and TC 212. **'Analytical methods'** are discussed in *WORKING GROUP 03* of ISO/TC 276. The focus is on the development of standards for cell characterisation, cell counting and viability and on nucleic acid quantification and sequencing, protein identification and quantification.

The *WORKING GROUP 04* **'Bioprocessing'** has identified standardisation needs in four major technologies spaces such as component materials control; bioreactor processes; collection, separation, purification and formulation; and handling, transportation & storage. Each category of materials/technology space may affect many current and future applications. At the moment, no obvious overlap to BBMRI-ERIC human biobanks is observed.

WORKING GROUP 05 **'Data Processing and Integration'** aims at developing standards for traceable and interoperable data together with integrated data processing for biotechnology/life science. The preliminary work item (PWI) has been received from the German expert group, which maps existing community standards in the field relevant to the Biotechnology scope of the TC 276. As the newly established working group, it is currently working on defining precise use cases and analysis of needs and gaps for the upcoming data integration standards.

The Work Programme of BBMRI-ERIC is aligned with these ISO activities, which we see as key developments for reaching jointly agreed quality standards worldwide as a substantial achievement for the biobanking community.

BBMRI-ERIC'S INVOLVEMENT AS OBERVER LIAISON:

ISO/TC 276 'Biotechnology'

WORKING GROUP 01
'Terminology'

WORKING GROUP 02
'Biobank and Bioresources'

WORKING GROUP 03
'Analytical methods'

WORKING GROUP 04
'Bioprocessing'

WORKING GROUP 05
'Data Processing and Integration'

ISO/TC 212 'Clinical Laboratory Testing and In Vitro Diagnostic Test Systems'

WORKING GROUP 04
'Microbiology and Molecular Methods'

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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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