CONNECT BIOBANKS,
INCREASE VISIBILITY,
MAKE NEW TREATMENTS
POSSIBLE.

ANNUAL REPORT
2019
Biobanks (and Biomolecular Resources Centres) means collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and micro-organisms that might contribute to the understanding of the physiology and diseases of humans.

BBMRI-ERIC Statutes, Article 1(1)
PART 1
EXECUTIVE SUMMARY
CONNECT BIOBANKS,
INCREASE VISIBILITY,
MAKE NEW TREATMENTS POSSIBLE.
Dear delegates of the Assembly, dear National Node Directors, dear Sir/Madam,

We are pleased to report another thriving year for BBMRI-ERIC. Together with the National Nodes, representing 20 Member States and one international organization, we delivered on our commitments. It is a fine experience to exceed one’s expectations and be able to share our key achievements of 2019 with you. Most notable of these was the successful completion of the EU-funded project ADOPT BBMRI-ERIC, which allowed us to boost many of our core services in both maturity and outreach.

10,480 DATASETS AVAILABLE IN THE COLORECTAL CANCER COHORT

Bringing together 25 biobanks from 12 of our Member Countries, BBMRI-ERIC was able to create a colorectal cancer cohort (CRC-Cohort) of 10,480 datasets from across Europe to be used for future cancer research. The cohort consists of rich diagnostic and treatment data with the corresponding tumour tissue samples. The CRC-Cohort has been complemented by whole slide image scans of the available FFPE material – currently more than 26 terabytes of the WSI images have been collected.

Access to biobanks is key for the successful development of precision medicine and ultimately, to make new treatments possible. Creating the CRC-Cohort demonstrates the capability and feasibility of European biobanks, especially when pooling resources to enable better research.

The CRC-Cohort was developed as part of the EU-funded project ADOPT BBMRI-ERIC; now that the project is complete, the cohort is a permanent asset of BBMRI. As a long-term joint European endeavour, it enables existing, well-established biobanks to connect with BBMRI-ERIC and to obtain increased recognition and visibility for their research assets, which is further expected to bring along new users and novel data. Additional biobanks are continuing to provide datasets, and we welcome further contributions.

BBMRI-ERIC operates as a facilitator providing access to the centrally stored data, while access to any specific samples or additional data will be granted by the partner biobanks based on their standard access procedures.

Collecting the CRC-Cohort datasets across Europe has been a valuable learning experience for BBMRI-ERIC. The heterogeneity and magnitude of data quality, various administrative and regulatory procedures in a multinational setting, together with certain organisational, contractual and communication challenges occasionally delayed the compilation process – but within our deliverables we have documented how to overcome these issues in order to repeat this process for other diseases in the future.

The CRC-Cohort is expected to enable high-quality research and innovation that will help improve colorectal cancer treatment and facilitate precision medicine. The CRC-Cohort as such is not restricted to any specific research approach; it will enable a large spectrum of different types of research. Furthermore, the procedures and the IT tools developed within the cohort are expected to be reusable in subsequent efforts focusing on different disease entities. The lessons learned in the context of the CRC-Cohort are expected to greatly facilitate similar efforts in the future.
COMMON SERVICE IT

Work of the Common Service IT (CS IT) has been mostly focused on operations of the existing portfolio of IT services and their conservative development. This resulted in extensive operational support of Directory and Negotiator services, improvements in the data quality in the Directory (work performed by the National Nodes, supported by the central CS IT), as well as conservative development aiming at improving users’ experience, and the above-mentioned CRC-Cohort. Highlights include the following:

• Updates of the production version of the Directory

• Design and initial implementation of fundamental new features for the new Directory release including shopping cart concept, functionalities for biobank networks, new security architecture allowing finer grained data access and modification control, and ontology mapping to support searches across different coding schemes.

• Updated Negotiator, including support for multiple sources of requests, including usability improvements in the user interface, support for uploading files by biobanks in both public and private parts of access negotiation.

• Extensive backend development of the Negotiator, including support for the complete BBMRI-ERIC Access Policy pipeline, support for monitoring performance of the biobanks by the representatives of the respective biobank networks (e.g. National Nodes), support for more complex state of the request, allowing for more structured and thus more efficient communication between biobank representatives and the requester, etc.

• Deployed new LifeSciences Hostel (part of BBMRI-ERIC Authentication and Authorization Infrastructure - AAI).

• BBMRI-ERIC AAI has been migrated to a new high-availability operational infrastructure.

• Collection and analysis of user feedback for the main Directory, Negotiator, and AAI services, including tests with focus groups. This has been used to implement user experience improvements and to inform the CS IT in 2020 and onward.

• Finished development of the MIABIS Sample/Donor Component, a metadata model of samples and donors to be used as a basis of Locator and other similar donor-level and sample-level findability systems, and submitted it for publication. Development of a new version of MIABIS Core Component (version 3) has begun.

• Piloting Locator service into pilot in collaboration with German Biobank Alliance and its further development.

• Updates of the BiBBoX platform - an open-source software system to support setup and operations of biobanks - including support for i2b2, support for provenance generation, and support for OMOP data model and mappings.

In 2019, the tender for the new Common Service IT was prepared, approved and published, resulting in one application received by the end of the year, following an evaluation and relaunch in 2020.
ELSI SERVICES & RESEARCH

In 2019, we established a leaner, more service-oriented structure, building our services on research relating to ethical, legal and societal issues. We did this whilst ensuring the sustainability of our basic services for the benefit of both the biobanking and biomedical sciences communities:

- The ELSI Knowledge Base, which is an open-access resource platform, containing practical knowledge and information (e.g., How-to-Guides)
- The ELSI Helpdesk Network, which works in partnership with a network of ethical and legal experts coming from academia and practice from our Member and Observer Countries (approx. 30 requests directly to HQ)
- The Ethics Check, which is a support service for researchers who are applying for H2020 research projects or similar initiatives. We assist with the compulsory Ethics Self-Assessment section during the application phase (e.g., CINECA, EUCAN-Connect, EOSC-Life, EDIREX)
- We organise coordinated responses to relevant public consultations, where applicable.

Additionally, we deem research relating to ethical, legal and societal issues as fundamental to staying up to date with and contributing knowledge to current practices in both the biomedical scientific and regulatory field. Currently, ELSI expertise is requested as a service in several projects (e.g., guidance on GDPR compliance, assessing qualitatively societal implications). This includes HQ as well as experts from the National Nodes’ ELSI network.

Notably, ELSI Services have been requested most often by several project consortia already in the proposal phase, where demand exceeded our capabilities to meet each individual request for collaboration. We mitigated by expanding our webinars and training workshops, where we aim to improve overall understanding and awareness of legal and ethical issues arising in the field and therewith regulatory compliance in practice.

QUALITY MANAGEMENT

BBMRI.QM focused on providing services to stimulate QM improvements and performance evaluation in biobanks.

- QM training and support: In 2019, important steps were taken to provide training on the new international standard “General Requirements for Biobanking, ISO 20387:2018”. This joint BBMRI-ERIC training and education programme was presented as an online course, split into 22 sessions in which the individual chapters of the standard were discussed. Renowned experts gave comprehensive presentations on requirements, definitions and the practical application. 220 registrants from 20 countries followed the training sessions regularly. The recordings remain available for refreshing individual chapters. Also, at the Europe Biobank Week in Lübeck, the topic was prominently featured.
- QM knowledge hub: Designated QM tasks in projects like ConcePTION, SPIDIA4P, EDIREX, IC2PerMed and ClinMARK have been delivered according to plan. In late 2019, the EU-funded project CY-Biobank was kicked off, with a major QM contribution seconded from Malta University (Joanna Vella).
- QM auditing and performance evaluation: More than 60 Self-Assessment Surveys (SAS) have been requested by National Node biobanks. In addition, the admission of biobank certificates led to 32 quality marks (Q-marks) in the Directory. Furthermore, eight BBMRI-ERIC SAS are currently revised by the European Standard (CEN/TS) to international Standard (ISO) and will be available in 2020.
- BBMRI-QM is committed to developing new QM trainings for biobankers and biomedical researchers; hence, together with the National Nodes, the COST action proposal “Good Standardization Practice for biomedical research – GSPbmr” was initiated and submitted. It comprises 46 researchers and experts contributing to the application across 20 countries, three research infrastructures (BBMRI, EATRIS, ECRIN) and one international organisation (IARC). Within the BBMRI-ERIC Working Group for QM5, several National Nodes together with the main drivers of Poland and Germany joined forces to develop a general QM guideline, which follows the approaches of the biobanking standard ISO 20387:2018 and ISO 9001:2015.
A milestone in visibility for the importance of implementing standards within our community was reached in the European Parliament when BBMRI-ERIC and the SPIDIA4P consortium initiated an event to raise awareness of why sample quality is important. This opened the door for further cooperation with relevant interest groups such as the European (EA) or international organisation (ILAC) for accreditation as well as with several national accreditation organizations such as DAkkS, UKAS, TÜRKAK, and ESYD, which are particularly relevant for future accreditation of biobanks.

STAKEHOLDER FORUM

The BBMRI-ERIC Stakeholder Forum is the main interface for European patients’ organisations, civil society, industry and academia to interact with the biobanking universe.

The patients’ pillar of the Stakeholder Forum continued on the path set in 2017 and reinforced in 2018. The patients’ pillar is now solid and well-integrated in the life of BBMRI-ERIC. Following the end of Alastair Kent’s mandate, the Forum adopted new rules of procedure and elected a new Chair, Richard Stephens, former Chair of the NCRI Consumer Liaison Group/Consumer Forum in the UK, and expert patient advocate. The patients’ pillar grew in size: we welcomed Veerle Aertsen, EUPATI Belgium co-founder and patient ambassador. We moved on to further develop the Stakeholder Engagement Experts Task Force, to translate the successes with the Stakeholder Forum into actionable support for the National Nodes. The main outcome was a joint Stakeholder Forum/Engagement Experts’ meeting held during the Europe Biobank Week, aiming at:

- Creating a network of people from the National Nodes who deal with patients’ engagement, industry collaboration, stakeholders’ outreach, sustainability, etc.
- Connecting the Stakeholder Forum members with the National Nodes to see if there can be synergies at the national level
- Finding out if there are joint projects and collaborations the National Nodes can do with BBMRI-ERIC Headquarters and the Stakeholder Forum members.

As a result, the group identified key action points for the future and kicked off several autonomous collaborations, which have already resulted in a few project proposals submitted for funding, co-created by patients and BBMRI National Nodes.

Biobanking is indeed one crucial component of the treatment development pipeline. However, a divide exists between biobanks and industry researchers, which means that millions of samples and associated data collected and stored at the highest standards are left unused. To achieve BBMRI’s mission we needed to bridge that divide. In establishing the Stakeholder Forum’s industry pillar, we aim to connect with industry partners to learn about their issues, expectations and obstacles related to biobanking, so that we can co-develop solutions. The first step took place at Europe Biobank Week 2019, where we held a workshop with representatives of industry (pharma, medtech, and biobank service providers). The objective of the workshop was for the industry representatives to explain the issues they face in relation to biobanking, for example related to the quality of samples, standards, interoperability of IT systems, and ethical and legal issues. Following the workshop, a core team of industry representatives and BBMRI partner biobanks was put together with the objective of continuing the conversation and planning activities for 2020. The ultimate goal of the collaboration with industry is to create a long-term, sustainable, equitable space where industry and biobanks can exchange ideas for the benefit of patients across Europe – and beyond.

INCREASING THE VISIBILITY OF SERVICES AND PROJECTS

Increasing the visibility of BBMRI-ERIC through project work and by highlighting the developed services was a key focus in 2019.

After consulting our CS IT user forum and conducting user observations of the Directory, we created a social media campaign to highlight cohorts and collections from our member biobanks, thanks to coordination with nearly all of our National Nodes. Additionally, our former Director General Erik Steinfelder gave a series of introductory webinars on the use of the Directory from the point of view of a researcher and a biobanker. Petr Holub and Robert Reih were available to answer more in-depth, technical questions. This investment significantly increased the visibility and findability of both the Directory and Negotiator for all stakeholders, from patient organisations to research institutes and industry. Over 100 different researchers were looking for samples and associated data and connected with BBMRI-ERIC for support to make the right connections, matching the idea for a research project with the availability of samples.

Along the same lines, significant additions to the ELSI Services & Research section of our website were made, promoting the BBMRI-ERIC, as well as national ELSI Helpdesks (custom-based service) and the ELSI Knowledge Base (open access resource platform), and support was continually given to the Quality department. We invested time in social media, increasing the number of posts and quadrupling the number of Twitter impressions from Q1 to Q4. Creating video content where possible, as well as photos and graphics, made the significant increases in our KPIs possible. Progress was measured on a monthly basis on specific communication KPIs: number of followers, impressions and engagements, all of which increased by at least two-fold in this time period. We also gained 510 new Twitter followers, 285 new LinkedIn contacts, and 525,000 total impressions on Twitter and LinkedIn. This expertise secured our co-leadership of communication work packages in EU-funded projects such as EOSC-Life and RI-VIS.
FROM GRAZ, VIA BRUSSELS TO RIO

Our virtual communication strategy was well complemented by several live events. Here is a selection of three events which promoted BBMRI to the lay public, policy makers and researchers.

In September 2019, TEDx, the global initiative to spread ideas, came to the Medical University of Graz with the theme “Think Creative. Be innovative”. Former Director General Erik Steinfelder and BBMRI at Director Kurt Zatloukal were invited to speak at this popular event. Erik Steinfelder posed the question whether innovation is distracting us from the resources right in front of us. The speech focused on the fact that the narrative about innovation might be too focused on the future, new breakthrough technologies, gadgets and tools, while we should take a step back and focus on what is available around us and implement available innovative ideas in today’s life. Innovation is needed and crucial, for example to tackle complex diseases and make new treatments possible in the future. However, exploiting the potential of existing solutions is equally important. A practical example is the need to use (and make available) samples currently stored in biobanks, rather than focusing on collecting new ones.

SPIDIA4P enabled us to discuss quality standards at the European Parliament. Can new international and European standards increase patients’ safety by reducing the negative impact of external factors on in vitro diagnostic test results, thus ensuring that patients obtain diagnoses that are as objective as possible? Can these standards help to decrease uncertainty for industry players during the discovery, research, development and clearance process of new IVDs? These questions were discussed during an event at the European Parliament, hosted by MEP Meissner (ALDE, Germany) and MEP Wierinck (ALDE, Belgium). The event gave the opportunity to all actors working in the field of personalized medicine, in vitro diagnostics and standardization to present and discuss the main regulatory challenges during the discovery and development of new biomarkers for in vitro diagnostic medical devices (IVDs) and personalized medicine solutions to policy makers.

During a three-day workshop in Rio de Janeiro, funded by the EU-funded project ADOPT BBMRI-ERIC, more than 60 biobankers from 6 Latin American countries came together to share firsthand experience and establish connections between local biobanks and the European infrastructure.

The workshop was part of the deliverables of ADOPT BBMRI-ERIC and focused on the role of biobanking in modern medicine. Presenters from biobanks, hospitals and universities shared their experiences, which triggered lively debates among the participants. In particular, the event focused on disseminating the results of ADOPT BBMRI-ERIC and helping the Latin American biobanking community to come together. Key issues in the setup and management of biobanks were discussed, such as the power of small collections for very specific studies, the need for automation, high quality and the willingness of sharing samples. ADOPT BBMRI-ERIC provided a unique opportunity to meet and share problems and expectations. Following, BBMRI-ERIC facilitated the creation of a pan-Latin American action list to build upon the momentum set by ADOPT BBMRI-ERIC and create a more stable continental collaboration on biobanking. Volunteers from Brazil, Argentina, Mexico and Chile stepped forward to coordinate and lead the dialogue on biobanking in the region and make the first steps in shaping the freshly built network.
EUROPE BIOBANK WEEK IN LÜBECK

The most important event of the year remained the Europe Biobank Week. With the theme “Biobanking for a Healthier World”, our 2019 conference attracted 750 attendees, speakers and sponsors from 47 countries to Lübeck, Germany. With sessions on a variety of topics from quality management to IT to ELSI, as well as a Stakeholder Debate, Ethics Cafe, Pitch Your Innovative Idea pop-up theater, and more unique events, participants were able to expand and deepen their knowledge of issues related to biobanking and personalized medicine. Networking opportunities were abundant, with a Young Biobankers’ evening, Advanced Biobankers’ dinner, our nautical-themed Networking Dinner on the harbor, and plenty of catered breaks.

Among the 53 exhibitors were several of our National Nodes: Austria, Belgium, Cyprus, Germany, Italy, Poland, Sweden, Switzerland and the UK. A highlight for our Nodes was a pre-conference workshop on social media tailored especially to communications representatives in biobanking. ZN, a digital marketing company based in Brussels, brought in a speaker to share strategies on creating compelling messages on Twitter and navigating the world of social media. We were able to immediately implement several strategies learned at the Europe Biobank Week 2019.

ALLIANCE WITH EATRIS AND ECRIN

The European Research Area suffers from substantial duplication and fragmentation of strategies, expertise and services, due to the broad range of stakeholders required in the drug development pipeline. This often results in competition rather than cooperation, and in the creation of silos.

In the field of biomedical research an alarmingly high percentage of scientific papers cannot be reliably reproduced by other researchers. BBMRI, EATRIS and ECRIN believe that they are ideally placed in the landscape of treatment development to provide standardised services and coherent, pre-competitive support to all researchers - this would greatly benefit academic and industry researchers and decrease duplication.

Since 2018, discussions have been ongoing amongst BBMRI, EATRIS and ECRIN leadership to consider the creation of an alliance of medical research infrastructures. In 2019, we explored the internal factors that drive the discussion towards better cooperation and integration of the three medical RIs, including the need to reach a critical mass of resources and competencies, broadening the spectrum of support and services, to boost visibility for users and policymakers at EU and global levels, to better align our strategies, and to avoid duplication or gaps. Ultimately, a Memorandum of Understanding was signed to explore further how to develop integrated service pipelines such as health innovation.

ERIC FORUM

2019 also saw the kick-off of the ERIC Forum project, a Horizon 2020 Coordination and Support Action (CSA) aimed at providing resources for the functioning and development of the ERIC Forum: the informal organisation that brings together all ERICs. The project is coordinated by BBMRI-ERIC. Until 2023, BBMRI will be part of the Secretariat of the ERIC Forum, supporting the Forum’s Chair and ensuring full symbiosis between the EU-funded project and the activities of the Forum. In 2019, BBMRI focused on establishing the key structures needed to run both the project and the ERIC Forum as a whole. In this context, BBMRI had a pivotal role in reinforcing links between the ERICs and key EU decision makers, such as the European Commission Unit on Research and Industrial Infrastructures, the European Strategy Forum on Research Infrastructures (ESFRI), the European Research Area Committee (ERAC) and others.
CODE OF CONDUCT FOR HEALTH RESEARCH

Health research today takes place at the intersection of machine learning and health care -- especially in relation to the secondary use of data. Our Code of Conduct for Health Research initiative has started with considering the needs of biobanks, clinical trials, studies, cohorts, registries, and genome databases’ data for harmonized data set. It also has to take into account the link with patient-owned data and electronic health records. This contributes to the improvement of prevention, diagnosis, drug development and therapies to foster personalized medicine. Consequently, the secondary use of health care data is included. An enlargement to primary use is conceivable, but dependent on timeline and resources. Ultimately, we aim for an EU-wide code under GDPR Art. 40 as a tool for ensuring smoother legal and ethical compliance. In autumn 2019, a joint meeting with national code initiatives from Italy, the Netherlands, Norway, Belgium, Poland, GEANT, ESOMAR and EUCROF took place, where we agreed that the codes should be as complementary as possible and further collaboration is desirable. Draft sections of the code on consent, legal basis and anonymization/pseudonymization are currently discussed in expert groups, most notably in the context of the EU-funded project CORBEL. Wider public consultation has been delayed due to the complexity of country derogations.

LEVERAGING EUROPEAN INFRASTRUCTURES TO ACCESS 1 MILLION HUMAN GENOMES BY 2022

Human genomics is undergoing significant change from being a predominantly research-driven activity to one driven through health care, as many countries in Europe now have nascent precision medicine programmes (as reported by Nature). To maximize the value of the genomic data generated, data sharing between institutions and across countries needs to be enabled. In recognition of this challenge, 21 European countries recently signed a declaration to transnationally share data on at least 1 million human genomes by 2022. BBMRI follows this initiative closely. Several BBMRI-related experts on both the European and national levels are actively involved in the 1+ Million Genomes ELSI Working Group (e.g., Michaela Th. Mayrhofer for BBMRI-ERIC, Olga Tzorzatou from Greece and Signe Mezinska from Latvia). This approach ensures the inclusion of our community’s knowledge, requirements and concerns as regards to setting up structures enabling the appropriate sharing of sensitive data.

FINANCE BUDGET AND PROJECTS

Building on past achievements, 2019 was a successful year for BBMRI-ERIC. Among the main highlights are the completion of ADOPT BBMRI-ERIC, our biggest EU-funded project yet (in terms of impact and financial contribution); one of the most successful Europe Bio-bank Week events, delivering an income that exceeded all forecasts; and the kick-off of 8 new projects, cementing a solid financial position for the following years. Our financial objectives are to create a sustainable income stream to achieve BBMRI-ERIC’s strategic goals. While the membership contributions of roughly 2.8m € support the core services related to ELSI, IT, QM and the Stakeholder Forum, the EU funding secures a steady income stream for specialized services and targeted deliverables. In 2019 eight new EU-funded projects launched, to support major initiatives around sustainability and visibility of research infrastructures (ERIC-Forum, RI-VIS), creating an open collaborative space for digital biology (EOSC-Life), rare diseases (EJP RD), and development and excellence of national structures (CY-Biobank), to name a few. These projects will contribute a total of 4.5m € for the next 7 years and ensure the necessary funding to deliver on our commitments.

These achievements put BBMRI-ERIC on solid ground, both scientifically and financially, for the years to come.

Sincerely on behalf of the HQ team,

Michaela Th. Mayrhofer & Carmen Cristea Interim Co-Directors General April 2020
# Services

## DIRECTORY

<table>
<thead>
<tr>
<th>Biobanks Connected</th>
<th>Collections</th>
<th>Countries Contributing Collections</th>
<th>Average Users Per Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>715</td>
<td>1617</td>
<td>17</td>
<td>478</td>
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## NEGOTIATOR

<table>
<thead>
<tr>
<th>Collections Represented</th>
<th>Total Users</th>
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<tbody>
<tr>
<td>307</td>
<td>390</td>
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</table>

## QA

<table>
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<tr>
<th>Self-Assessment Survey Completions</th>
<th>Additional Collections with Q Mark</th>
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<tr>
<td>54</td>
<td>32</td>
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</table>

## ELSI

<table>
<thead>
<tr>
<th>Successful Response Rate for Helpdesk Questions</th>
<th>Ethics Checks for H2020 EU Projects</th>
</tr>
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<tbody>
<tr>
<td>93%</td>
<td>15</td>
</tr>
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</table>
PART 2
FINANCIAL INFORMATION
CONNECT BIOBANKS,
INCREASE VISIBILITY,
MAKE NEW TREATMENTS POSSIBLE.
## Profit & Loss Statement

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turnover</td>
<td>888,860</td>
<td>2,892,951</td>
<td>3,050,231</td>
<td>4,091,202</td>
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<tr>
<td>Other operating income</td>
<td>-</td>
<td>629</td>
<td>1,068</td>
<td>10,882</td>
</tr>
<tr>
<td>Staff expenses</td>
<td>(1,554,036)</td>
<td>(1,689,010)</td>
<td>(1,647,023)</td>
<td>(1,840,023)</td>
</tr>
<tr>
<td>Amortization</td>
<td>(30,020)</td>
<td>(29,518)</td>
<td>(35,896)</td>
<td>(31,683)</td>
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<td>Other operating expenses</td>
<td>(1,172,010)</td>
<td>(1,367,820)</td>
<td>(1,464,964)</td>
<td>(1,676,029)</td>
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<tr>
<td><strong>Operating result</strong></td>
<td>(1,867,207)</td>
<td>(192,768)</td>
<td>(96,584)</td>
<td>554,349</td>
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<tr>
<td>Other interest and similar income</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Interest and similar expenses</td>
<td>(58)</td>
<td>(30)</td>
<td>(41)</td>
<td>-</td>
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<tr>
<td><strong>Financial result</strong></td>
<td>(58)</td>
<td>(30)</td>
<td>(41)</td>
<td>-</td>
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<tr>
<td>Loss from operating activities, Earnings before taxes</td>
<td>(1,867,265)</td>
<td>(192,798)</td>
<td>(96,626)</td>
<td>554,349</td>
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<tr>
<td>Taxes on income and revenue</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Profit of the year</strong></td>
<td>(1,867,265)</td>
<td>(192,798)</td>
<td>(96,626)</td>
<td>554,349</td>
</tr>
<tr>
<td>Reversal of profit reserves</td>
<td>1,867,265</td>
<td>192,798</td>
<td>96,626</td>
<td>-</td>
</tr>
<tr>
<td>Allocation to profit reserves</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>(554,348)</td>
</tr>
<tr>
<td>Profit carried forward from the previous years</td>
<td>367,775</td>
<td>367,775</td>
<td>367,775</td>
<td>367,775</td>
</tr>
<tr>
<td><strong>Balance sheet profit</strong></td>
<td>367,775</td>
<td>367,775</td>
<td>367,775</td>
<td>367,775</td>
</tr>
</tbody>
</table>
Key Facts & Figures

17 member states

18 projects underway in 2019

2.8 m overall budget

4 observers

SOCIAL MEDIA

510 new followers

285 new followers

505,000 impressions
## Balance Sheet

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
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<tr>
<td>Intangible Assets</td>
<td>2,560</td>
<td>1,280</td>
<td>8,459</td>
<td>5,639</td>
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<td>Tangible Assets</td>
<td>87,759</td>
<td>73,274</td>
<td>55,924</td>
<td>66,339</td>
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<td><strong>Fixed Assets</strong></td>
<td>90,320</td>
<td>74,554</td>
<td>64,382</td>
<td>71,978</td>
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<tr>
<td>Receivables and other Assets</td>
<td>145,488</td>
<td>199,669</td>
<td>1,164,191</td>
<td>343,225</td>
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<tr>
<td>Receivables arising from deliveries services</td>
<td>9,249</td>
<td>126,626</td>
<td>134,301</td>
<td>86,743</td>
</tr>
<tr>
<td>Other receivables and assets</td>
<td>136,239</td>
<td>73,043</td>
<td>1,029,890</td>
<td>256,482</td>
</tr>
<tr>
<td>Cash on hand and Bank deposits</td>
<td>1,970,135</td>
<td>2,189,624</td>
<td>1,645,101</td>
<td>2,916,641</td>
</tr>
<tr>
<td><strong>Current Assets</strong></td>
<td>2,115,623</td>
<td>2,389,293</td>
<td>2,809,292</td>
<td>3,259,867</td>
</tr>
<tr>
<td>Prepaid expenses, deferred charges</td>
<td>3,581</td>
<td>5,919</td>
<td>13,332</td>
<td>5,031</td>
</tr>
<tr>
<td><strong>Assets</strong></td>
<td>2,209,523</td>
<td>2,469,766</td>
<td>2,887,006</td>
<td>3,336,876</td>
</tr>
<tr>
<td>Reserves pursuant to the articles of association</td>
<td>326,097</td>
<td>133,300</td>
<td>36,674</td>
<td>591,022</td>
</tr>
<tr>
<td>Balance sheet profit</td>
<td>367,775</td>
<td>367,775</td>
<td>367,775</td>
<td>367,775</td>
</tr>
<tr>
<td><strong>Capital and Reserves</strong></td>
<td>693,872</td>
<td>501,075</td>
<td>404,449</td>
<td>958,797</td>
</tr>
<tr>
<td>Other accruals</td>
<td>52,800</td>
<td>128,178</td>
<td>832,308</td>
<td>157,473</td>
</tr>
<tr>
<td><strong>Accruals</strong></td>
<td>52,800</td>
<td>128,178</td>
<td>832,308</td>
<td>157,473</td>
</tr>
<tr>
<td>Liabilities arising from deliveries and services</td>
<td>54,179</td>
<td>58,187</td>
<td>164,723</td>
<td>226,636</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>204,924</td>
<td>157,418</td>
<td>131,022</td>
<td>385,357</td>
</tr>
<tr>
<td><strong>Liabilities</strong></td>
<td>259,104</td>
<td>215,604</td>
<td>295,745</td>
<td>611,993</td>
</tr>
<tr>
<td>Deferred income</td>
<td>1,203,748</td>
<td>1,624,910</td>
<td>1,354,505</td>
<td>1,608,612</td>
</tr>
<tr>
<td><strong>Liabilities and Owner´s Equity</strong></td>
<td>2,209,523</td>
<td>2,469,766</td>
<td>2,887,006</td>
<td>3,336,876</td>
</tr>
</tbody>
</table>
## Cash Flow

<table>
<thead>
<tr>
<th>In EUR</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profit of the year</td>
<td>(1,867,265)</td>
<td>(192,798)</td>
<td>(96,626)</td>
<td>554,349</td>
</tr>
<tr>
<td>Amortization</td>
<td>29,955</td>
<td>28,096</td>
<td>31,878</td>
<td>31,683</td>
</tr>
<tr>
<td><strong>Cash Flow from the Result</strong></td>
<td>(1,837,309)</td>
<td>(164,702)</td>
<td>(64,748)</td>
<td>586,032</td>
</tr>
<tr>
<td>Receivables arising from deliveries services</td>
<td>(9,119)</td>
<td>(117,377)</td>
<td>(7,675)</td>
<td>47,558</td>
</tr>
<tr>
<td>Other receivables and assets</td>
<td>(43,190)</td>
<td>63,196</td>
<td>(956,847)</td>
<td>773,407</td>
</tr>
<tr>
<td>Liabilities arising from deliveries and services</td>
<td>22,772</td>
<td>4,007</td>
<td>106,536</td>
<td>61,913</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>180,102</td>
<td>(47,507)</td>
<td>(26,396)</td>
<td>254,335</td>
</tr>
<tr>
<td>Prepaid expenses, deferred charges</td>
<td>(3,331)</td>
<td>(2,337)</td>
<td>(7,414)</td>
<td>8,301</td>
</tr>
<tr>
<td>Accruals</td>
<td>39,500</td>
<td>496,540</td>
<td>433,725</td>
<td>(420,727)</td>
</tr>
<tr>
<td><strong>Working Capital</strong></td>
<td>186,733</td>
<td>396,523</td>
<td>(458,070)</td>
<td>724,788</td>
</tr>
<tr>
<td><strong>Cash Flow from Operations</strong></td>
<td>(1,650,576)</td>
<td>231,820</td>
<td>(522,817)</td>
<td>1,310,820</td>
</tr>
<tr>
<td>Investing / Deinvesting</td>
<td>(4,315)</td>
<td>(12,331)</td>
<td>(21,706)</td>
<td>(39,280)</td>
</tr>
<tr>
<td><strong>Cash Flow from Investing Activities</strong></td>
<td>(4,315)</td>
<td>(12,331)</td>
<td>(21,706)</td>
<td>(39,280)</td>
</tr>
<tr>
<td>Capital and Reserves</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cash Flow from Financing Activities</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total Cash Flow</strong></td>
<td>(1,654,891)</td>
<td>219,490</td>
<td>(544,523)</td>
<td>1,271,540</td>
</tr>
</tbody>
</table>

- **Cash Beginning**: 3,625,026 1,970,135 2,189,624 1,645,101
- **Δ**: (1,654,891) 219,490 (544,523) 1,271,540
- **Cash End**: 1,970,135 2,189,624 1,645,101 2,916,641
PART 3
PROJECTS
CONNECT BIOBANKS, INCREASE VISIBILITY, MAKE NEW TREATMENTS POSSIBLE.
Projects Launched in 2019

We are excited to announce that the following 8 projects, funded by the European Commission, officially launched in 2019. In addition, 7 new projects (DIAMONDS, CETOCOEN Excellence, RABBIT 2, IC2PerMed, EuCanImage, B1MG and BIGPICTURE) are planned to start in 2020.

We completed several other projects in 2019: ADOPT BBMRI-ERIC, EOSCpilot and AARC2. The projects CliniMARK, CORBEL, euCanSHare, ID-EPTRI and SPIDIA4P were ongoing in 2019.

<table>
<thead>
<tr>
<th></th>
<th>CINECA</th>
<th>EJP RD</th>
<th>ERIC Forum</th>
<th>EUCAN-Connect</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBMRI-ERIC Budget</td>
<td>€ 314,682.50</td>
<td>BBMRI-ERIC Budget*</td>
<td>€ 181,250.00</td>
<td>€ 399,326.25</td>
</tr>
<tr>
<td>Start Date</td>
<td>2019 1 JANUARY</td>
<td>2019 1 JANUARY</td>
<td>2019 1 JANUARY</td>
<td>2019 1 JANUARY</td>
</tr>
<tr>
<td></td>
<td>International flagship collaboration with Canada for human data storage, integration and sharing to enable personalised medicine approaches</td>
<td>European Joint Programme on Rare Diseases creates a comprehensive, sustainable ecosystem allowing a virtuous circle between research, care and medical innovation</td>
<td>Policy and international cooperation measures for research infrastructures</td>
<td>A federated FAIR platform enabling large-scale analysis of high-value cohort data connecting Europe and Canada in personalized health</td>
</tr>
</tbody>
</table>

|                   | RI-VIS              | EOSC-Life            | ConcePTION           | CY-Biobank            |
| BBMRI-ERIC Budget| € 248,500.00        | BBMRI-ERIC Budget*  | € 328,420.00          | € 1,285,815.00        |
| Start Date        | 2019 1 FEBRUARY     | 2019 1 MARCH         | 2019 1 APRIL         | 2019 1 OCTOBER        |
|                   | Expanding research infrastructure visibility to strengthen strategic partnerships | Providing an open collaborative space for digital biology in Europe | Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding: validated and regulatory endorsed workflows for fast, optimised evidence generation | Center of Excellence in Biobanking and Biomedical Research and the Cyprus human genome project: Expanding research infrastructure visibility to strengthen strategic partnerships |

*Budget figure includes funding for BBMRI-ERIC headquarters and linked third parties

We completed several other projects in 2019: ADOPT BBMRI-ERIC, EOSCpilot and AARC2. The projects CliniMARK, CORBEL, euCanSHare, ID-EPTRI and SPIDIA4P were ongoing in 2019.
Our National and Organizational Nodes are the powerhouses behind the work we do. They coordinate the biobanks within their countries while actively contributing to research and growing our sample collections. Here is a snapshot of what makes each Node unique, and we encourage readers to see additional information on each Node’s individual website.
PART 4

NODES
CONNECT BIOBANKS,
INCREASE VISIBILITY,
MAKE NEW TREATMENTS POSSIBLE.
TOP 3 KEY SUCCESSES IN 2019

1. Harmonization & standardization: Contribution to development of new ISO standards and CEN/TS; recertification of BBMRI.at quality management (QM) coordinators completed; QM course held; broad consent template and example biobank strategy developed at certain partners serving as basis for national harmonization; BBMRI-ERIC Self-Assessment-Tool updated/maintained

2. Data Management: Biobanks from all public Medical Universities listed in BBMRI.at Catalog & BBMRI-ERIC Directory; one of the nodes i) with the highest number of quality-marked samples and ii) most actively using the Negotiator; establishment of a high capacity digitalization process for pathology tissue slides; e-lectures/presentations on data quality in biobanking; complementing biobank samples with digital images of tissue slides; work on new data access model and safe data environment for biobanks

3. Stakeholder and user information and engagement: Meeting of BBMRI.at with BBMRI.it/cy/cz to explore synergies held; university biobanking workshops for children and numerous guided biobank tours performed; education for different stakeholders provided (e.g. 2nd MSc Biobanking at MUG); BSL-3 facility ready for autopsies and lab work with highly infectious pathogens

ADDITIONAL COMMENTS

Specific strengths of BBMRI.at:
- Solid community of BBMRI.at partners
- Advanced integration of biobanking in hospital systems
- Project leader and expert contributions to the development of CEN/TS and ISO standards (e.g., CEN/TC 140, ISO/TC 212, ISO/TC 276)
- Pioneering role for QM activities of BBMRI-ERIC:
  - Development of a Self-Assessment Tool to assess conformity with CEN/TS and its joint development for pan-European use with the BBMRI-ERIC QM expert group
  - Organization of hands-on training courses for pre-analytical sample processing, building biobanks, as well as a MSc (Master of Science) in Biobanking (Biobank Graz)
  - Commitment of partner biobanks to and conduction of BBMRI at QM cross audits (since 2017)
- Biobank Graz – one of the largest biobanks in Europe awarded with several prizes
- High-throughput facility for digitalization of tissue slides established at Med Uni Graz
- BBMRI at Biobank Catalogue with all partner biobanks and their collections (established: 2013)
- Developing the role of biobanks as key resource provider for developing AI algorithms for healthcare
- Conducting of discussion rounds/interviews with citizens/patients
- Engagement of the public (particularly children) in workshops and events
TOP 3 KEY SUCCESSES IN 2019

1. New governance structure for BBMRI.be implemented: From 2019 onwards, the new governance structure of BBMRI.be was implemented. This implies that all Belgian biobanks with translational research potential as well as biobank users that are seeking structural research collaborations can join the BBMRI.be network. In 2019, three new biobanks were included in the network: Oncological biobank of the GZA Hospitals, Jessa Biobank and UCLouvain Biolibrary. With these new partners, our network now connects 16 biobanks that are linked to public institutions such as hospitals, universities and research centers.

2. Biobank Day: On November 4th, 2019, the Belgian Biobanking Day was organized by BBMRI.be and Greiner. Nearly 80 people registered for the meeting of whom about 43% of the BBMRI.be network. The rest of the attendants were mainly researchers from universities or other scientific institutes (39%) and representatives from biotech or pharma (17%). All presentations, ranging from disease-specific collections to general population studies, from human samples to micro-organisms were very nice showcases of how biobanks are a crucial pillar to move research forward.

3. Frontiers in Medicine Research Topic: In 2019, BBMRI.be hosted a Research Topic for Frontiers in Medicine: “Biobanks as Essential Tools for Translational Research: The Belgian Landscape”. Within this research topic, containing 11 biobank manuscripts, we focused on the challenges Belgian biobanks and biobank networks are facing along the road towards implementation and sustainability and how these can be overcome. We also share some success stories illustrating how, over a decade, the BBMRI.be biobank network has managed to build strong cornerstones and become a fertile substrate for human biospecimen samples management and access for translational research purposes.

The full Research Topic can be found here: https://www.frontiersin.org/research-topics/8144/biobanks-as-essential-tools-for-translational-research-the-belgian-landscape
TOP 3 KEY SUCCESSES IN 2019

1. Financial support for the establishment of the National Node received by the Ministry of Education and Science
2. Installation of new LIMS for Biobanking management at Molecular Medicine Center, MU-Sofia
3. Initial survey done for mapping the available collections across research institutions in Bulgaria

ADDITIONAL COMMENTS

BBMRI-ERIC and BBMRI.bg were presented during the European Researcher’s night and BioTech Atelier 2019.
TOP 3 KEY SUCCESSES IN 2019

1. Funding through the Horizon 2020 for creating a Center of Excellence in Research and Innovation, in collaboration with three partners:
   - BBMRI-ERIC, Graz, Austria,
   - Medical University of Graz, Austria,
   - RTD TALOS Limited, Cyprus

   Funding is from EU (€15 mi, years 1-7), the Cyprus government (€15 mi, years 1-15), and the University of Cyprus (€8 mi, years 1-15).

2. Funding from, and collaboration with the Broad Institute of MIT and Harvard, for carrying out the first clinical trial of MUC1 kidney disease in a cohort of Cypriot patients.

3. Funding for starting a new project on the genetics and biomarker discovery in inherited kidney disorders.

ADDITIONAL COMMENTS

The biobanking landscape in Cyprus is still developing, with a relatively small number of trained scientific personnel. We are actively working with our partners in BBMRI-ERIC and Medical University of Graz to train more people and establish high quality standards in order to sustain quality data and material for research.
TOP 3 KEY SUCCESSES IN 2019

1. Launch Sample Locator
2. Introduction of European IT tools for the use of research samples and data with a key contribution of BBMRI-CZ employees of the Czech Republic
3. Collaboration with academic research institutions and partners in industry, cooperation with newly participating entities (Institute of Rheumatology in Prague, RECETOX MU Brno)

ADDITIONAL COMMENTS

Newly established processes:
• BBM MCI newly collects and stores mononuclear cells of patients with cancer diagnoses.
• BBM 1. LF CU - newly collects control blood from the transfusion department of the General University Hospital.
• BBM LF - Fresh samples of breast cancer were transferred from the University Hospital tissue biobank.
• BBM LF - Stability studies of selected tumor markers CEA and CA19-9 were performed. Analysis of anti-Müllerian hormone (AMH) using ELISA and chemiluminescence automated method according to ISBER protocol was realized.
• BBM LF UP - The laboratory has begun to offer experience in the area of massively parallel sequencing in the form of core facility services. Participation in an international study on standardized reference samples with somatic mutations for massively parallel tumor DNA sequencing.
• Optimization of the method for testing tumor mutation burden by panel sequencing of 486 genes.

* For 2019: LTS tissue collection: 14,262 new samples, samples of tissue in RNA later: 3,224, serum collection: 5,793 new samples, plasma collection: 3,827 new samples, blood collection of 2,140 new samples, DNA collection of 3569 new samples, new urine samples collection: 731, new PBMNC: collection of 649 samples

** For 2019: 1,883 of frozen tissue samples, 597 of LTS serum samples, 15 of plasma samples, 698 of DNA samples, 682 of serum STS samples
TOP 3 KEY SUCCESSES IN 2019

1. Seven new biobank alliance partners: In 2019, GBA has been expanded to include seven new partners located in Berlin, Dresden, Essen, Freiburg, Marburg, Regensburg, and Tübingen. GBA now comprises of 18 biobank sites and two IT development centres. The newly admitted biobanks underwent an application process to join the alliance. They now participate in the extensive activities in quality management, connect to the alliance’s IT network, benefit from GBN’s further training offers and workshops and from the regular exchange between the partners.

2. Search tool “Sample Locator” officially launched: Thanks to GBN’s Sample Locator (samplelocator.bbmri.de) medical researchers are able to search across GBA partners and further biobanks for relevant biosamples. The decentralised online search is connected to BBMRI-ERIC’s “Negotiator” tool which enables direct communication between scientists and biobanks to negotiate sample requests. GBN head Michael Hummel presented the Sample Locator at the Europe Biobank Week 2019 in Lübeck.

3. Cooperation between biobanks and industry: GBN and GBA published the “Position Statement from the German Biobank Alliance on the Cooperation Between Academic Biobanks and Industry Partners” open access (https://doi.org/10.1089/bio.2019.0042). It was one of Biobanking and Biopreservation’s five most downloaded papers in 2019. Together with BBMRI-ERIC, GBN also organised a focus group with patient representatives to define the conditions under which the participating representatives would accept cooperation between academic biobanks and industry partners. The event took place in early 2020.

ADDITIONAL COMMENTS

During the Europe Biobank Week 2019 in Lübeck, the former director of the French network BIOBANQUES Georges Dagher praised GBN’s audit concept: “I congratulate the German Biobank Node on this excellent internal auditing system, which is unprecedented in Europe and should be used by other countries as a model. It allows the adequate quality of samples and related data to be better ensured.”
TOP 3 KEY SUCCESSES IN 2019

1. Estonian Biobank (EstBB) size was increased to 200,000 secured funding for genotyping them all with Illumina GSA.

2. 105 papers published in international peer review journals.

3. 2,500 people received the personal feedback from the EstBB on different diseases and traits incl. polygenic risk scores (PRS). Additionally, 500 females received personal feedback on their polygenic risk scores and monogenic factors contributing to breast cancer risk.

BBMRI.EE node is consisting currently of the Estonian Biobank. It was a political decision 20 years ago to pool recourses (human and funds) in a small country into one program which could cover the entire population.

TOP 3 AREAS OF EXPERTISE

1. Personalized medicine, including biobank-driven national scale projects

2. Whole genome association studies and polygenic risk scores

3. Recall of biobank participants and translational projects with genome research data being used together with clinical data in order to introduce the personal medicine and personal prevention into everyday practice.

TOP 3 AREAS OF EXPERTISE

1. Personalized medicine, including biobank-driven national scale projects

2. Whole genome association studies and polygenic risk scores

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EGCUT broad feedback initiative
TOP 3 KEY SUCCESSES IN 2019

1. One-Stop Shop Fingenious® service launched in 2019 covering all Finnish public biobanks
2. FinnGen - successful execution of international public-private biobank study
3. FinnGen delivered genotype data returned to biobanks for additional biobank studies

FINLAND

| Number of biobanks | 10 |
| Number of samples | ~ 100,000 |
| Total size of sample collections | ~ 7,200,000 |
| Number of samples/data used for research | ~ 130,000 |

ABOUT THE NODE

BBMRI.fi (www.bbmri.fi) is a research infrastructure comprising all public and academic biobanks in Finland (later referred as Finnish Biobanks). Finnish Biobanks were established and are hosted by the Finnish universities, hospital districts, the National Institute for Health and Welfare, and the Finnish Red Cross Blood Service. Finnish Biobank Cooperative – FINBB was founded in 2017 and is coordinating, developing and serving the operative actions of all Finnish Biobanks. Finnish Biobanks participate actively in implementation of the BBMRI-ERIC Work Program with specific emphasis in providing Common Services for IT, Quality and Ethical and Legal Issues. FINBB is the Finnish National Node of the European level BBMRI-ERIC infrastructure (www.bbmri-eric.eu).

TOP 3 AREAS OF EXPERTISE

1. High quality samples with related clinical data
2. Hospital real world data retrieval and analytics in data lake infrastructure
3. Core common national processes for feasibility studies in all public biobanks
TOP 3 KEY SUCCESSES IN 2019

1. Introduction of the ISO 20387:2018 to national BRC with the support BBMRI-ERIC Webinars
2. Support for two national cohorts for the constitution and conservation of collections
3. Support for the establishment of a biobank of embryonic and fetal tissues

Since 2018, the NN was in a restructuring period facing departure of FTE and reorientation of the project on supporting quality of biological collections and cohorts.

TOP 3 AREAS OF EXPERTISE

1. Quality
2. ELSI
3. Population- & clinical-based cohorts

FRANCE

- Number of biobanks and stand-alone collections: 96
- Number of samples/size of collections: > 11,000,000
- Number of samples/data used for research: > 500,000
TOP KEY SUCCESSES IN 2019

1. Official presentation of BBMRI-GR in the context of BBMRI-ERIC, during a national event organized by the Ministry of Development of Greece regarding the role of research infrastructures in research and development.

2. Organization of a BBMRI-GR meeting with the participation of representatives from all BBMRI-GR partners discussed the current situation in Greece, the issues that need to be addressed, the details of establishing a functional Greek network of biobanks and most importantly to improve the connection of the network with BBMRI-ERIC. In this context, database and bioinformatics experts participating in the Greek network have prepared a detailed roadmap on all aspects of the networking procedure. Important issues related to the regulations governing the Greek network have been discussed and a flexible scheme was adopted.

3. Standard Operating Procedures and existing guidelines will be distributed to all participating nodes of the network and will be followed in every aspect of the biobanking procedures.

4. BBMRI-GR coordinates all Greek Biobanks participating in the Greek Flagship Program on Precision Oncology. BBMRI-GR supervises biobanks of specimens from cohorts of patients with particular types of malignant neoplasms with all available clinical information.

5. BBMRI-GR participates in the Greek Flagship Program on fighting the COVID-19 pandemic. BBMRI-GR coordinates and manages the national COVID-19 Biobank as a centralized resource to collect, store, and disseminate biological specimens and clinical data for researchers in Greece and elsewhere. SARS-CoV-2 viral genomes are being sequenced in parallel with patients’ DNA samples to obtain a clearer picture of the spread, distribution, and scale of the epidemic in Greece and to investigate the dynamic interactions of the virus with human cells aiming to identify genes playing critical role in the virus pathophysiology.

6. Dr. Olga Tzortzatou, lawyer at the Biomedical Research Foundation of the Academy of Athens, provides her services to BBMRI-ERIC ELSI through an “In-kind Agreement” as a data and ethics expert providing, among others, consultancy on cases which arrive at the ELSI Helpdesk. She has also contributed to the drafting of Consultations to International and European Institutions that BBMRI-ERIC has issued. Finally, she participated in EBW 2019.
The Italian node of BBMRI (BBMRI.it), established in 2013, is a distributed infrastructure including biobanks and biological resource centers located throughout Italy and a large community of researchers implicated in disease-oriented projects that relies on the use of collections of biological resources. BBMRI.it includes National Institute of Health, CNR, 19 universities, 33 research hospitals (IRCCS), 45 hospitals, 14 associations of patients and 92 biobanks, Biological Resources Centres and Collections organized in thematic networks and regional networks with a matrix architecture. BBMRI.it has developed a web portal and Common Services for ICT, Quality and ELSI have been set up to support the network. The CS IT adopted the BBMRI-ERIC standards and created the national IT infrastructure developing tools to improve interoperability of research databases. The CS Quality has been implemented on guidelines/best practices, harmonizing operational procedures, developing criteria for the accreditation and certification of biobanks, implementing the quality management system criteria of BBMRI-ERIC in the Italian network, promoting training on the issues of quality. The CS ELSI works as an instrument at the service of all stakeholders, from biobanks to the Ethics Committees, from patient’ associations to researchers and it's a real liaison between the national node and the European infrastructure on the ELSI state of art. Annually, BBMRI.it Help Desk process a median of 250 requests related to ethical and legal issues and 300 requests to quality matters.

**Specific Strengths**
- Number and quality of the Italian biobanks (population, genetic, diseases oriented and archived tissues biobanks) with high quality samples and associated data
- Health-care integrated biobanking
- Link between biomedical research and clinical care in the IRCCS network
- Close collaboration with patient associations, scientific society and the bio-industries

**TOP 3 AREAS OF EXPERTISE**
1. Healthcare integrated biobanking, bringing radiomics into multi-omics framework
2. ELSI
3. Secure IT solution for managing big data and sensitive data

**TOP 3 KEY SUCCESSES IN 2019**
1. Coordinated biobanking: samples are collected at research hospitals (IRCCS) using the same SOPs, access procedures and informed consent.
2. Development and implementation of biobank evaluation, site visit and audit process
3. Implementation of the Informed Consent Matrix and development of the Access Policy and MTA

**ADDITIONAL COMMENTS**
The dissemination and communication activities have been designed to involve the key audiences and stakeholders and to maximize awareness of BBMRI.it’s objectives and activities: enhancing the reputation and visibility of BBMRI.it; contributing to competitiveness and addressing societal challenges; building a strong bond between decision-makers and the scientific community. The ‘toolbox’ of the BBMRI.it’s communication includes: Website (thousands of monthly visits); Twitter (428 followers, about 11,000 views/month); Linkedin (134 followers, up to 1,000 impressions/month); Facebook (257 followers, up to 200 impressions/month); Youtube (about 2,639 impressions, about 40 hours of video delivered).

* 69 BBs in BBMRI-ERIC Directory comply with quality and ELSI requirements, 23 BBs are improving their Quality System and are assisted by the Quality Common Service
** The number of samples/data used for research varies according to the type of biobank (i.e. RD BBs, diseases oriented BB) ranging from 1% to 15%
TOP 3 KEY SUCCESSES IN 2019

1. Biological sample digitalization for research, by participation in national large-scale sequencing centre development and participation in research project for next generation sequencing data obtainment

2. Organization of national-level activities for biobanks and researchers about ELSI, QM and data protection and local level consultations. Promotion of Biobank law for coming into force in Latvia

3. Participation in development of more than 10 national-level and more than 5 international-level research projects; proposals includes areas of diabetes, tumour research, rare disease, ELSI and other

ADDITIONAL COMMENTS

In 2019 the survey on public’s awareness and attitudes towards research biobanks in Latvia was carried out. The obtained results indicate that awareness of general society about research biobanks in Latvia has deceased since 2010 Eurobarometer survey, however, the number of respondents who are willing to donate biological samples and personal data to a biobank has increased from 25.8% to 40.7% since 2010.
BBMRI.mt

MALTA

ABOVE THE NODE

1
Number of biobanks
and stand-alone collections

~ 90,000
Number of samples/
size of collections in 14 collections

1,000
Number of samples/
data used for research

5
Number of projects
supported

The Malta NN is the smallest within the BBMRI-ERIC. It was established at the University of Malta, Faculty of Medicine and Surgery in conjunction with the signing of the ERIC, after many years of biobanking. The first collection was held as part of the Thalassaemia Project supported by the Malta DH and a grant from WHO. Bio-Banking continued to develop with support of particular collections with research grants and public or private sector funding. The PI is co-founder of Euro-Bio-Bank, the first European network of Rare Disease Bio-Banking. The Malta NN takes active part in BBMRI activities with special interest in quality measures and rare disease matters. It is also interested in the further development of Rare Disease Bio-Banking and a broader Euro-Mediterranean engagement.

TOP 3 AREAS OF EXPERTISE

1. Rare Diseases
2. Globin research
3. Mitochondria

TOP 3 KEY SUCCESSES IN 2019

1. A reference Maltese Genome
2. ADOPT CRC cohort contribution and competition
3. Rare Disease events

ADDITIONAL COMMENTS

The NN intends to re-structure in 2019 - 2020 to pursue growth with a clinical biobank in the main hospital and a social co-operative. It seeks to improve sustainability of funding and governance beyond research grant mechanisms. Within BBMRI the Malta NN shall promote further interest in:

1. Organization of consortia for competitive funding in Bio-Bank-Led Research
2. Rare Disease Bio-Banking
3. The Euro-Mediterranean Platform
It is the mission of BBMRI.nl to maximize the use of bio samples, images and data for health research on the prevention, diagnosis and treatment of diseases. For this, we make sure these resources are available in a FAIR way: Findable, Accessible, Interoperable and Reusable. We do this in compliance with ethical, legal and privacy demands, and with active participation of donors, citizens and patients. Without reinventing the wheel, we envision that samples and data will be exchanged and reused for various purposes in an efficient, effective and meaningful way, and in compliance with ethics, legislation and society’s needs and wishes.

To contribute optimally to this vision, BBMRI-NL provides:
- access to biosamples, images and data
- tools to capture, integrate and analyze data, and
- support on ethical, legal and societal implications.

BBMRI.nl is one of the clusters on the Dutch national roadmap for Large-Scale Research Facilities. Non-regular funding is made available for clusters on this roadmap through competitive calls by NWO (The Netherlands Organization for Scientific Research).

For that reason, BBMRI.nl is organized as a typical research (and development) consortium, with various work packages. Please check out the website for more info www.bbmri.nl.

BBMRI.nl was one of the founding members of BBMRI-ERIC and is member since 2009.

BBMRI.nl, EATRIS.nl, DCRF (Dutch equivalent to ECRIN) and DTL/ELIX-IR-NL have jointly embarked on a common roadmap for a collective Personalized Health & Medicine Research Infrastructure in The Netherlands: Health-RI (www.health-ri.org).

**TOP 3 AREAS OF EXPERTISE**

1. Population omics/Imaging
2. IT for FAIR samples and data
3. ELSI

**TOP 3 KEY SUCCESSES IN 2019**

1. The ELSI Servicedesk, launched in 2018, receives many good credits and, more importantly, many visits (8000+) and in-depth questions (8)
2. The combination Catalogue-Podium (Find+Request) is in use
3. All preparative work for establishing Health-RI has led to the set-up of the Health-RI organization and legal entity in February 2020
TOP 3 AREAS OF EXPERTISE

1. Initiating and running population-based biobanks
2. State-of-the-art clinical biobanks for research
3. Digitized biobank data - secure solution for handling sensitive big data

TOP 3 KEY SUCCESSES IN 2019

1. Two automated storages installed and adopted; Biobank Haukeland (Western Norway Regional Health Authority) and Janus Serum Bank (Cancer Registry of Norway)
2. "Multicentre biobanking" piloted. Samples from radical prostatectomies were collected at hospitals in all Health Regions, using the same SOPs.
3. Three clinical biobanks established at different university hospitals

Biobank Norway (bbmri.no) is a large-scale national research infrastructure for clinical and population based biobanks, established in 2011. Over the last 4 years, Biobank Norway has increased the number of users exponentially, offering a wide range of well described, richly annotated bio-specimens and corresponding health related data, which has contributed to several hundred research projects subsequently published in a vast number of high-profiled publications.
**TOP 3 KEY SUCCESSES IN 2019**

1. Stakeholders and public information engagement: organization of the 3rd National Biobanking Conference and Workshop; conducting QMS audits for biobanks; performing QMS Self Assessment Surveys by Polish Biobanks; creation of the Polish Biobanking Platform (www.polskasiecbiobankow.pl); increasing visibility of BBMRI.pl on websites and social media; organization of the on-site and on-line trainings (e.g. tissue biobanking, QMS, ELSI, financial model of biobank); organization of “Biobanking of Biological Material” course for Pharmacy and Laboratory Diagnostics students at Wroclaw Medical University.


**ADDITIONAL COMMENTS**

**Top publications:**

* (population & disease specific), each collection: 10-10,000 samples.
TOP 3 KEY SUCCESSES IN 2019

1. Improving sample access, leading to a significant increase in sample output to researchers: A main priority during 2019 has been facilitating access to samples for the scientific community. One project cluster has prioritised activities increasing output capabilities of regional joint biobank service facilities, aiming to improve sample access on a national scale. Focus areas include sample handling, reformatting, and improved sample data. In addition, a guide document has been put together with the objective to facilitate access to samples for research and clinical trials, providing guidance for researchers and companies on getting access to existing samples in Swedish biobanks, as well as collecting new samples from persons in Sweden. These initiatives have been highly successful, leading to steadily increasing sample output.

2. Further strengthening sample service and multicentre study coordination: In order to facilitate sample access for researchers, and to stimulate research using Sweden’s rich biobanking sample collections, national sample service coordinators were appointed in 2018. Coordinators provide support to researchers in terms of collecting and accessing samples, as well as guidance to biobank services and existing cohorts/sample collections open to collaboration. In 2019, they successfully coordinated several multicentre studies nationally.

3. Finalising a national IT strategy and launching IT projects with the objective of supporting and stimulating biobank research: As a step towards the implementation of a national IT strategy for biobanking, a national project manager and an IT and operations group were appointed in 2018. The work of the group in 2018-2019 was structured in dialogue with researchers connected to Biobank Sweden, and included performing needs assessments, developing a national IT strategy plan with risk/consequence and time/cost assessments, as well as carrying out prioritisation evaluations for IT initiatives. The national IT strategy was also finalised in 2019, and numerous other projects were launched to support and stimulate biobank research.

* 450 biobanks managed by 6 regional biobank centres
Swiss Biobanking Platform

TOP 3 AREAS OF EXPERTISE

1. **SBP harmonized documentations**: Harmonized documentations (e.g., best practices, SOPs, templates) setting up the foundation for a Swiss biobanking guidance and promoting harmonized practice in accordance with the European and international requirements.

2. **Biobank SQAN**: An interactive tool to help biobanks get compliant with the minimal requirements in terms of governance, process, and quality management, which integrates the different documentations presented below. Through Biobank SQAN labels are delivered as a recognition for compliance with the following minimal requirements:

   a. Ethical and legal issues for the VITA label (governance)
   b. Operational issues for the NORMA label (process)
   c. Quality issues for the OPTIMA label (QMS).

3. **SBP directory**: Visibility of biobanks at the Swiss and European levels through a directory and a request portal for researchers to access high quality samples.

TOP 3 KEY SUCCESSES IN 2019

1. The strategy developed at SBP is to provide biobanks with the necessary documentations to build up and maintain state-of-the-art biobanks, called the SBP guidance (on the left side of the pyramid below). This guidance consists of policies, procedures, and support documents such as templates of forms and datasets. This guidance should be considered as the national foundation allowing harmonization and interoperability of biobanks.

2. To support biobanks in the development of their governance and quality strategies, SBP developed an interactive tool to help biobanks get compliant with the minimal requirements in terms of governance, process, and quality management issues, integrating the different documentations listed above. This tool is an online solution developed in collaboration with Vital-IT, called the Biobank Solution for Quality Assessment and Normalization – “the Biobank SQAN”.

3. A national Material Transfer Agreement (MTA) template was published to govern the transfer and use of human biological material made available by a provider to a non-profit third party wishing to use this research material for its own research purposes. This template will serve SBP clients and researchers. The use of this template is limited to exchanges between academic institutions and is not suitable for exchanges with for-profit organizations.

In Switzerland, biobanks operate with heterogeneous processes, are not registered, making the search for and comparability of samples difficult and their use critical due to compatibility issues of the different sampling methods applied. Moreover, biobanking practice has greatly evolved over the last years, from the individual collection of biological material to professional infrastructures dealing with ethical and legal issues, accessibility and data sharing, reproducibility, data protection and quality leading to a dramatic increase in the costs of biobanking activities. SBP has been created to respond to the needs of the Swiss research community facing these challenges.

SBP is centralizing information on human and non-human biobanks and data collections, which have been established for serving specific scientific questions and ensuring broad access to these data for research purposes. It holds a register of biobanks and data collections in Switzerland. It provides up-to-date technical know-how and training for biobanking and IT management (e.g., “good biobanking practices”, know-how on sampling, samples conservation and information processing), information and counselling on legal and ethical aspects, quality and interoperability of biobanking. Moreover, SBP links Swiss biobanks or networks of biobanks with the European Biobanking and Biomolecular Research Infrastructure (BBMRI-ERIC) as the Swiss national node. It ensures the harmonization of biobanking practices with international and EU standards, provides information on biobanks networks abroad and the related activities.
TOP 3 AREAS OF EXPERTISE

1. Rare and undiagnosed diseases: Clinical expertise on rare diseases and a repository of large consanguineous families

2. Education and training for biobanks

3. Rare cancers and cancer: Clinical expertise on hereditary & sporadic solid and hematological cancers, and a repository of tissue, blood and bone marrow samples.

TOP 3 KEY SUCCESSES IN 2019

1. Organization and participation of several local, national and international education and training activities were held to increase awareness of the importance of Biobanking to create a comprehensive and sustainable rare diseases research ecosystem in Turkey (e.g. Seminars on “The Role of Biobanks in Medical Research and BBMRI-ERIC” on 21-23th of February 2019 in Adana, 22th of November 2019 in Izmir, and 13-14th of December 2019 in Malatya; “Rare Diseases Research Information Day” on 11th of June 2019 by TÜBİTAK’s Bilateral and Multilateral Relations Department at Acibadem University Kerem Aydınlar Campus / Istanbul, ACURare; Teleconferences on Data Harmonization, ELSI and FAIR Principles, Training Methods and programmes with project partners of European Rare Disease Project- EJP RD partners; attendance of “Quality Experts to BBMRI-QM ISO 20387” web conferences; attendance to “EJPRD Biobank Course” in Latvia in 2019)

2. Rare Diseases and Cancer Biobanks projects to increase biological sample & data collection in Turkey, funded by TUSEB calls on Applied Projects in the Field of Personalized and Translational Medicine

3. Contribution to the National Standard Development for Biobanking in Turkey (TÜRKAK, Turkish Accreditation Council) harmonization studies for the General Requirements for Biobanking, ISO 20387
The UK Node, also known as the UKCRC Tissue Directory and Coordination Centre (TDCC) is hosted by the University of Nottingham and University College London. TDCC has a remit to ensure existing resources are used before more samples are collected - therefore TDCC clearly does not further compound the challenge by collecting yet more samples. This also ensures TDCC is independent from any biobank or collection in the UK and can always act as a trusted intermediary. The sole remit is to make sure existing resources can be discovered and accessed, with a revived drive for transparency across the whole ecosystem. This is why we do not and cannot count sample numbers and we believe strongly that biobanking must move away from such metrics if we are to be successful and remain relevant to the increasingly digital world.

We achieve our goal by focusing on the discovery of biobanks, their capabilities, the datasets they can provide and working with industry in a friendly and collaborative environment. All of this technical work is underpinned by world leading engagement activities to ensure we understand the requirements of the researchers who are seeking to connect and engage with biobanks to support their research. We all must do more in collaboration and in the open to make sure we prevent the current greatest mis-use of samples in research, their non-use.

### TOP 3 AREAS OF EXPERTISE

1. Discovery processes, systems and best practice
2. Engagement of key stakeholders
3. Co-creation and collaboration with industry

### TOP 3 KEY SUCCESSES IN 2019

1. Transparency principles launched with Tissue Solutions and Scientist.com the initial signatories (https://biobankinguk.org/transparency-principles/)
2. Supported industry accessing UK samples (https://biobankinguk.org/uk-tissue-for-global-diagnostics/)
3. Highlighted the environmental cost of biobanking and why there is more to sustainability than funding (https://biobankinguk.org/environmental-sustainability-in-biobanking/)
International Agency for Research on Cancer

1. Working closely under the guidance of BBMRI-ERIC for the Infradev - European Paediatric Translational Research Infrastructure project (EPTRI)
2. The Biobank and Population Cohort Network (BCNet) was strengthened further to include biobanks in 34 institutional/governmental facilities across 26 Low- and Middle-Income Countries.

The International Agency for Research on Cancer (IARC) is an executive Agency of the World Health Organization (WHO). The IARC Biobank is part of the Laboratory Services and Biobank group at IARC, and constitutes a fundamental infrastructure of the organisation. The IARC Biobank is one of the largest, most varied and richest International collections of samples in the world.

The Biobank is publicly funded, (approximately 60% of its budget is provided by IARC Participating States through the regular budget and the remainder is from research grants) and hosts over 150 different studies, led or coordinated by IARC scientists over the last three decades.

The IARC Biobank contains both population-based collections from research projects focusing on gene-environment interactions (as in the European Prospective Investigation into Cancer and Nutrition (EPIC) study) and disease-based collections which focus on biomarkers (as in the International Head and Neck Cancer Epidemiology (INHANCE)). Study designs include case-series, prevalence studies, case-control and cohort studies, etc.

### TOP 3 AREAS OF EXPERTISE

1. Supporting international studies on cancer
2. Supporting the creation of international guidelines
3. Supporting operations and training in Low- and Middle-Income Countries

### TOP 3 KEY SUCCESSES IN 2019

1. Working closely under the guidance of BBMRI-ERIC for the Infradev - European Paediatric Translational Research Infrastructure project (EPTRI)
2. The Biobank and Population Cohort Network (BCNet) was strengthened further to include biobanks in 34 institutional/governmental facilities across 26 Low- and Middle-Income Countries.
Notwithstanding any statutory right of third parties to receive or inspect it, this audit report is addressed exclusively to the governing bodies of the Company. The digital copy may not be distributed to third parties unless such distribution is expressly permitted under the terms of engagement agreed between the Company and Ernst & Young Wirtschaftsprüfungsgesellschaft m.b.H.

Considering the requirements of Sec. 274 (7) and (8) Austrian Company Code (UGB), the electronic version does not replace the hardcopy but is an electronic copy thereof.
ANNEX
AUDITOR’S REPORT

BBMRI-ERIC, Graz

Report on the Audit of the Financial Statements as of December 31, 2019 (Translation)

Duplicate

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TABLE OF CONTENT

1. Audit contract and performance of the engagement 1
2. Breakdown and description of significant items in the financial statements 2
3. Summary of audit findings 3
3.1. Compliance of the accounting system and the financial statements 3
3.2. Information provided 3
3.3. Reporting in accordance with Section 273 (2) and (3) Austrian Company Code UGB (exercising the duty to report) 3
4. Auditor’s Report 4-6

INDEX OF APPENDICES

Appendix 1 Financial Statements as of December 31, 2019
Appendix 2 General Conditions of Contract for the Public Accounting Professions
To the co-acting Directors General
BBMRI-ERIC,
Graz

We have completed the audit of the financial statements as of December 31, 2019 of

Biobanking and BioMolecular resources Research Infrastructure -
European Research Infrastructure Consortium (BBMRI-ERIC), Graz
(referred to as "the Company"),

and report on the result of our audit as follows:

1. AUDIT CONTRACT AND PERFORMANCE OF THE ENGAGEMENT

The Company, represented by the Director General, concluded an audit contract with us to audit the financial statements as of December 31, 2019, including the accounting system pursuant to Sections 269 et seqq. Austrian Company Code UGB.

The Company is a small corporation pursuant to Section 221 Austrian Company Code UGB.

The audit is a voluntary audit.

The audit included assessing whether the statutory requirements were adhered to concerning the preparation of the financial statements.

We conducted our audit in accordance with the legal requirements and generally accepted standards on auditing as applied in Austria. These standards require that we comply with International Standards on Auditing. An auditor conducting an audit obtains reasonable assurance about whether the financial statements are free from material misstatement. Absolute assurance is not attainable due to the inherent limitations of any accounting and internal control system and due to the sample-based test nature of an audit, there is an unavoidable risk that material misstatements in the financial statements remain undetected. Areas which are generally covered in special engagements were not included in our scope of work.
We performed the audit, with interruptions, in April 2020 mainly at our premises in Vienna. The audit was substantially completed at the date of this report.

Auditor responsible for the proper performance of the engagement is Mr. Erich Lehner, Austrian Certified Public Accountant.

Our audit is based on the audit contract concluded with the Company. The "General Conditions of Contract for the Public Accounting Professions" issued by the Austrian Chamber of Tax Advisers and Auditors (refer to Appendix 2) form an integral part of the audit contract. These conditions of contract do not only apply to the Company and the auditor, but also to third parties. Section 275 Austrian Company Code UGB applies with regard to our responsibility and liability as auditors towards the Company and towards third parties.

2. BREAKDOWN AND DESCRIPTION OF SIGNIFICANT ITEMS IN THE FINANCIAL STATEMENTS

The breakdown and description of all significant financial statement items are included in the notes to the financial statements. Therefore, we refer to the respective disclosures made by the co-acting Directors General in the notes to the financial statements.
3. SUMMARY OF AUDIT FINDINGS

3.1. Compliance of the accounting system and the financial statements

During our audit, we obtained evidence that the statutory requirements and generally accepted accounting principles in Austria have been complied with.

In line with our risk and controls based audit approach and to the extent we considered necessary for the purpose of expressing an opinion, we considered internal controls related to sub processes of the financial reporting process as part of our audit.

With regard to the compliance of the financial statements with all applicable statutory requirements we refer to the auditor’s report.

3.2. Information provided

The co-acting Directors General provided all evidence and explanations requested by us. We obtained a representation letter signed by the co-acting Directors General which we included in our working papers.

3.3. Reporting in accordance with Section 273 (2) and (3) Austrian Company Code UGB (exercising the duty to report)

During our audit we did not note any facts which indicate there could be substantial doubt about the Company's ability to continue as a going concern, or which indicate a material deterioration of the Company's performance or a material offence of the co-acting Directors General or its employees against Austrian law or the Company's articles of association. We did not note any material weaknesses in the internal controls over the financial reporting process. The financial statements do not meet the requirements for the assumed need of reorganization in accordance with Section 22 Paragraph 1 Subsection 1 URG (Austrian Corporate Restructuring Act).
4. **AUDITOR’S REPORT *)**

Report on the Financial Statements

Audit Opinion

We have audited the financial statements of

**Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium (BBMRI-ERIC), Graz,**

These financial statements comprise the balance sheet as of December 31, 2019 the income statement for the fiscal year then ended and the notes.

Based on our audit the accompanying financial statements were prepared in accordance with the legal regulations and present fairly, in all material respects, the assets and the financial position of the Company as of December 31, 2019 and its financial performance for the year then ended in accordance with Austrian Generally Accepted Accounting Principles.

Basis for Opinion

We conducted our audit in accordance with Austrian Standards on Auditing. Those standards require that we comply with International Standards on Auditing (ISA). Our responsibilities under those regulations and standards are further described in the "Auditor’s Responsibilities for the Audit of the Financial Statements" section of our report. We are independent of the Company in accordance with the Austrian General Accepted Accounting Principles and professional requirements and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibility and liability as auditor is guided by Section 275 par. 2 Austrian Company Code UGB (liability regulations for the audit of small and medium-sized companies) and is limited to a total of 2 million Euros towards the Company and towards third parties.

**Responsibilities of Company's legal representative for the Financial Statements**

The Company's legal representatives are responsible for the preparation of the financial statements in accordance with Austrian Generally Accepted Accounting Principles, for them to present a true and fair view of the assets, the financial position and the financial performance of the Company and for such internal controls as management determines are necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.
In preparing the financial statements, management is responsible for assessing the Company’s ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

**Auditor’s Responsibilities for the Audit of the Financial Statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor’s report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Austrian Standards on Auditing, which require the application of ISA, always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with Austrian Standards on Auditing, which require the application of ISA, we exercise professional judgment and maintain professional scepticism throughout the audit.

We also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
conclude on the appropriateness of management’s use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company’s ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor’s report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor’s report. However, future events or conditions may cause the Company to cease to continue as a going concern.

- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Comments on the Management Report

Pursuant to Section 243 (4) UGB the audited company did not prepare a management report.

Vienna, April 22, 2020

Ernst & Young
Wirtschaftsprüfungsgesellschaft m.b.H.

Erich Lehner mp    Gerald Steckbauer mp
Wirtschaftsprüfer / Certified Public Accountant  Wirtschaftsprüfer / Certified Public Accountant

*) This report is a translation of the original report in German, which is solely valid. Publication or sharing with third parties of the financial statements together with our auditor’s opinion is only allowed if the financial statements are identical with the German audited version. This audit opinion is only applicable to the German and complete financial statements with the management report. Section 281 paragraph 2 UGB (Austrian Company Code) applies to alternated versions.
Legal Notice

Interim Co-Directors General
Carmen Cristea
Michaela Th. Mayrhofer

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Vat Number
ATU 68520549

Bank Details
Name of bank: Hypo Steiermark
IBAN: AT55 5600 0201 4139 7630
BIC: HYSTAT2G

This legal notice applies to the following internet addresses:
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https://www.linkedin.com/company/bbmri-eric
https://www.youtube.com/channel/UCL2h13WcvK4jLq6AkFner4Q

Court Jurisdiction
Court of Justice of the European Union

Name
Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium (BBMRI-ERIC)

Legal Entity
European Research Infrastructure Consortium (ERIC)

Entry Into Force
On November 30, 2013, the BBMRI-ERIC Statutes were published in the Official Journal of the European Union and entered into force three days after publication on 3 December 2013. As from this date, the Biobanking and Biomolecular resources Research Infrastructure (BBMRI) was officially awarded the Community legal framework for a European Research Infrastructure Consortium (ERIC) and is henceforth to be called BBMRI-ERIC.

Philosophy, Nature and Purpose of Business
BBMRI-ERIC is designed to facilitate the joint establishment and operation of research infrastructures of European interest. The ERIC status allows pulling together biobanks and biomolecular resources into a pan-European facility and providing access to collections of partner biobanks and biomolecular resources, their expertise and services on a non-economic basis. BBMRI-ERIC is established for an unlimited period of time.

Procurement and Tax Exemption
BBMRI-ERIC benefits from tax exemption as outlined in Article 6 of the BBMRI-ERIC Statutes.

Members
Kingdom of Belgium, Republic of Bulgaria, Czech Republic, Federal Republic of Germany, Republic of Estonia, Hellenic Republic, French Republic, Italian Republic, Republic of Latvia, Republic of Malta, Kingdom of the Netherlands, Kingdom of Norway, Republic of Austria, Republic of Poland, Republic of Finland, Kingdom of Sweden, United Kingdom of Great Britain and Northern Ireland

Observers
Republic of Cyprus, Swiss Confederation, Republic of Turkey, International Agency for Research on Cancer (IARC/WHO)

Values
The activities of BBMRI-ERIC shall be politically neutral and guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance and human values.