MAKING NEW TREAT MENTS POSSIBLE

BBMRI.at
Biobanking and BioMolecular resources Research Infrastructure Austria

BBMRI.AT #2

PROJECT PROPOSAL

SUMMARY

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SUMMARY

In the first funding period of BBMRI.at (BBMRI.at #1, 2013-2018) the national node was established and a highly collaborative biobanking community was developed by engaging with all Medical Universities in Austria.

Key achievements were that BBMRI.at had a leading role in Austria and BBMRI-ERIC in developing and implementing European and international standards related to biobanking (i.e., CEN Technical Specifications on sample pre-analytics that will become ISO Standards this year). These standards served as a common reference for harmonizing biobanks in Austria and for improving sample quality. Further achievements were the development of broadly agreed common Material Transfer Agreements, the building of a toolbox of open source biobanking-related software tools, the cataloguing of samples available at Austrian biobanks, establishing a stakeholder engagement platform with the Austrian biotech and pharma industry, and the evaluation of citizens' perceptions on biobanking to optimize procedures and governance models.

In the second funding period (BBMRI.at #2, 2018-2023) the operation of Austrian biobanks should be further improved and their sustainability ensured. For this goal, major emphasis will be placed on user needs by engagement with different user communities from academia and industry and by continuous monitoring of emerging needs. Related to this, BBMRI.at will promote the role of quality of biosamples to improve research data reproducibility as prerequisite for reuse and integration of data generated by analysis of biosamples. Therefore, major emphasis will be placed on implementation of biobanking-related CEN and ISO standards, which will become particularly important to fulfil requirements of the new European In-Vitro Diagnostics Regulation.
In addition to sample quality, data quality will also be a key topic and solutions will be developed to link biosamples with associated medical as well as meta data on quality. Furthermore, existing data management solutions have to be updated to comply with the European General Data Protection Regulation and its national implementation. These activities should ensure that Austrian biobanks are well prepared to address current and upcoming user needs.
To improve access to biosamples and data a dedicated work package will be responsible for optimizing and harmonizing access procedures across Austria and in compliance with the BBMRI-ERIC access policy. To increase the visibility of Austrian biobanks and their use so called "lighthouse collections" will be established. These collections should be leading biobanks in the international biobanking landscape and of exceptional value to certain users.
The dynamics of societal expectations in the context of rapidly developing science and new legal frameworks will be assessed to provide key input into governance models and the development of a sustainable biobanking strategy. This work on societal issues will also feed into the BBMRI-ERIC Common Service ELSI.
Finally, BBMRI.at #2 will finance the operation of the Austrian National Node and the required activities and should enable the efficient integration and participation in BBMRI-ERIC of the Austrian biobanking community.

PREVIOUS WORK OF BBMRI.AT #1 (2013-2018)

Within its first four years (2013-2017), BBMRI.at achieved the establishment of a successfully collaborating biobanking community by engaging with all Medical Universities in Austria and the creation of a National Node, which actively cooperates with the BBMRI-ERIC headquarters; its National Nodes and other (inter)national programmes and initiatives. BBMRI.at was pioneering several key developments in the biobanking field at the national and European levels, such as developing and supporting the implementation of international (CEN and ISO) standards for sample pre-analytics, which are key to improve data reproducibility and reliability. This has major impact on making research data FAIR for open data and open science, to reduce attrition in developments in pharma and biotech industry, and to improve medical diagnostics. BBMRI.at is centrally involved in developing new models of engaging with industry with special emphasis on public-private-partnerships (i.e., BBMRI-ERIC approved Expert Centers). This model has attracted major attention by the European Commission in the context of open science and open data, and is developed further in a variety of EU-projects (e.g., BBMRI-LPC, ADOPT BBMRI-ERIC, CORBEL). Furthermore, BBMRI.at provided key assets for the establishment of the Austrian Competence Center for biomarker research CBmed and enabled CBmed to be come the first BBMRI-ERIC approved Expert Center.

Major activities and achievements are summarized below:

Community building:
Starting from a very heterogeneous biobanking community in Austria with many investigator level collections, BBMRI.at succeeded in building a community that engaged in a common process to establish a national biobanking infrastructure as part of BBMRI-ERIC. The continuously increasing number of institutions, biobanks and collections participating in BBMRI.at provides evidence for this development. Furthermore, initiatives outside the classical academic biobanking field (e.g., the human biomonitoring platform of the Austria Environment Agency) also established close and fruitful collaboration with BBMRI.at.

Harmonization and standardization of procedures:
A central activity to enable collaboration and integration of biobanks and collections into a national research infrastructure is to harmonize and standardize procedures. To achieve this goal BBMRI.at used European and international standards (CEN Technical Specification [CEN/TS], which now become ISO Standards) as common reference. The CEN/TS refer to the ISO accreditation Standard 15189 and provide details on sample pre-analytics (including steps from sample collection to transport, processing and storage) to ensure reliable and reproducible analytical results, which has to be a main objective of biobanks. The early commitment towards compliance with international standards had major implications on the activities in all work packages and became a horizontal activity for BBMRI.at, which was led by the Medical University of Vienna (MUV).

In this context, BBMRI.at also exerted a pioneering role for quality management (QM) activities of BBMRI-ERIC and was the first national node that has performed internal cross-audits of their biobanks. This is based on the active engagement in developing European and international standards for sample pre-analytics (CEN/TS and ISO standards) as the Medical University of Graz (MUG) was involved in developing the scientific basis for the CEN/TS (as partner of the FP7 SPIDIA project) and became member of the Austrian Standards Institute and national delegate to CEN and ISO committees being responsible for drafting several standards.

Furthermore, BBMRI.at facilitated the implementation of CEN/TS in biobanks by holding hands–on courses and developing a self-assessment tool (performed by MUG and the Medical University of Innsbruck (MUI)) to assess fulfilment of requirements of CEN/TS.

Data management:

Data management becomes an increasingly important issue in the context of biobanking. In addition to providing information on samples available in biobanks (e.g., biobank catalogue), medical and molecular information associated with samples are more and more recognized as key resources for research. Therefore, BBMRI.at had a series of activities related to data management, which were led by the Alpen Adria University. These activities comprised the establishment of the BBMRI.at directory as interface to the BBMRI-ERIC Directory, exploring opportunities how to access data from electronic health records, complementation of tissue samples by digital images (for this goal BBMRI.at is closely linked to a national digital pathology initiative), and the development of a repository for open source biobank software called BiBBoX. Furthermore, BBMRI.at was closely collaborating with BBMRI-ERIC on the implementation of the General Data Protection Regulation (GDPR) in biobanking. Noteworthy, BBMRI.at was among the first national nodes to provide data to the BBMRI-ERIC directory and was the first national node that has assessed biobanks and their collections for meeting CEN/TS requirements.

Improving access:

Access to samples and data from biobanks is a highly regulated, complex and long-lasting process, which often does not sufficiently support user needs. In order to improve access, BBMRI.at (under leadership of the University of Veterinary Medicine Vienna; VetMed) was centrally involved in developing nationally harmonized Informed Consent (ICs) and Material Transfer Agreements (MTAs).

BBMRI.at further developed the concept of Expert Centres, which are a new type of public-private partnership to improve collaboration with industry and facilitate access to quality-defined samples for industry. In this context BBMRI.at contributed to BBMRI-ERIC in several EU projects (BBMRI-LPC, ADOPT BBMRI-ERIC, CORBEL) and supported the establishment of the first BBMRI-approved Expert Centre, which is CBmed.

Stakeholder and user engagement:

The different stakeholder groups were addressed in different and tailored approaches. BBMRI.at used Citizen-Expert-Panels to directly engage with the public and patients, in particular (under the leadership of the Life Sciences Governance Institute and the University of Vienna). The Citizen-Expert-Panels provided a structured environment, on the one hand, to inform stakeholders about biobanking and BBMRI, and, on the other hand, to obtain valuable insight into interests and concerns of stakeholders, which provided guidance for the development of BBMRI.at.

We explored user needs of industry by using a series of activities including structured interviews, workshops and the establishment of a Translational Science Forum (under leadership of VetMed). In addition, we performed engagement with medical professionals and academic researchers in the context of scientific conferences and collaboration with academic societies (e.g., ESP, OECI).

MAJOR GOALS OF BBMRI.AT #2 (2018-2023)

Building on the work performed during BBMRI.at #1, the focus of BBMRI.at #2 is on improving the operation of BBMRI.at biobanks and promoting their role at the national and European levels. In order to achieve this goal a better understanding of the needs of different user communities and support from key stakeholders are needed. Therefore, the planned activities of BBMRI.at #2 are strongly driven by user and societal needs. For this reason the different user communities (e.g., researchers from academia and industry requiring access to biobanks for basic biomedical research, epidemiological studies, applied research or development of diagnostics and drugs) will be

approached and engaged with by a series of tailored initiatives. This user-centered work will be a horizontal activity of all work packages. It should provide important information on how to optimize operation of BBMRI.at and Austrian biobanks (e.g., what types of samples and data are needed, what are the quality requirements, which information should be provided by websites, directory and catalogues etc.).

In order to raise users' awareness on how Austrian biobanks can support high quality research, so called "lighthouse collections" will be promoted by work package 1. These lighthouse collections should be collections that are of exceptional value to certain users and are a specific strength of Austria as compared to the international biobanking landscape. By this means BBMRI.at will increase the international visibility and use of advanced collections creating an incentive that these collections will be opened to international user communities and at the same time will raise interest in Austrian biobanks in general.

A major driver of developments in biobanking is that the international priorities related to open data and open science raised awareness and needs concerning findability, access, interoperability and reproducibility of research data (FAIR data) generated by analysis of biosamples (Wilkinson et al., 2016). A general trend in biobanking is that the relevance of biosamples not only depends on the type and quality of the biospecimen but also on the associated information. Furthermore, lessons learned from BBMRI.nl show that access to data generated by analysis of biosamples (e.g., whole genome sequences, metabolome or proteome data) targets a larger user community than access to original biosamples. Therefore, the work package on Data Management (WP 2) will in addition to supporting all other work packages have dedicated tasks on defining quality of data, as a prerequisite for FAIR data with special emphasis on requirements of health-related data (Holub et al.,2018). In this context the compliance with the European Data Protection Regulation and its national implementation has to be addressed.

New user needs are generated by the regulation 2017/746 of the European Parliament and Council on in-vitro diagnostic medical devices which raised a major demand on access to human biological samples that meet international standards for verification of performance of in-vitro diagnostics. To address these emerging user needs BBMRI.at is placing much emphasis on implementing CEN (European Committee for Standardization) Technical Specifications on sample pre-analytics and the new biobanking ISO standard (Doucet et al., 2017). Since existing biosamples only in part fulfil the requirements of the new standards, BBMRI.at #2 will support with work package 3 the rapid implementation of these standards to ensure that newly collected samples are suited to address future user needs (see Hofer et al., 2016 describing an IT-tool for standard implementation already developed within BBMRI.at #1). By promoting standardization of pre-analytical processes and by enabling access to quality-defined samples and data, BBMRI.at will make a major contribution to improving reproducibility of research data. This would have also major financial implications since significant investments into research are currently lost because of insufficient research data reproducibility (Freedman et al., 2015).

One major feedback obtained during BBMRI.at #1 and conclusions drawn from participating in the EU-funded project BBMRI-LPC was that access procedures have to become more efficient and time from user request to access provided to samples and data has to be shortened. For this reason BBMRI.at #2 has foreseen a new work package (WP 5) dedicated to improving access and to harmonizing access procedures across Austrian biobanks. In this context major emphasis will be placed on efficient interaction with BBMRI-ERIC (following the BBMRI-ERIC Access Policy) and utilization of tools developed by the BBMRI-ERIC common service IT (BBMRI-ERIC directory and negotiator).

Another major goal of BBMRI.at #2 will be to support the sustainable operation of Austrian biobanks. The most important factor for sustainable operation of biobanks is that resources and services provided by biobanks are readily used. However a challenge in this context is that the operation of high-quality biobanks requires major financial resources and the return of this investment is generated outside of the biobanking environment. There are two not exclusive options to address this situation to obtain sustainable funding for biobanks. First, society recognizes the importance of biobanks as guardian of a common good (i.e., key resources donated by people for the advancement of science and medicine) and supports long-term public funding of biobanks. Second, users who benefit and generate value from resources provided by biobanks pay for access, thereby generating some cost recovery contributing to sustainable operation of biobanks. It is generally accepted that public biobanks even when they generate some income from access fees will always rely on public funding (Clement et al., 2014) . Otherwise they will lose their role as public key resource providers and operate like a company serving the highest revenue generating market. In order to create important input for finding the best model for sustainable operation and

funding of biobanks that meets societal expectations we have dedicated one work package (WP4) to this issue. The focus of BBMRI.at on societal issues related to biobanking matches well the activities of BBMRI-ERIC that in its common service ELSI has strong expertise in ethical and legal issues but lacks contributions on societal issues. Austria will, therefore, also make with the proposed work programme of WP4 a major contribution to BBMRI-ERIC and the biobanking community in general.

In addition to organizing and harmonizing the Austrian biobanking community, BBMRI.at has to operate the national node for Austria's participation in BBMRI-ERIC. The National Node Director (Univ. Prof. Dr. Kurt Zatloukal, MUG) and the Deputy Director (Prof. Dr. Georg Göbel, MUI) have to participate in the BBMRI-ERIC management committee contributing to the development and execution of the annual work programme. Furthermore the national node director will link the Austrian biobanking community with the activities of BBMRI-ERIC to ensure efficient and broad participation of Austria at the European level. In BBMRI.at #2 interaction and collaboration with other national nodes will also become a major activity since many biobanking-related issues are similar in most member states so that enhanced collaboration of national nodes would increase capacities and improve interoperability.

With this proposed work programme BBMRI.at aims at helping Austrian biobanks to take a leading role in the international biobanking field and to be well prepared to address upcoming needs, such as providing efficient access to biosamples and data highly relevant in terms of composition and quality for modern biomedical research. Thereby, BBMRI.at contributes to increase the excellence and competitiveness of Austrian academic and industrial research. Furthermore, BBMRI.at together with BBMRI-ERIC addresses several of the European science policy goals by its strong focus on making research data generated by analysis of biosamples FAIR as a key contribution towards open data and open science. Furthermore, the proposed activities for public engagement contribute to increase the public understanding of biobanks and provides guidance for biobanks to increase their impact on society.