German Biobank Node
bbmri.de

Editorial

Dear colleagues and biobankers,

Welcome to the first issue of our newsletter, which aims to inform you about ongoing activities in the biobanking field in Germany and in the European context of BBMRI-ERIC. Although this newsletter is primarily targeted at the German community, we would also like to share the information with our partners in international biobanking. Therefore the language of the newsletter is English.

Since this is the first edition, we'd like to inform you in more detail about the projects the German Biobank Node (GBN) has initiated since 2014 in Germany as well as the activities within the pan-European network BBMRI-ERIC. We plan to give updates every 3 months and invite all of you to contribute topics for upcoming newsletters which might be of interest to the community.

National and European activities are increasingly converging – this is true for the concerted efforts to build an IT infrastructure connecting biobanks, and it is true for the efforts to define a set of standards for quality assurance in biobanking. For both of these core issues GBN aims to link German expertise nationally in the ongoing work packages as well as within the BBMRI-ERIC network.

The German landscape is multifaceted and heterogeneous, from individual biobanks to complex network structures like the *German Health Research Centers* (DZGs). We would like to intensify the dialogue with you – so please give us feedback after reading this first newsletter! We will be happy to include your suggestions and ideas in the forthcoming issues.

Best wishes,
Michael Hummel & Cornelia Rufenach

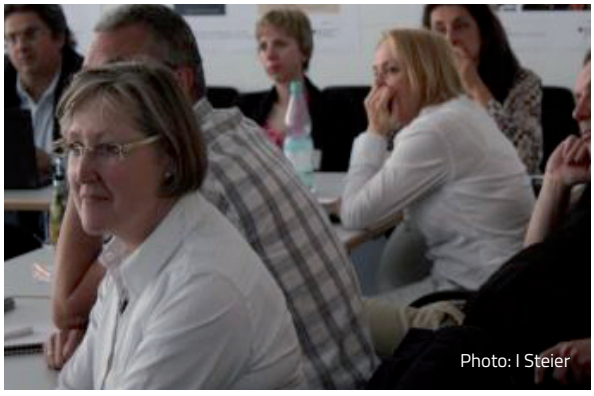
Inside GBN

Towards a harmonized IT structure

The IT situation in Germany is complex since there are many biobanks in a large number of locations – and even at the same location several different biobanks often exist. This causes not only a huge heterogeneity of the IT structures but many different data formats. Therefore the aim of the IT work package in the German Biobank Node (GBN) is to develop a harmonized IT concept for the exchange of data between German biobanks at the national as well as the European level. The tasks are:

1. Overview of IT structures of the biomaterial banks in Germany as listed in the German Biobank Registry and used in research networks.
2. Development of a general specification for data exchange including a concept for the IT infrastructure, formal descriptions of this infrastructure, and a pilot test phase with a few German biobanks.
3. Development of a concept for a legally compliant and efficient interface between the German (GBN) and European (BBMRI-ERIC) infrastructures which includes the respective technical specifications.

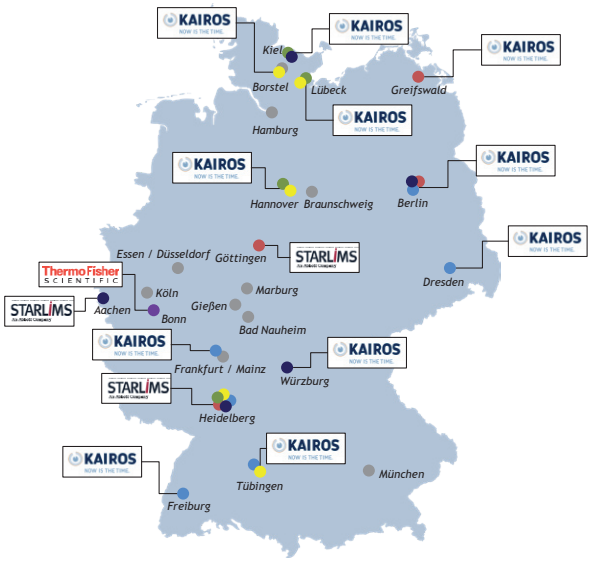
In order to analyze the current state of IT solutions in German biobanks and to discuss requirements for interaction with the European network, two workshops were organized by GBN. At the first meeting in November 2014, IT managers mainly from individual biobanks came together; in the second workshop in June 2015, IT managers from large network structures like the *German Health Research Centers* (DZGs) and the *National Cohort* met for a one-day meeting under the leadership of Hans-Ulrich Prokosch and Ines Leb from Erlangen.



IT-Workshop in Berlin

From the "inventory" it became clear that there is a mixture of large centralized and smaller individual clinical biobanks. The centralized biobank structure such as Berlin Charité, University of Kiel, and Hannover Medical School mainly employ CentraXX or STARLIMS systems as biobank management software (Fig. 1) and have 2-4 employees for IT support. SPREC or comparable parameters are used in most biobanks for quality assessment. MIABIS 2.0 for annotation of the biospecimens is usually not implemented but the existing annotation tools are closely related to MIABIS. Of course, ID management is available in all biobanks. Although many biobanks rely for the pseudonymization on publically available tools (Mainzelliste) additional solutions are additionally in use.

For the *German Health Research Centers* (DZGs), representatives reported on the biobank IT structure, annotations and data exchange options of their networks. All centers have in common that they have several locations distributed all over Germany. To support data exchange within the German *Consortium for Translational Cancer Research* (DKTK), which is spread over 10 sites, a "bridgehead server model" has been established. As explained by Frank Ückert, the "bridgeheads" are located behind the firewalls of the DKTK partners; most of them have already been successfully implemented by August 2015. These



DZL *German Center for Lung Research*
DKTK *German Consortium for Translational Cancer Research*
DZHK *German Center for Cardiovascular Research*
DZIF *German Center for Infection Research*
DZNE *German Center for Neurodegenerative Diseases*
cBMB *centralized biobanks*

Figure 1: Status quo (07.2015) of the implemented (or planned) biobank management systems in German Biobanks

bridgeheads provide decentralized search capabilities, and a web-based search tool allows DKTK researchers to search multiple repositories simultaneously. A flexible approach with a central metadata repository supports bridging of the natural data heterogeneity gap. However no search result is returned to a researcher before the local data owner gives his consent. If a match is found, the institute possessing the data is notified and can then decide to enter a collaboration agreement with the user.

At the *German Center for Cardiovascular Research* (DZHK), which was presented by Christiane Heiss, the patient data for individual research projects are entered in a web-based remote data entry tool (secuTrial, which is hosted in Göttingen) at individual DZHK study centers. A centralized LIMS is currently being being planed through a call for tenders. An agreement stipulates that all collected data and samples can be provided to all DZHK researchers as well as to external researchers and thus can be used across other studies. At the *German Center for Lung Research* (DZL) a search catalog based on an access database has been established to search in retrospective collections, reports Clemens Ruppert. For prospectively collected samples a central data warehouse (based on the i2b2 tool suite) is under development which will link sample search to phenotyping data. The IT infrastructure of the *German Center for Infection Research* (DZIF) is currently still under construction as presented by Gabriele Anton. For new sample collections a DZIF ZIMS (Central Information and Management System) is planned, which contains data sets for individual samples. More detailed information on the different DZG structures can be found on the respective websites.

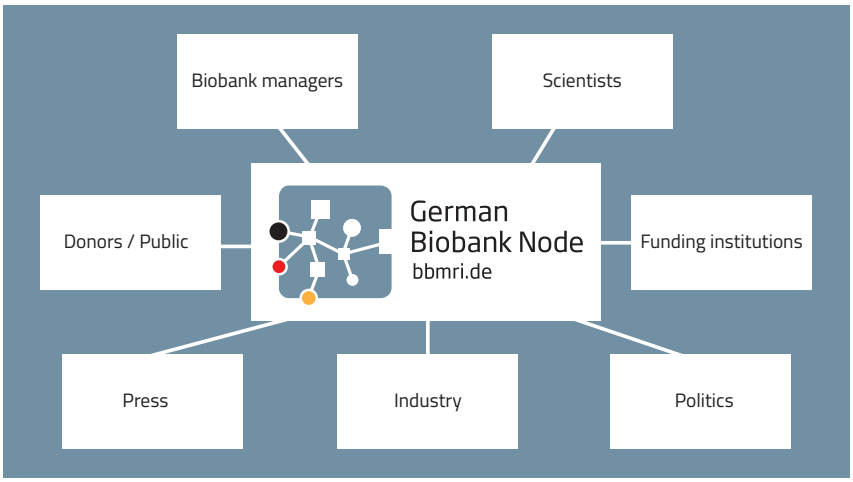
In the final round table discussion most of the biobanks stated their willingness to share samples and data in collaborations at the national and European level. However, two aspects have been pointed out repeatedly to be essential: data sovereignty must be guaranteed as well as the availability of the necessary technical and manpower resources. Also, it is important for the biobanks to build up network structures from the bottom up, meaning first locally at the site, then across Germany, and finally through a link to the EU network. However rules, which are derived from network activities needs to be considered in order to ensure compatibility lateron. More and more, centralized and quality-assured biobanks will become service providers, not only for molecular testing and certified storage, but also for sample searches in other cooperating biobanks. Biobanking is still in its infancy and a general awareness and trust have to be built up to reduce fears about misuse. The IT concept has to support research in every way. Therefore the concept for a new IT structure needs to take these aspects into account. Partners like the centralized biomaterial banks and DZGs, which are already at an ad-

vanced stage with their networking activities, must test new concepts for the exchange of data in a pilot phase before it is released to a broader biobank community in Germany. A complete overview of the workshop results and follow-up analysis will be presented at the Biobank Symposium in December 2015 in Berlin.

Focus on work package 4: public engagement

The term "biobanking" is mostly unknown in the general public and even employees of medical hospitals have difficulties in describing what a biobank might be. The most frequent association in this context is "blood" or "sperm donation". Therefore, the aim of work package 4 of the German Biobank Node GBN is to develop concepts for an effective public engagament to convey a positive and transparent image of biobanking in Germany, including its social and ethical aspects. This is a key requirement in order to achieve broad acceptance of biobanks in the public consciousness, and thus to establish biobanks as relevant infrastructures for biomedical research in Germany and Europe.

In 2014, the team responsible for public engagement activities (Roland Jahns, Wiebke Lesch and Antje Schütt) started a careful analysis of different stakeholder groups. For the stakeholder group "patients"/ biobank participants about 200 donors in Würzburg, Heidelberg, and Hannover were interviewed about their attitudes toward an understanding of biobanks using a standardized questionnaire. The evaluation of the patient survey shows that the willingness to donate biomaterials is high and the attitude towards donation is mostly positive. Participants want to support research and hope that disease detection and treatment options could be improved by analyzing their donated materials. However, when asked for their definition of the term "biobank", only about half of them gave a correct answer, even though they were previously informed about the scope of biomedical research and the use of their donated biomaterials. In addition, there seem to be some differences between patients and healthy biobank donors. A more detailed analysis will be presented at the National Biobank Symposium in Berlin on 10. December 2015.



Stakeholders of GBN

The research shows that patient information and involvement should be improved and that there is a need for continued education even after the donation. Therefore, one of the next steps is to implement a concept for a website on biobanking that features easily accessible information for patients and the public. The website can be used by all German biobanks to attract and educate these target groups. In addition, templates for print materials like flyers, brochures, and posters will be developed which can be adapted locally by biobanks to their specific requirements. The production of a generic short trailer on biobanking is another pilot project, but the discussion during the working group meeting revealed that this tool will require careful translation of the information in order to reach the different target groups.
One particular stakeholder group being analyzed in this project are biobank managers and scientists who use donated biomaterials for biomedical research. From qualitative interviews with a representative number of biobank managers and scientists it became apparent that biobanks need professional communication in order to create confidence among all involved parties. With the increased centralization of biobank structures, it appears even more important to provide information on governance structures, procedures, and ethical issues so that clinicians are motivated to get involved in biobanking. In this respect communication tasks were defined that will be realized with the support of GBN.

From the interviews with scientists who were asked about their attitudes, desires, and motivation it also became apparent that there is a strong need to manage their expectations towards biobanking, e.g. which services the biobank infrastructure can (or cannot) provide. Centralized biobanks are still quite unknown among scientists in terms of collection and access processes,

Open Biobank Day in Würzburg

governance, and the possible scientific and/or individual benefits. Activities like training and information events could reduce such hurdles.

The GBN website is being constructed in order to reach these stakeholder groups. Currently, the content and the visual appearance of the website are being revised. In addition, a quarterly newsletter with short reports on German and European activities has been launched to provide regular information to the biobanking community – here, we present the first edition. The detailed results of the surveys and interviews will be presented at the National Biobank Symposium in December.

Quality management

Although the quality of analyzed data is strongly dependent on the quality of biomaterials, sample quality is often not emphasized in scientific publications (1). To improve this situation quality management has been a key topic of biobanking activities in Germany for more than 10 years. Therefore it is addressed in both the working group "Biomaterial banks" of TMF e.V. (AG BMB; established 2003) and in the working group "Tumor biobanks" of the *Comprehensive Cancer Centers* (CCC; established 2006). Joint SOPs and project management rules have been developed by the latter and implemented by several CCC tissue biobanks. Tissue biobank accreditation was taken up by the *National Accreditation Authority* (DAkkS) in 2007 and, as the first fully accredited tissue biobank in 2009, the tissue bank of the NCT Heidelberg has served as a blueprint for biobank accreditation since then. But as the existing norms for accreditation and certification do not have biobanking as their main focus, the TMF working group "Biomaterial banks" has published a book called *Biobanking – Checklist for Quality Assurance* (Berlin 2008, TMF book series, vol. 5) to support high-quality and legally secure construction and development of biobanks.

The *International Organization for Standardization* (ISO) is currently working on a set of standards for biotechnology. The focus of ISO/TC 276 is to identify and address standardization needs and gaps related to biotechnology. One of the five working groups, on biobanks and bioresources, is headed by Georges Dagher (INSERM, Paris, France). The German national mirror group on biobanking is led by Christina Schröder (IBMT, Potsdam) and is part of the DIN (*Deutsches Institut für Normung*, German Institute for Standardization) standardization project. Since 2014 a gap analysis has been performed and the finalized agreed standards are expected for 2017. In addition, publicly funded institutions or networks in Germany like the cBMBs (*centralized biomaterial banks*), the DZGs (*German Health Research Centers*) and the NaKo (*German National Cohort*) have started their own QM activities.

Now the German Biobank Node aims to bring all these activities together in order to create a set of recommendations that is accepted throughout Germany. This effort will be oriented towards the international ISO and the national DIN standardization process in close communication with the BBMRI community.

This work package in GBN is aiming at developing an in-depth concept for quality management for liquid and tissue biobanking. Since the main steps for quality control are comparable for both types of biospecimen, the tasks are nearly identical. However, different expertise is required to achieve these tasks and therefore this work package has two parts – liquid and tissue – but the overall concept and general procedures will be consolidated.

The project was initiated at a workshop in July this year. About 30 participants from 11 biobanks, the NaKo and the DZGs met in Heidelberg to discuss how the different concepts in QM could be harmonized.

In a first step, the existing processes were organized using the example of a process landscape. The second step was to define a matrix of the core processes which are relevant in biobanking. This matrix was developed during the workshop and is available online in the GBN intranet. The biobanks will now add their existing SOPs for the different core processes in a structured way. Based on the collected SOPs a revision and comparison of existing SOPs will be performed at the next workshop where the differences (local variations versus differences in principle) will be classified. This harmonization process will finally lead to a generic QM documentation (Fig. 1) which describes all aspects of liquid and tissue biobanking. The agreed SOPs can afterwards be used as a blueprint with local adaptations for all German biobanks.

It is envisaged that GBN will actively bring the consolidated results into the DIN/ISO process since there is a strong overlap of tasks and persons involved from the German side. GBN therefore generated an additional position in order to coordinate all necessary steps within the DIN and GBN working groups. This way the process will be supported effectively and move towards a national standardization in a reasonable time. The results will be presented at the National Biobank Symposium and will hopefully find a broad consent within the biobank community. Especially for smaller biobanks or newly starting biobanks, GBN wishes to support them and enable them to achieve good quality standards without having to reinvent everything from scratch.

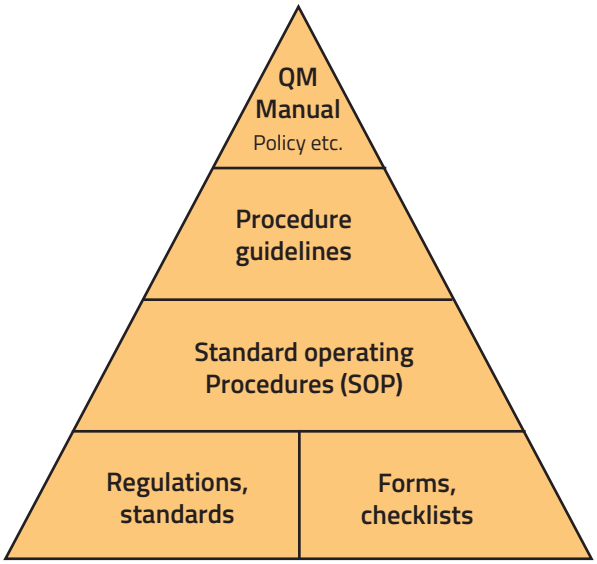


Figure 1: Example of the structure of a QM documentation; the QM manual describes the whole QM system and the organization itself; all other processes are displayed in procedure guidelines and standard operating procedures (SOPs).

A major issue within QM is the quality of the sample material. This was discussed at the workshop as well. The quality of liquid samples is still difficult to determine, as there are no commonly accepted criteria. For blood samples the HIL index (Hemolysis, Icterus, and Lipemia) may be used, for RNA the RIN measurement (RNA Integrity Number), and for DNA the DIN (DNA Integrity Number), although the latter is currently still limited to a few devices. Standardized proficiency testing for DIN and RIN is under discussion so that differences between individual devices can be detected. For quality assessment of DNA the suggestion is to define "fit for purpose" areas, from very high quality (appropriate for Southern blotting or whole genome sequencing) to very low quality (appropriate for single short PCR reads). The quality could be monitored by instruments or manually via an agarose gel application. The way forward has yet to be resolved and requires further discussion in the next workshop.

Another topic is key performance indicators for biobanks. These are becoming more and more important for raising funds to demonstrate professionalism, especially in QM. The discussion has just started and has to be continued. So for the next workshop as well as the Biobanking Symposium in December there are plenty of QM issues to discuss within the community.

(1) Simeon-Dubach D and Perren A. Better provenance for biobank samples. Nature 2011; 475: 454-455.

Inauguration meeting of GBN Scientific Advisory Board

On 16 September the Scientific Advisory Board (SAB) of GBN met for the first time. This event took place in the historical lecture hall ruine at the Berlin Museum of Medical History at the Charité. The members of the SAB are representatives of different fields of interest in biobanking such as IT, quality, ethics, patient interests, population-based aspects and clinical aspects. The leaders of the GBN work packages, H.-U. Prokosch, P. Schirmacher, M. Kiehntopf and R. Jahns, presented the ongoing activities and first results as described elsewhere in this newsletter. After intense discussions of the various topics, the SAB gave the following feedback:
The SAB saw that the beginning of the project has not been easy and acknowledged that a lot has been achieved since the start of GBN despite the relatively low budget available for projects. The SAB recommended

pursuing the work on all fronts since all these topics are very important. The SAB especially recommended increasing the visibility of ongoing activities to patients and end-users of biomaterial samples. Therefore GBN was encouraged to pursue the PR work and create a tool box to support local PR activities of biobanks in Germany. With respect to the activities in quality management, the SAB urged GBN to get active in the ISO process and send a delegate to the ISO committee since the timelines for the next steps are tight. Further, the SAB congratulated GBN for taking the lead in the common service IT of BBMRI-ERIC and therefore being the central point of contact for the IT activities in Europe and playing an important role in the networking process. In addition, the recommendation to GBN was to develop a matrix for performance indicators to have a basis for measuring the progress and success of its activities. Finally, the SAB recommended that the Ministry of Research should pursue the funding of GBN and increase the funding volume so that GBN can establish itself as a central point of contact for all biobanking activities in Germany. GBN would like to thank the SAB for fruitful discussions, the very positive and encouraging feedback and valuable recommendations which will be incorporated into our future work.

The members of the Scientific Advisory Board (from left to right): Johann Eder, Kurt Zatloukal, Kristian Hveem, Fay Betsou, Jochen Taupitz, Anja Klinner.

BBMRI-ERIC

A catalogue of biobanks in Europe: the BBMRI-ERIC directory

The BBMRI-ERIC directory is the first IT tool to be made publicly available in 2015. It provides aggregate information on European biobanks that are willing to participate in external activities. The central goals are (i) to increase the visibility of the biobanks, (ii) to provide contact information for sharing experience on biobank activities, and (iii) to enable researchers to find relevant samples and/or data as well as infrastructures to store samples. The first version of the directory (1.0) was released in July 2015. The 58 data fields are based on MIABIS 2.0 (using the biobank and the contact information entities). In its initial form, the directory has a biobank-centric perspective, i.e. no collections are included. However, the directory asks for material types that are stored, e.g., DNA, plasma, tissue, or urine.

The data for the biobank catalogue stem in most cases from national registries (according to the hub & spoke principle) and are stored in an LDAP directory, to which two web interfaces exist. The interface given by the link http://bbmri-eric.eu/bbmri-eric-directory-1.0 is integrated directly into the website of BBMRI-ERIC, using the LifeRay portal. The second interface (http://directory-molgenis.bbmri-eric.eu/) is provided together with the BBMRI.nl National Node catalogue, using the MOLGENIS framework. It allows the import of data in JSON (JavaScript Object Notation). The current map of the biobanks in the BBMRI-ERIC directory shows that the German area, with ten red points, is rather sparse (see Figure 1). BBMRI.de (via the German biobank registry, hosted by TMF) delivered data on ten biobanks who filled in more than the contact information. In addition to expanding the directory, BBMRI.de will try to motivate more biobanks to provide detailed information.

Version 2.0 of the BBMRI-ERIC directory is expected to be released in November 2015. The main innovation is the inclusion of the collection level, which allows description of the samples in the biobanks by smaller natural chunks, and this enables improved search possibilities for finding relevant samples (already possible in the German biobank registry). Besides that, it will also be possible to describe the networks to which the collections or biobanks belong or to specify the type of collection, e.g., cohort, longitudinal, population-based, as well as access rules to the data and samples. These innovations necessitate an extension of the number

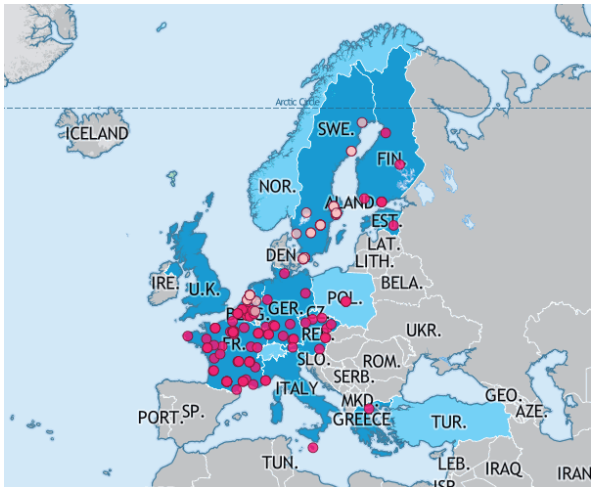


Figure 1: Map of European biobanks listed in the BBMRI-directory 1.0

of data fields. However, the data management process also resulted in simplifications of the 1.0 data model, e.g., using materialStoredBlood as a field instead of the four data fields biobankMaterialStoredWholeBlood, biobankMaterialStoredPBC, biobankMaterialStored-Plasma, and biobankMaterialStoredSerumin. So far, the extensions have led to 111 data fields in the new directory.

The BBMRI-ERIC directory can be regarded as a milestone for the central goal of the common service IT in BBMRI: providing a sample locator that allows finding out how many samples with specific characteristics one can expect to gather. It will be important to assess the utility of the 2.0 version with quantitative metrics and to receive feedback from users as well as biobanks in order to have some indications of how relevant such a sample locator is in practice.

Murat Sariyar

Common Service IT of BBMRI-ERIC

1. Technical overview

The pan-European Biobanking and BioMolecular resources Research Infrastructure (BBMRI) is a distributed biomedical and life science infrastructure for sustainable storage and dissemination of biobank samples and associated data in Europe. BBMRI-ERIC will provide access to the collections of partner biobanks and biomolecular resources, their expertise and services on a non-commercial basis.

The BBMRI-ERIC COMMON SERVICE IT (CS-IT) has the mission to deliver expertise, services, and tools relevant to the pursuance of tasks and activities of BBMRI-ERIC. It will be complemented by the H2020 INFRADEV-3 project ADOPT, designed to accelerate development and deployment of tools needed for BBMRI-ERIC. The project proposal has eight work packages (WP), depicted in Figure 1 – Overview of services, and it was accepted by the European Commission on 16 April 2015. Leading responsibility and resource assignment for ADOPT.WP3 lies with Michael Hummel (head of BBMR.de). Work, project governance, documentation and reporting of ADOPT and CS-IT will be done in a unified manner. Each work package (WP) has a leading team member. However, all team members help out in each WP within the resources limitation, even if it is not specifically listed. Some tasks are going to be executed within the ADOPT project.

2. Project management

Towards enforcing data harmonization and facilitating collaboration, a project management team will be responsible for planning and coordinating tasks, timetable management and revision, as well as reporting to BBMRI-ERIC and the various committees. The current status of the project will be made available to the scientific community and the public. Semi-annual CS-IT meetings and visits will be organized as well as workshops. Presentations and exchanges at congresses are also to be supported, in addition to exploration and collaboration with other research infrastructure initiatives.

3. Directory Service

The Directory Service (WP1) will enable the discovery of public summarized information on biobanks and their collections by networking registries of national nodes and networks. It aims to provide a single access point to the European biobank network and to lay the basis for national and trans-national research consortia based on samples and data from various sites. Only summary level/anonymous information will be shared via the Directory to ensure protection of biobank donor privacy and comply with Ethical, Legal and Social Implications (ELSI). This service enables interested parties, such as researchers, biobankers, funding agencies and policy makers, to easily find, browse and aggregate biobank and content information both in overview and in detail. In particular, the Directory will enable researchers to easily identify biobanks that potentially have samples/data of interest.

The BBMRI-ERIC Directory is a networked service with a data structure in which each node can share information to be aggregated centrally. Information sharing will be based on an open source data sharing protocol,

which will be made simple so that new information sources (i.e. national nodes and networks) can easily integrate it into their software. In the pilot, a lightweight protocol has been developed to share summary level information between the existing catalogues of the national nodes and networks and the BBMRI-ERIC central Directory. This system is based on LDAP or REST, which can be easily implemented by local IT departments. In addition, a toolkit will be provided to help nodes and consortia add their data to the Directory Service.

4. Sample Locator

This component aims at providing availability information of samples and sample-related data from the biobanks to the researchers (consumers) through a federated querying mechanism. The Sample Locator will be integrated with ontology mapping tools, developed in WP8, in order to support the heterogeneity of the European data structures. This approach extends the BBMRI-ERIC Directory (WP1), which is a catalogue-like solution with only summary level data, by enabling the processing of requests on a sample-based level and giving the biobanks full control over individual data requests.

The decentralized search concept supports specifying search queries based on items defined in the metadata repository (WP8) and the asynchronous interaction with the participating biobanks. An exposé, describing the research question and supplying the contact information of the inquiring partners, completes the request, which is made available to all participating biobanks. The request interface of the local biobanks, the connector, retrieves the query and the results locally. These results are presented to the person in charge of the biobank, together with the exposé and the inquirer's contact information. Finally, the data owner decides what to reply. The response process can be automated for trusted requesters if the local data/biobank owner so desires. However, no data are shared without the explicit consent of the data owner. The connector will offer a built-in component to pseudonymize data and also match data (regarding the same patient/proband) locally from different databases.

A Sample Locator Genomic Query service will be developed to allow biobanks to harness the molecular information they have available to help researchers in sample selection. The service will be based on genomic information associated with the managed biosamples and support simple query semantics (i.e., at the level of allele presence at a given genomic position).

5. Proof of concept

As a proof of practicability of the complete framework, an automated or semi-automated collection of 7,000 cases is planned. The financial resources of this work package will be reserved for use at a later stage of the project, as it is not possible to determine, at this stage, all the biobanks that are already able to deliver the requested information electronically. Biobanks which express their needs shall provide a brief description of the required tasks and the related funding. The steering committee of the CS-IT will discuss these requests with the IT core group and prepare a decision for the Management Committee.

6. Services for the national nodes

In order to ensure the conception and availability of relevant and practical services for the national nodes, BBMRI-ERIC CS-IT will offer hosting services, e.g. for the Sample Locator (WP2) and Directory Service (WP1). These services will provide hosting of the Directory and Sample Locator for national nodes who cannot host the

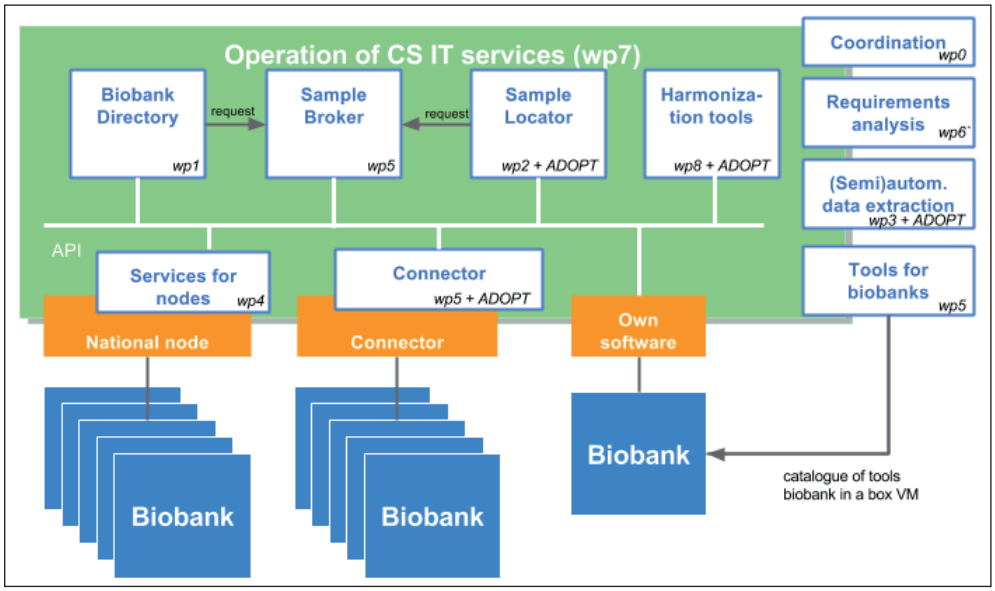


Figure 1: Overview of services

service nationally and/or don't yet have a national Directory. This includes aiding data loading and customization of the styling (e.g. national node logo and front page text).

7. Sharing, harmonizing and integrating

Existing biobank software tools will be reviewed and evaluated each year and the results will be catalogued. Relevant tools will be selected and made available in a virtual machine. Featured with randomly generated example data, interested biobanks can use this virtual machine to rapidly evaluate software solutions. For example, BBMRI.se has deployed an open source LIMS ("open specimen"1) and BBMRI.it is studying potential mechanisms to integrate commercial LIMS systems within the toolbox. Other examples are the pseudonymization systems such as the German "Mainzelliste"2, a tool to aid linking together data records from different sources, and "OME Omero", an open source platform for the management and analysis of bioimages, including digital pathology slides; and the BioSHaRE/P3G/Maelstrom systems for federated data analysis, DataSHIELD/Opal.

A starting version of the catalogue of software tools can be found at http://www.biobankapps.com, which is being developed in BBMRI.fr with potential collaboration of other ESFRIs such as ELIXIR (https://elixir-registry.cbs.dtu.dk/). The software registry will cover both commercial and open source systems with a half-year update and provide faceted browsing (application area, functionality, cost, etc.), evaluation reports and usage scenarios. Finally, central user/group authentication and authorization will be implemented so that permissions can be managed centrally and users can log in to all applications using a single sign-on (SSO) system.

8. User-centred development and testing

The biobanking community features a diverse, dynamic and expanding group of stakeholders. To help the CS-IT services understand the users' needs, a feedback collection system will be selected and deployed. Based on the analysis of the users of the BBMRI-ERIC CS-IT platform, the use cases will be identified and prioritized, taking also into consideration the capability of biobanks across Europe. The use cases will be re-evaluated during the five-year plan to ensure that the needs of all stakeholders are continuously considered.

User and key performance evaluation of CS-IT services will be carried out. Automatic usage statistics will be combined with conventional questionnaires to evaluate the effectiveness of services. The output of these evaluations will feed back into the latter phases of the use cases service as well as into the documentation and user guides. Additionally, a guide will be provided to new users of the CS-IT. Frequently asked questions and doubts about the project will be highlighted.

9. Operations and collaboration tools

In order to provide a sustainable operation of the BBMRI-ERIC Services and provide IT tools to facilitate communication, WP7 – Operations and collaboration tools has been defined. This work package involves management of the hardware and software to run collaboration tools, including installation, updates, support and maintenance. The operations of the catalogue/sample access/request help desk developed in the BBMRI-LPC (Large Prospective Cohorts) project are included in WP8, as well as the maintenance of the BBMRI-related tools developed in the BioMedBridges, namely ontology vocabularies and their mappings, secure access, and the Biosample database. Also comprised are user support, training and dissemination of the services and designing a business model that can facilitate the long-term sustainability of the services via, for example, service fees.

10. IT Harmonization

The process of delivering data to the centralized Directory and the Sample Locator to form data availability statistics demands the processing of requests over data derived from different biobanks, where a common language or ontology will be essential. For this purpose, relevant terms and ontologies with respect to the attributes and value lists present in the data of a participating biobank will have to be agreed upon. Local data elements will be mapped, including artifacts such as biobank metadata characterization, quality indicators for biosamples, and terminologies/ontologies for diseases. The scope and depth of the ontology used needs to be defined in terms of minimum and optional data sets.

SPREC, Biobank lexicons and MIABIS 2.0 are good starting points, as well as ontology mapping experiences from other European projects with a similar challenge. After initial analysis, further focus could be set in providing translation specifications for clinical information, available via HL7, DICOM, and other standards under the IHE umbrella and in utilizing standards common in medicine such as ICD-10 and SNOMED. At the same time, advanced clinical formats based on the ISO standard (ISO 13606-2), e.g. openEHR, will be considered, given their ability to describe and query structured and precise clinical information in an implementation-independent way.

The Common Services IT of BBMRI-ERIC will be a huge challenge for all developing partners in the next five years. The international team has already succeeded in overcoming the first difficulties and has shown an enormous motivation to move forward – even before funding.

Diogo Alexandre

[1] http://www.openspecimen.org/

[2] https://www.unimedizin-mainz.de/imbei/informatik/ag-verbundforschung/mainzelliste.html

BBMRI-ERIC Common Service ELSI met in Paris

The Common Service ELSI aims to facilitate the cross-border exchange of human biological resources and data for research uses, share knowledge and experience as well as to develop best practices and a secure legal and ethical framework for such exchange. The team consists of experts from all BBMRI-ERIC Member States in the areas of law, ethics and the social sciences. Several team members had already met in the context of smaller working groups or task forces such as the *Writing Group for the Statement regarding the General Data Protection Regulation Draft*. Many Common Service ELSI team members had contributed to the preparation of the 'Day of Action' or engaged in talking to, in total, more than 30 Members of the European Parliament on 16 June 2015. On 8-9 September 2015, the entire BBMRI-ERIC Common Service ELSI team came together for the first time as a group in Paris. The meeting started with an internal part, which was followed by a workshop with external experts and international guests on "Sharing and Access to Data and Human Biospecimens for the Benefit of Patients – Towards a BBMRI-ERIC Policy".

The BBMRI-ERIC CS ELSI team meeting took place in the morning of 8 September 2015. The goal of the meeting was to discuss the past, present and future activities of the CS ELSI and to decide on the Work Plan and its priorities for the end of 2015 and for 2016. In addition, research projects in which BBMRI-ERIC is participating were presented and the CS ELSI team involvement was discussed.

Finally, some core tasks and the leading persons were identified: Gauthier Chassang is in charge of developing the database of ELSI experts. Irene Schlünder will coordinate the integration of existing ELSI tools (such as hSERN, Legal Wiki, and LAT) into a one-stop platform maintained by the BBMRI-ERIC headquarters in Graz. Building on the integration of tools, Mats Hansson will be responsible for putting in place the 'Help Desk'. Anne Cambon-Thomsen will finalize the 'Ethics Check'. Jasper Bovenberg will set up a dialogue and workshop with Research Ethics Committees from all over Europe and develop ideas for Education and Training Programs. Marialuisa Lavitrano will lead the establishment of procedures to enhance public debate and engagement with society.

Finally, the meeting was a nice opportunity to meet all the colleagues personally and learn about the ethical, legal and societal (ELSI) expertise which they bring to the table for the common goal.

The Workshop 'Sharing and Access to Data and Human Biospecimens for the Benefit of Patients – Towards a BBMRI-ERIC Policy' started in the afternoon of 8 September 2015. It was intended to facilitate the sharing of experience on the ethical, legal and social aspects of samples and data sharing in research and biobanking throughout Europe. In addition to the ELSI team, representatives from the National Nodes and several well-known experts enriched the discussion with their experience and insight.

The CS ELSI met in Paris

The participants identified and discussed the key elements for setting up a BBMRI-ERIC policy for access to samples and data. They agreed to develop a general framework to be complemented by contract templates. As a first step, summaries on the main aspects will be prepared to facilitate further work on this framework: Jane Reichel will provide an overview of the legal framework for establishing a sharing policy for BBMRI. Roland Jahns will summarize the debate of the Permanent Working Party of the German Medical Ethics Committees on donors' consent, which has led to a template for informed consent concerning the donation, storage, and utilization of biological materials as well as collecting, processing, and usage of (related) data in biobanks' (http://www.ak-med-ethik-komm.de/index.php/de/antragstellung/biobanken). Isabelle Huys will give an overview of intellectual property rights issues. Anne Cambon-Thomsen will make her ongoing work on intellectual investments and BRIF available to BBMRI, and Gilian Martin will show ways to facilitate trust in BBMRI from patients' and other stakeholders' organizations. The framework could start with the development of a more high-level charter, which then has to be translated into concrete operational documents, such as a Code of Conduct and Standard Operational Rules.

The workshop has made the enthusiasm of all involved experts visible. It was a kick-off for great undertakings in the field of biobanking in a secure legal and ethical framework. Much work lies ahead and huge efforts are required to achieve these ambitious goals: the Common Service ELSI is ready to address them!

Irene Schlünder

German Centers for Health Research (DZG)

DZL Biobanking Platform

Biomaterials are a key component in translational lung research. They are the basis for the development of new pathomechanistic concepts, innovative therapies and individualized treatment options ("individualized medicine", "targeted therapy"), the identification of prognostically relevant biomarkers, and the verification of basic science findings.

The overall aim of the DZL (German Center for Lung Reserch) Biobanking Platform is the collection and storage of biospecimens and associated medical data on different pulmonary diseases, considering all necessary legal standards. Easy access to biomaterial and associated clinical data will be provided for researchers within the DZL and from outside. The Biobanking Platform involves all DZL sites and a strong focus is on harmonization of quality control and data management procedures.

The following steps have been taken in order to achieve these goals:

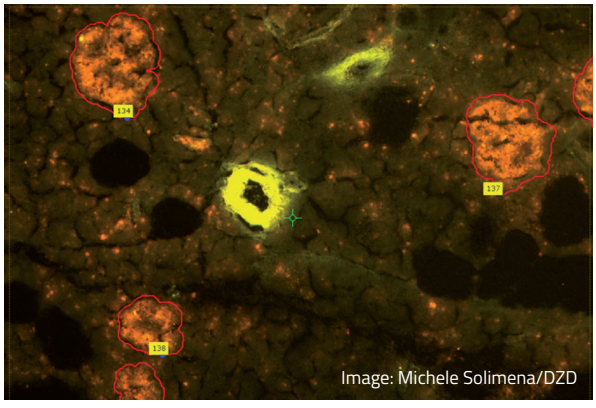
- Implementation of a database of existing (retrospective) biomaterials, covering type and storage location, contact address, consent level, existing ethics vote, and phenotyping data linked to the biobanking portal.
- Development of the following documents and procedures for the prospective biomaterial collection:

  - DZL Biobanking Platform by-laws and Material Request Form
  - DZL-wide, harmonized broad consent form, essentially based on the most recent version of a broad consent form developed by the Arbeitsgruppe Biobanken im Arbeitskreis medizinischer Ethikkommissionen (AK-EK)
  - DZL data protection concept, based on the most recent standards, as adopted by the TMF
  - Harmonized SOPs for development of these documents and for single procedures related to biobanking
  - Software solutions for DZL centralized Pat- and Lab-ID generation
  - Implementation of DZL data management structure including the DZL data warehouse based on i2b2.

Clemens Ruppert

Human Pancreatic Islets Biobank established in the DZD

Since 2014 the German Center for Diabetes Research (DZD) has been building up a unique biobank with human pancreatic islets from special surgical specimens under the direction of Prof. Michele Solimena, director of the Paul Langerhans Institute Dresden of the Helmholtz Zentrum München at the Carl Gustav Carus University Medical Center Dresden (PLID).



Automated Recognition of Human Pancreatic Islets for Laser Capture Microdissection

The bio samples are derived from metabolically phenotyped diabetic and non-diabetic patients undergoing partial pancreatectomy. Currently three hospitals associated with DZD partner sites in Dresden, Tübingen and Düsseldorf are collecting islet samples. Protocols for laser capture microdissection (LCM) developed by the DZD ensure high-quality preparations of RNA samples suitable for the analysis of genetic and epigenetic traits. Frozen, paraffin- and epon-embedded pancreatic tissue sections are available for morphological and functional testing of the islets. Sera, plasma and red blood cells from the same subjects are collected in parallel, allowing the determination of common clinical parameters.

The DZD Human Islet Biobank is a unique source of specific human biomaterial for diabetes research. The project was initiated together with IMIDIA (Innovative Medicines Initiative for Diabetes).

Brigitte Fröhlich

German Biobank Node
bbmri.de

News & Events

New calls of BMBF expected

The new calls of the Federal Ministry of Education and Research to fund activities in biobanking and medicine informatics are expected in November – we keep you posted!

BBMRI-LPC Scientific Call for Access

BBMRI-LPC supports innovative research projects in large prospective cohorts (LPC) across Europe. More information on http://bbmri-lpc.iarc.fr/mica/

Topping-out ceremony for Berlin's new biobank

Celebrating the topping-out ceremony for Berlin's new biobank

The Berlin Institute of Health (BIH) and the Charité – Universitätsmedizin Berlin celebrated the topping-out ceremony for their new state-of-the-art biobank building. BIH and Charité are investing 3.9 million euros in this joint biobank effort, which will be completed by April 2016. More than two million samples from patients of the Charité as well as from clinical trials or BIH research projects can be stored under quality-controlled conditions at various temperatures (+4° to -196°C). "A special feature of the new biobank are the various storage options," explains Michael Hummel, head of the BIH/Charité-biobank. In a new automated storage system (-80°C) about a million samples can be stored and another million samples in liquid nitrogen. In addition the biobank has offices and laboratories for processing and analysis of the samples: "We see ourselves as a service provider for research," says Michael Hummel, "and work closely together with the BIH-omics and bioinformatics technology platforms." GBN congratulates them on this milestone, which will strengthen the translational research in Berlin by providing an excellent research infrastructure.

'Safe Harbour' no longer valid

On 6 October 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 was invalid. As a result of this decision, EU biobanks, registries and researchers who transfer personal data (which under circumstances could include coded or pseudonymized data) of EU citizens to the United States can no longer validly do so on the basis of the SHP. All biobanks should check whether they operate under the SHP. If they do, they 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. For further information please read the information on www.bbmri-eric.eu.

ESBB & BBMRI-ERIC joined forces

On 30 September 2015, BBMRI-ERIC and ESBB formed a strategic alliance for the benefit of European biobanking efforts. Starting in 2016, the two organizations will jointly organize 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 emphasizes that biobanks are a European strength. The 2016 conference will take place in Vienna; the dates and location will be communicated soon.

Forthcoming events

4th National Biobank Symposium
9 and 10 December 2015, Berlin,
Best Western Hotel Steglitz International
www.biobanken.de/symposium

ISBER Annual Meeting & Exhibits
5 - 8 April 2016, Berlin, Maritim Hotel
www.isber.org

Imprint

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