

## Editorial

Dear colleagues,

For this issue, we have decided to wrap up the German Biobank Node's ongoing activities because the first funding period is almost at its end. We look back on two very intense years of discussions within all our work packages and are convinced that the "concept to develop concepts" has proven successful in every sense. We laid some important groundwork—especially for IT and quality, but also for public awareness and stakeholder analysis. In addition, we began involving the various biobank networks, such as cBMBs, DZGs and NaKo, and we can see that many collaborations have been initiated on different levels.

Now we have the opportunity to secure another round of funding to bring these concepts to life and to implement important structures—mainly within a consortium of ten biobanks (German Biobank Alliance), but with the prospect of rolling out implementation for all national biobanks. One future aim is to closely coordinate our activities with developments in medical informatics so as to build cross-linked infrastructures. Just recently, some brilliant examples of these infrastructures were showcased at the Europe Biobank Week in Vienna, which was jointly organized by BBMRI and ESBB. In this newsletter, we give you a short overview of the main topics discussed in the course of this international conference.

Michael Hummel & Cornelia Rufenach



## Europe Biobank Week 2016: European Biobanking Community meets to discuss Health Innovation

The Biobanking and BioMolecular Resources Research Infrastructures – European Research Infrastructure Consortium (BBMRI-ERIC) and the European and Middle Eastern Society for Biopreservation and Biobanking (ESBB) have joined forces, resulting in the Europe Biobank Week, a joint congress which took place from September 13 – 16, 2016 in Vienna, hosted by BBMRI.at. The theme of the congress: health innovation.

The congress brought together almost 700 biobanking experts from all over the world to discuss the future challenges for biobanking, such as biobanking governance, participation of patients and the public in biobanking, data privacy and management, precision and personalized medicine, quality and integrity of samples, environmental issues and international collaboration.

Biobanking is a specific European strength addressing the ongoing and future requirements particularly of Europe's health research frameworks. Biobanking is far more than a stand-alone structure but is evolving as

part of a larger set of cross-linked infrastructures with comprehensive data linkage. The nordic countries are following this path systematically; Finland leads the nordic alliance, but Denmark, Sweden and Norway are on the same track. Likewise, in the Netherlands, the new Health-Research Infrastructure is integrating several network activities (BBMRI, ELIXIR, EATRIS among others) in order to foster progress in personalized medicine and health research.

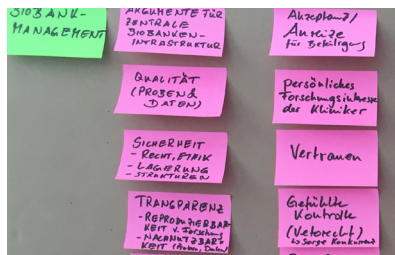
The German Biobank Node's activities were represented well on this occasion: Sabrina Schmitt from Heidelberg presented the German harmonization process in QM (Work Package 3) and Antje Schütt the results of the stakeholder analysis in WP 4; Cornelia Rufenach presented a poster on the GBN's overall activities.

We are sharing just a brief summary of the various conference topics here. For more details, please visit the event's mobile app, which offers a great overview of all sessions, including the abstracts (Link to the app at: [www.europebiobankweek.eu](http://www.europebiobankweek.eu)).

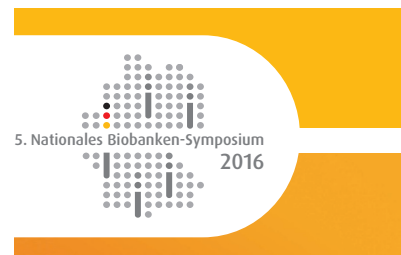
## Topics



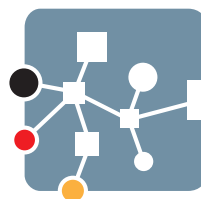
Europe Biobank Week 2016



GBN Report



Publications & Events



## Europe Biobank Week 2016

### Update on Ethical, Legal, and Societal Issues

At the Europe Biobank Week in Vienna, members of all European ethics committees (EC) had an initial discussion on the conditions of mutually recognizing European EC votes for medical research projects. Existing solutions, pitfalls and challenges at the European level were highlighted, and models of how to achieve mutual EC recognition were discussed. This dialogue is to be continued next year in Stockholm in order to further develop the initial agreements made at the Vienna meeting.

During the congress, a number of important ELSI themes were addressed, including new concepts and tools for public engagement (participation of patients and the public in biobanking) (B1, B6) and strategies for biobanks' public outreach (B7). Existing solutions for particular ELSI challenges were debated in session B2; A.M. Tassé (Montréal, Canada) reported on the difficulties of gathering biosamples from various studies for medical crossover projects, because study-specific consent forms do not always allow a use of the samples beyond the indicated purpose. To solve this issue, R. Jahns (Würzburg, Germany) proposed the German broad consent template, which would allow for cross-border exchange of biomaterials and related data. A. Cambon-Thomsen (Toulouse, France) presented the Bio-Resource Impact Factor (BRIF) initiative for facilitating the sharing of bioresources through incentives and tools, which still awaits broad implemen-

tation in order to trace bioresources and standardize the citation of bioresources in the academic literature according to the CoBRA guideline (BMC Med. 2015,13:266). Next, H. Langhof (Hannover, Germany) reported on the results of a survey on access policies in biobank research and their public availability. Internationally, only 14% of biobanks make their access policies publicly available. Lastly, P. Manders (Nijmegen, NL) proposed a workflow for dealing with unsolicited findings in (genetic) research, differing between "single candidate gene testing" and "whole exome analysis," the latter generally involving an "unsolicited findings committee." From an ethical and legal point of view, the presentation given by I. Schlünder

and M. Sariyar (TMF/GBN, C2) was of utmost interest to biobanks involved in genetic research; according to their reflections and in terms of current practice, whole genomic data cannot be anonymized.

The upcoming EU data protection regulation (GDPR) was another focus of the Europe Biobank Week. In the research context, no major changes are expected with regard to current data privacy procedures, except for an increased involvement of (and optional feedback to) donors.

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*Antje Schütt and Roland Jahns during the EBW 2016*

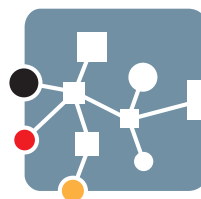
### Highlights in Public Engagement Sessions

The EBW program put a strong focus on the issue of public and participant engagement. "Today, participation is a key process and requirement in collaborative biobanking," said Sara Casati (Italy). According to her, precision medicine and big data are features of post-normal science (a notion coined by Funtowicz and Ravetz in the early

1990s) and of a paradigm of complexity characterized by pluralistic processes and by co-production of scientific knowledge. Participation, therefore, needs to be built in as part of an infrastructure.

Trust is key. Marianne Talbot (UK), a bioethicist and participant in the UK biobank, posed the question of what

the reasons for a potential loss of trust in the UK biobank might be. She mentioned three main possibilities: a breach of confidentiality, misuse of data, and if the initial consent were interpreted too generously, in which case one would "rather go back to the participants and get new consent," Talbot said. "Nothing about us,



without us" – this is what early patient activists in health research demanded. Francesco de Lorenzo (Italy), Board Member of the European Cancer Patient Coalition (ECPC), sees the partnership between biobanks and patients as mutually beneficial. "Reciprocity is key to ensure that the relationship between the biobank and the patients remains strong," he said. Engagement might be supported by technical platforms, as demonstrated by Madeleine Murtagh and Joel Minion (UK), who presented their ECOUSER

project, a virtual engagement project on the topic of trust and data linkage in biobanking. By using online forums, stakeholders are invited to interact with the existing evidence on a topic of shared concern and to respond and contribute additional ideas and links. The online discussion is analyzed to generate a conceptual framework of the phenomenon or issue considered. Thus, they gain a breadth of perspectives instead of the views of only a handful of representatives. On behalf of GBN, Antje Schütt (TMF)

presented the results of the WP4 survey on study participants' attitudes toward and understanding of biobanks and how these results feed into the development of a communication and engagement strategy for GBN and for biobanks throughout Germany.

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## Improved Quality across European Biobanks

Quality of processes and the resulting integrity of samples have an enormous impact on the reliability and reproducibility of scientific research results. Thus, the implementation of biobanking quality standards, as well as the harmonization of sample-related processes across Europe, was one of the main topics at the EBW. All over Europe, multiple efforts are underway to harmonize biobanking processes in order to achieve comparable and high levels of sample quality and data, and some of these efforts have already been quite successful (bbmri.at and bbmri.de). For the draft versions of the newly generated standards, ISO/TC 276 and ISO/TC 212, preanalytical conditions and actions for biobanking processes have already been taken into consideration. In addition, the results of the BBMRI-guided QM working groups were presented during the meeting in



Vienna. The groups benefit from the participation of several experts from different national nodes who bring their expertise in standards development to the table. These results will directly complement the ISO standards drafts. In the context of collection and downstream processing, there is an essential need to define standardized preanalytical workflows. The implementation of these workflows

will minimize negative influences on sample quality and on the respective results of subsequent "omics" analyses. Lively and productive discussions following the oral presentations as well as during poster sessions and coffee breaks made the EBW an inspiring and informative event.

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## Meeting Highlights: IT

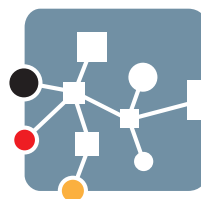
From the IT perspective, this year's EBW covered three key topics closely connected with BBMRI-ERIC's Common Service IT. The first of these is the linkage of various sources of information, including the biobanks. In this regard and in times characterized by big data, the topic of standardization and harmonization is becoming increasingly important for merging heterogeneous databases. This goes beyond mere data formatting, encompassing quality indicators and comprehensible

descriptions of procedures for handling samples and/or data as well. Secondly, the annotated list of relevant software products for the biobanking sector at <http://biobankapps.com/> should be mentioned. This makes finding potentially relevant open source tools, such as LIMS systems, significantly easier. The French and Austrian BBMRI nodes are working on making this software list available, and it will be a part of CS IT soon. A third key topic is the searchability of specimens stored in biobanks. CS IT

is already on the way in the direction of a sample locator in order to enable more detailed searches than are allowed by, for example, a national biobank registry on the basis of aggregated data. As an interim step in this direction, there will be a sample negotiator, which is to be rolled out in late 2016.

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## BBMRI-LPC Forum 2016

The 4th BBMRI Biobank Forum Meeting (former BBMRI LPC Forum) took place on 15-16 September as part of the Europe Biobank Week in Vienna, Austria. The aim of the BBMRI-LPC Forum has been to create a platform for transferring expertise from established European biobanks to new biobank initiatives under development in Eastern Europe and elsewhere. Through EU funding, BBMRI-LPC was able to provide financial support for two representatives from each Eastern European member state and associated state to participate in all the Forum meetings.

The BBMRI-LPC project will end in 2017, and the Forum will be continued as the European Biobank Forum within the framework of BBMRI-

ERIC. Thus, this last meeting was a joint effort on the part of BBMRI-LPC and BBMRI-ERIC in preparation for the changeover, and its focus was on the funding situation in Eastern European countries in the past and on future possibilities.

Markus Pasterk opened the meeting with an overview of the national RI roadmaps in Eastern European countries and the possibilities they provide for strengthening the biomedical field and for joining BBMRI-ERIC. On Friday morning, Jan-Eric Litton, Michaela Mayrhofer and Petr Holub presented BBMRI-ERIC's activities, as well as the common services ELSI and IT. Representatives from Lithuania, Latvia, Poland and Cyprus illustrated the situation in their respective countries

and the achievements of the last years in presentations on Thursday and Friday. On Thursday evening, BBMRI-LPC representatives and forum participants enjoyed a stimulating networking dinner in the "Schweizerhaus," a typical Prater restaurant. The meeting ended on Friday with the "tour de table," where all participants from emerging biobanks gave short updates on their countries with a focus on the financial situation. The meeting was chaired by Eero Vurio, organizer of the BBMRI-LPC Forum.

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Photo: Marko Kovic

## German Biobank Node

### Report on 1<sup>st</sup> funding period

The German Biobank Node (GBN) started in 2013, set up as a central platform for national biobanks that simultaneously acts as the national hub for the European initiative, BBMRI (Biobanking and Biomolecular Resources Research Infrastructure). Funded by the Federal Ministry of Education and Research, GBN has worked hard to foster networking and to harmonize the activities of all national biobanks. "Our initiative dovetails perfectly to current developments of the national and international biobanking community," says Prof. Michael Hummel, national

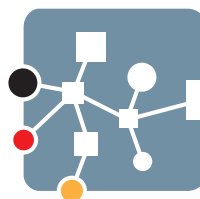
coordinator of GBN.

At the national level, an increasing number of central biomaterial banks have been established in recent years, and they cooperate with GBN to facilitate an exchange of knowledge and experiences, develop standards for quality assurance and concepts for IT interconnectivity as well as public outreach activities. These are prerequisites for enabling access to and for the use of biological samples and data for research. Biological samples and data collected by biobanks are valuable resources for innovations in personalized medicine, the develop-

ment of biomarkers, diagnostics and therapeutics.

On an international level, GBN comprises Germany's representation in BBMRI through the national coordinator, who takes part in BBMRI activities and assumes Germany's role in BBMRI.

Currently, GBN is in the process of wrapping up the results of the first funding period and preparing the work program for the second funding period. To this end, we would like to share some of the achievements of the work packages from the first funding period with you.



### WP1: Central Management Office as a Hub for the German Biobanking Community

The GBN central office is operating successfully as the central point of contact for the national biobank community and as the hub for BBMRI-ERIC. WP1 comprises GBN's management as well as its organizational tasks, including running overall project coordination

in close collaboration with the project teams. Corporate communication, public relations and public outreach are key tasks of the central office in close cooperation with WP4. In the expected next funding period, the central office will establish a governance structure and create a

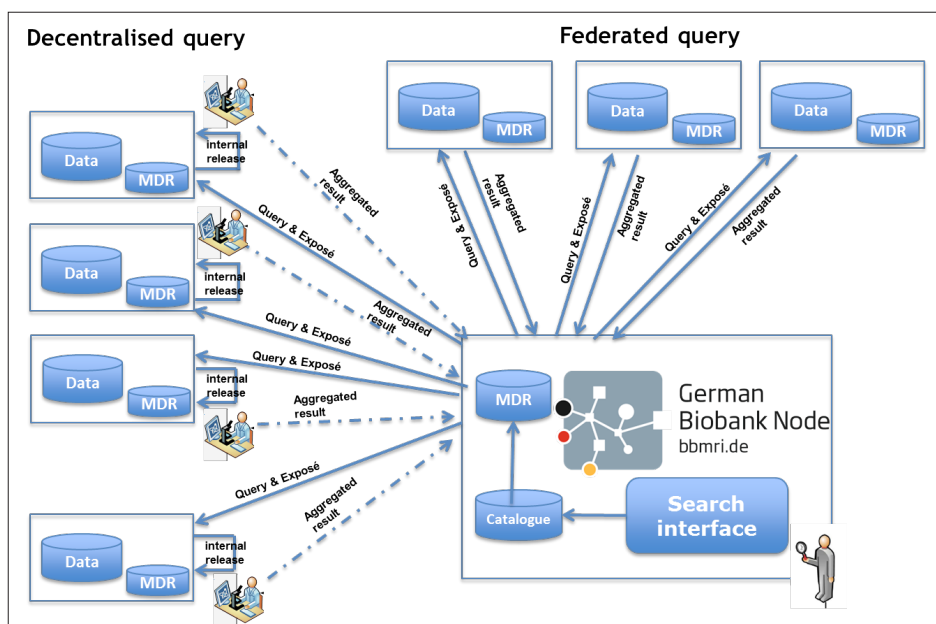
legal link between all participating biobanks and GBN with a consortium agreement allowing common operations among all partners as well as with other stakeholder groups (foremost BBMRI-ERIC).

### WP 2: Concept for an IT Network

The local IT situation – both for IT components in biobanking and general hospital information systems as well as IT infrastructures in the research field – is heterogeneous among the various locations throughout Germany. As a first step of harmonization, GBN's IT work package has addressed the current IT settings in several large biobanks. Seven centralized German biobanks (Aachen, Berlin-Charité, Heidelberg, Kiel, Würzburg, Munich, Hannover), as well as the biobanks of the German Health Research Centers,

were interviewed in a written survey and in two workshops, where the results were discussed in detail and summarized.

Based on this structured overview of existing database systems and data/attributes of the individual biobanks, a proposal for a future networking concept has been developed for Germany. The survey seems to show that it is not advisable or even



possible to generate one precisely tailored monolithic IT solution for all biobanks. Thus, the proposed concept for an IT framework for biobanking is intended to link local biobank IT systems with the German and BBMRI network using a very modular and generic approach. This will enable the German biobanks to interconnect their systems by integrating components which are missing from

their respective environments – in compliance with ethical guidelines and data privacy regulations. The IT tools and structures being proposed for supporting local infrastructures in order to prepare for an efficient integration into the European BBMRI-ERIC network will be developed during a next funding period expected to start in 2017.

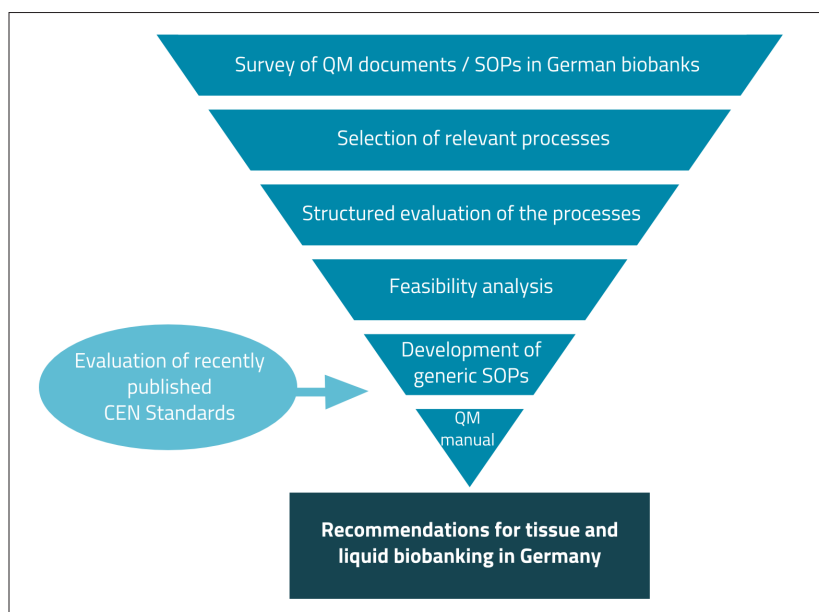
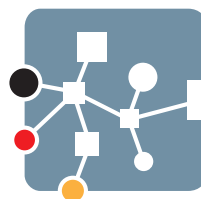
### WP3: Concept for Quality Management

Work package 3 in the German Biobank Node (GBN) aims to develop a detailed quality management (QM) concept for liquid and tissue samples in Germany. The project started with a joint workshop of GBN biobanks in July 2015 in Heidelberg. The responsible project partners had additional regular meetings evaluating a representative collection of standard ope-

rating procedures (SOPs) in German liquid and tissue biobanks. Based on these, a process matrix was generated.

Generic SOPs for both types of biobanks were drafted, harmonized and compared with various regulations and standards, including the technical specifications (CEN/TS) for "Molecular in Vitro Diagnostic

Examinations – Specifications for Pre-Examination Processes for Different Sample Types," in order to identify compliances and differences. Adaptations in the generic SOPs were needed in order to account for the special requirements of German biobanks. By focusing on sample quality, the project generated SOPs covering all relevant aspects



*GBN-WP3: Development of a Quality Management concept*

#### WP 4: Foster Public Outreach

Biobanks are essential resources for future biomedical research. However, biobanks are not very well known in the public or among relevant stakeholder groups. "We think it is very important to convey a positive image of biobanking in Germany, including its social and ethical aspects, in order to achieve broad acceptance of biobanks in the public," says Prof. Roland Jahns, Work Package Leader for Public Outreach in GBN. Experts worldwide are calling for a greater involvement of the various stakeholder groups in biobanking activities in order to create a better understanding of the purpose and future benefits of biobanks for precision medicine. Thus, the aims of this work package were to develop concepts for how to enhance donors' knowledge on biobanks and biomedical research and how to support German biobanks in their communication and stakeholder engagement activities.

In 2015, GBN initiated an analysis of different stakeholder groups with a special focus on donors, biobank managers and scientists. About 200 donors were asked about their attitudes toward and their understanding of biobanks. This analysis revealed significant knowledge gaps on the part of the

donors regarding the concepts of biobanking. Although willingness to support research is high, a significant number of donors have difficulties understanding the purpose of biobanking and how their samples are used.

Communication gaps are also relevant in other stakeholder groups; qualitative interviews with biobank managers underscore that they recognize an urgent need to engage with

internal target groups (researchers, clinicians) in order to foster collaboration and create confidence among all parties involved. Centralized biobanks should also provide transparent information regarding their governance, policies, procedures and ethical framework in order to build trust among clinicians and other relevant stakeholders.

*Wiebke Lesch & Cornelia Rufenach*

### GBN Educational Workshops

**6. December 2016**

Berlin, TMF e.V.

The results, which were compiled in the work packages QM and PR during the 1st funding period will be presented in two workshops. Practical hand-on information is conveyed and material for the daily work will be provided to the participants.

12:00 - 15:30

***Practical implementation of international Quality Standards for Biobanks***

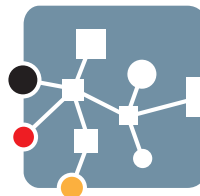
Organisation: Sabrina Schmitt, Bettina Meinung, Karl-Friedrich Becker

16:00 - 19:30

***Stakeholder Engagement for Biobanks***

Organisation: Antje Schütt, Wiebke Lesch

For more details and registration see: <http://www.bbmri.de>



## Publications

Chin WW, Wieschowski S, Prokein J, Illig T, Strech D (2016) Ethics Reporting in Biospecimen and Genetic Research: Current Practice and Suggestions for Changes. PLoS Biol. 2016 Aug 2;14(8):e1002521.

Khoury MJ, Galea S (2016) Will Precision Medicine Improve Population Health? JAMA. Published online August 18, 2016. doi:10.1001/jama.2016.12260

Biobank Perspectives Newsletter (bbmri.se): the Centre for Research Ethics & Bioethics (CRB) describes in this issue what BBMRI-ERIC's new federated Help-desk for ELSI-issues can offer. <http://www.crb.uu.se/biobank-perspectives/>

### BRIF progress

For learning more about how to cite your bioresource in articles see the new CoBRA tutorial!

The BRIF & journal editors' subgroup (A. Calzolari, P. Santoro & E. Bravo) has developed an educational video (5 min) showing how to use the CoBRA guideline with the aim of sharing it as an open access and publicly available tool. Link: <https://zenodo.org/record/55785#.V-0ZaTvgLSg>

## Calls

### CORBEL 1st Open Call for Research Projects

The CORBEL partners now launch an Open Call and thereby offer to all academic and industrial scientists in Europe the chance to accelerate their research project. Through defined pipelines, called Access Tracks, the services of more than 15 CORBEL partner institutes from 8 participating research infrastructures, including BBMRI, will be made accessible to interested scientists. The intention is to provide access to multiple research infrastructure services and benefit from user feedback in order to improve, where transitions between infrastructures are not as smooth as desirable.

For more information, please visit the project website:  
<http://www.corbel-project.eu/1st-open-call.html>

## Forthcoming Events

### GBN QM Workshop

4. October 2016  
Berlin, TMF e.V.  
<http://www.bbmri.de>

### GBN Educational Workshops

6. December 2016  
Berlin, TMF e.V.  
<http://www.bbmri.de>

### 5th National Biobank Symposium

7. - 8. December 2016  
Berlin, Mercure Hotel MOA Berlin  
<http://www.biobanken.de/de-de/symposium.aspx>

The **German Biobank Node (GBN)** is the central contact and exchange point for the German Biobank community - not only for researchers, but also for other stakeholder groups. Our aim is to facilitate exchanges of experience between national biobanks but also the participation in the European network of biobanks (BBMRI-ERIC). The development of standards for quality assurance as well as the elaboration of an IT concept for the sample and data exchange are our major projects.

### Imprint

German Biobank Node  
Newsletter Q3 September 2016

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