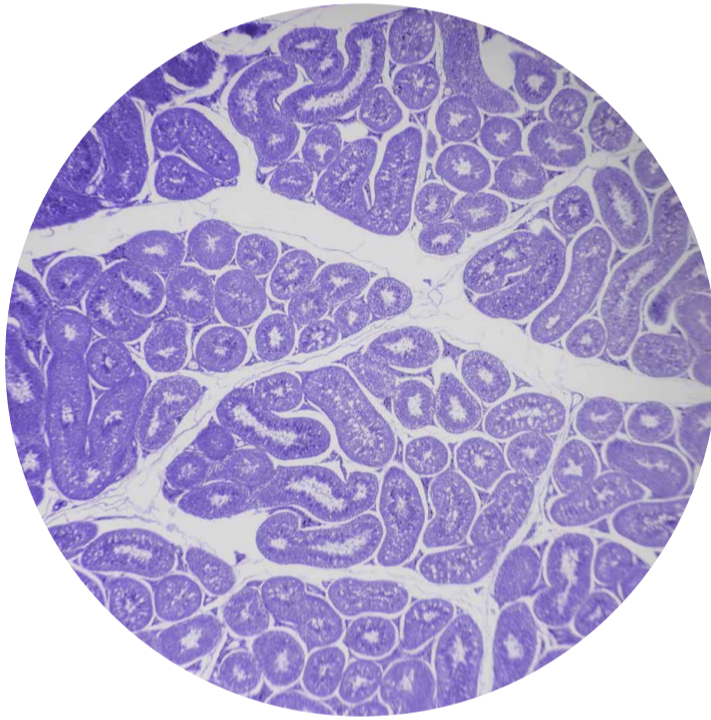


**CONNECT BIOBANKS,
INCREASE VISIBILITY,
FACILITATE ACCESS.**

ANNUAL **REPORT**

2021



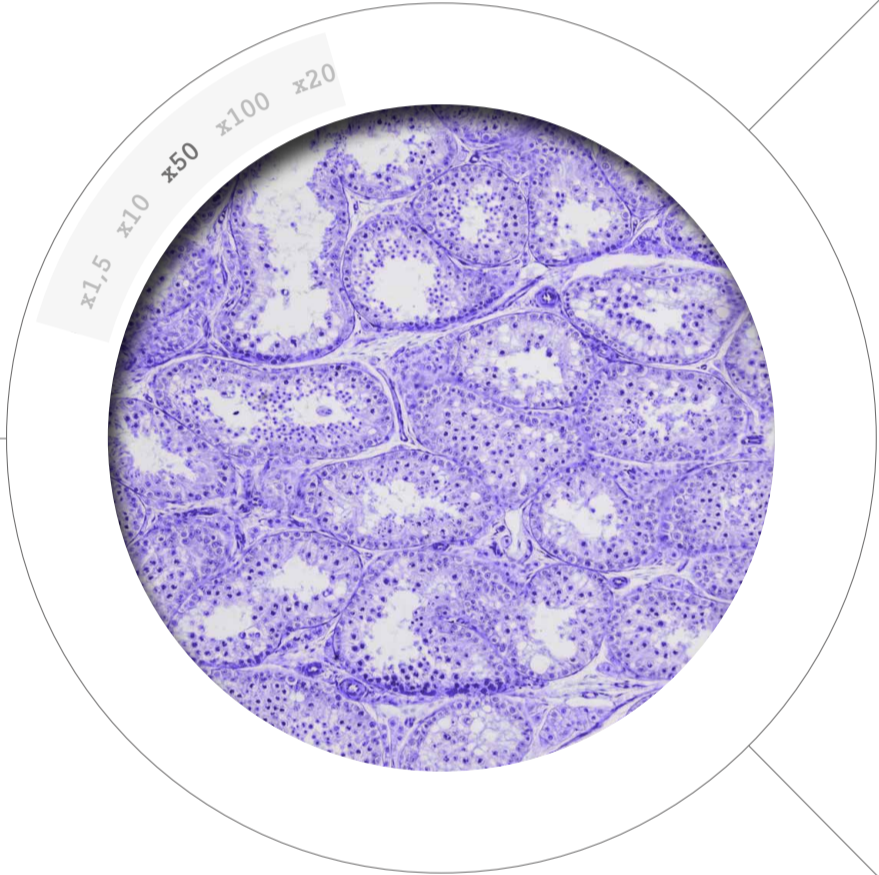
“

Biobanks (and Biomolecular Resources Centres) mean 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,
FACILITATE ACCESS.

INTRODUCTION

The past year has been continuously ruled by the COVID-19 pandemic. BBMRI reacted by further increasing its remote working capabilities, streamlining its management processes and partially restructuring the operational structures of its Headquarters. This enabled BBMRI-ERIC to further advance scientifically and to contribute substantially - by engaging BBMRI's National Nodes and Biobanks - to the COVID-19 proposals ISIDORE and BY-COVID, both being granted the same year. Furthermore, BBMRI successfully coordinated the CanSERV proposal hereby contributing to the acceleration of transnational research in line with the Cancer Mission Board recommendations. CanSERV proved to become a major community engaging cluster-project not only for BBMRI but almost all other partnering Research Infrastructures. CanSERV and EOSC4Cancer, to which the BBMRI community also contributes substantially, were both granted in early 2022. BBMRI increased its alignment with the European Commission on the Code of Conduct for Health Research development and the European Health Data Space 2 (EHDS2) preparation. BBMRI participated in the later proposal providing its IT eco-system dedicated to sensitive health data including its Federated Search and Analysis Platform. The latter is a wider BBMRI community achievement through an intensified datafication process starting with our International IT Symposium in January 2021 in partnership with ESBB. Our strong education activities were further corroborated by advancing towards CME-accredited BBMRI Academy trainings throughout the year and a successful digital Europe Biobank Week congress in November 2021.

BBMRI further grew in its membership and welcomed the communities from Hungary and Spain, the latter one joined BBMRI-ERIC as observer. Thereby, together with our National Nodes, representing 22 European countries and one international organization in 2021, we could not only deliver on the Work Programme 2021 but also ensure organisational stability and successful participation and leadership in several EU funded research proposals. It is thus with some pride that we present our key achievements.

ACHIEVEMENTS OF BBMRI-ERIC'S COMMON SERVICE IT

Following its new launch in April 2020, the Common Service IT (CS IT) has continued development of the services according to the framework plan submitted as a part of the CS IT tender and adjusted to the developing needs of the BBMRI-ERIC and its Nodes. CS IT also added to community engagement with appropriate support to users within the community.

The CS IT has focused on supporting the main mission of BBMRI-ERIC to make biobanks and their collection of biological material from BBMRI-ERIC Nodes findable and accessible. BBMRI-ERIC Directory, the service which ensures basic findability of all the biobanks from the Nodes, and additionally COVID-19 and rare diseases biobanks globally, has received continuous updates on usability: improving search and browsing experience, curating the data in collaboration with the Nodes, deploying FAIR Data Point on the Directory and enabling assignment of persistent identifiers to biobanks. Development of a new major version of the Negotiator 3.0 has started in 2021 with focus on fundamental expansion of flexibility of the platform (e.g., enabling access to services other than access to retrospective collections of samples and data, enabling dynamic construction of the access request forms based on the needs of biobanks participating in the given request). The production version of the Negotiator 2.x focused on usability improvements and integration of the Negotiator with the BBMRI-ERIC Federated Platform (see below).

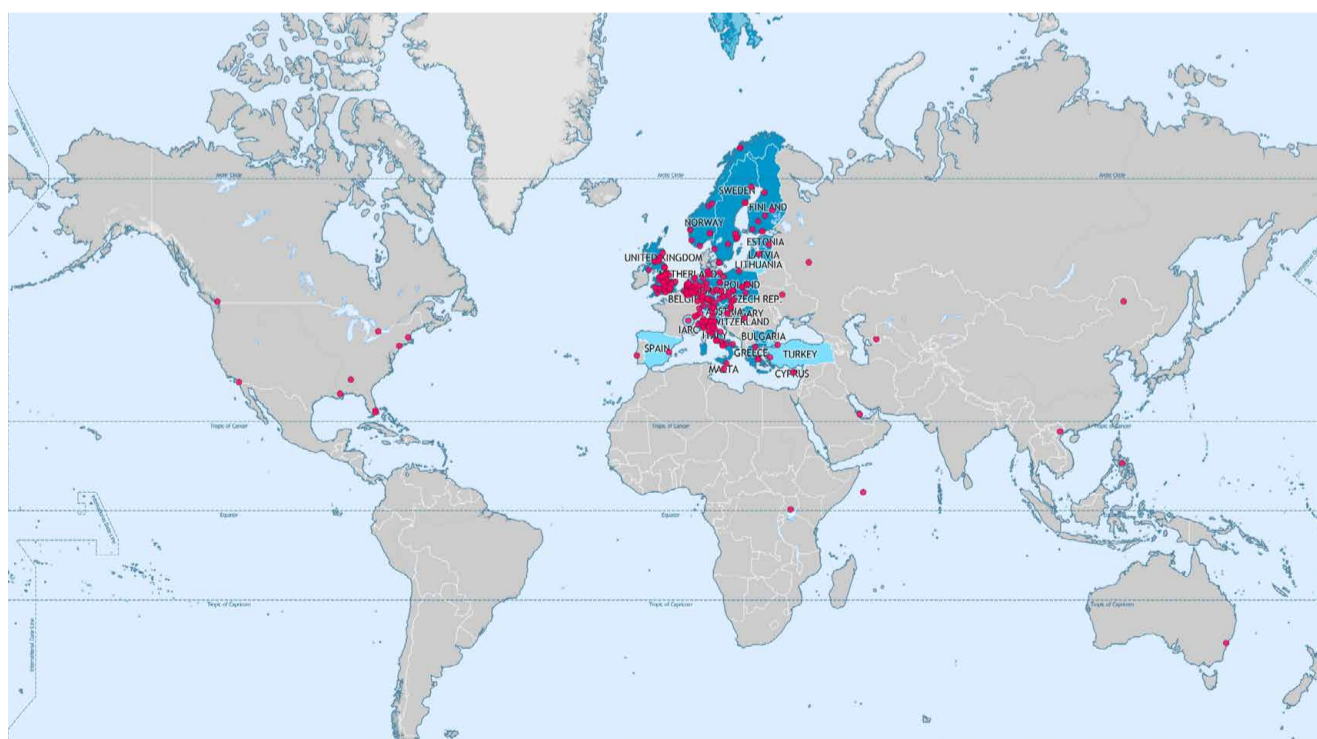


Figure: Biobanks listed in the Directory that offer COVID-19 related samples, cohorts and/or data.

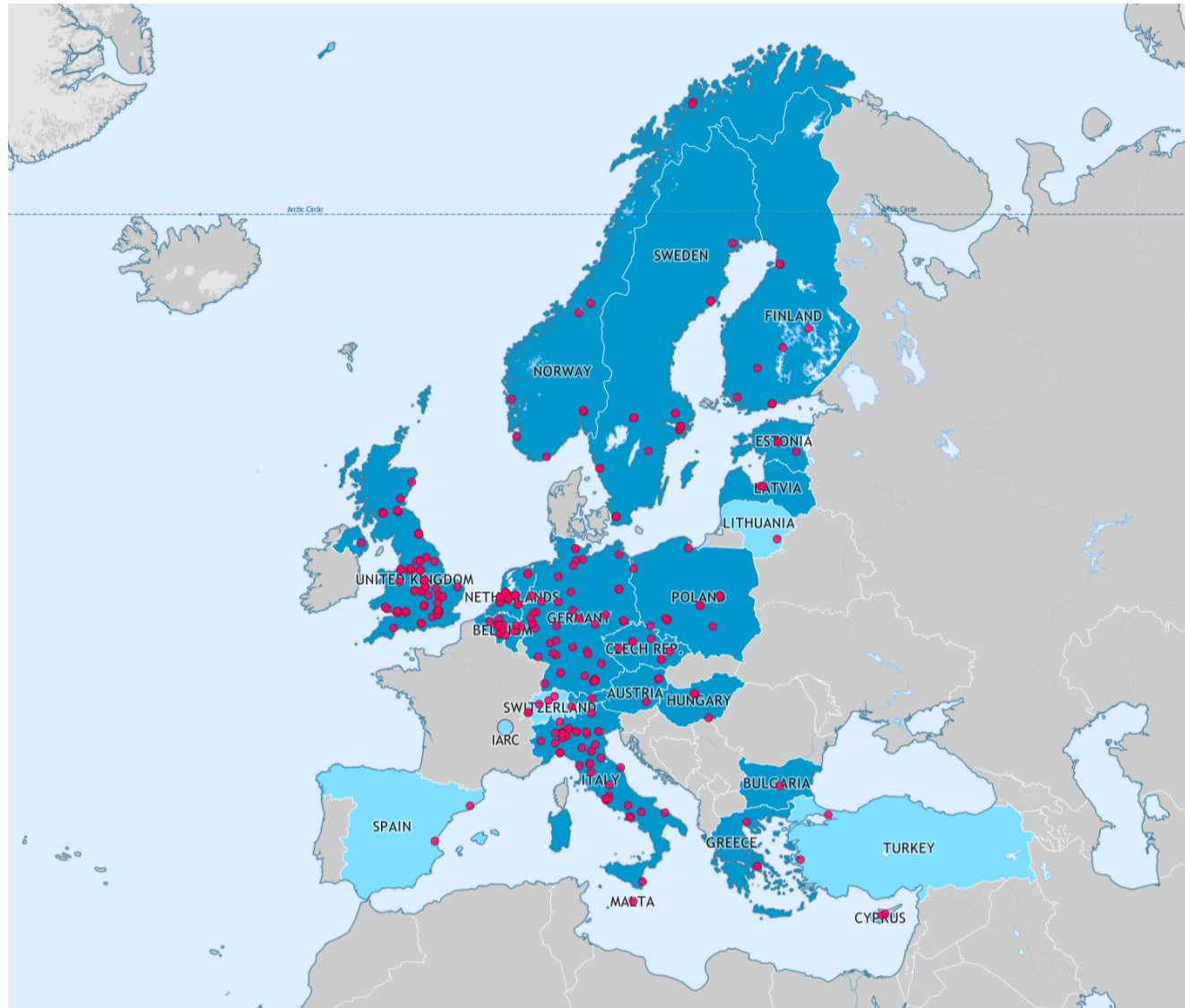


Figure: BBMRI Biobanks within Member States and Observers currently listed in the Directory.

In collaboration with the EOSC-Life project, the CS IT has supported deployment of LifeScience Authentication and Authorization Infrastructure (LS AAI), a common endeavor led by BBMRI-ERIC, ELIXIR and INSTRUMENT with participation of the whole life science Research Infrastructure cluster. CS IT has provided functionality requirements on LS AAI, focused on usability of it through the involvement of the CS IT UX team in design and testing of LS AAI, and prepared a migration plan to move from BBMRI-ERIC AAI to the increasingly adopted LS AAI.

The interoperability team has focused on further development of MIABIS and on setup of the Interoperability Forum. BBMRI-ERIC's MIABIS Core, which is the foundation of aggregated metadata descriptors of biobanks and their collections of biological specimen and data, has been revamped to become version 3.0 which shall be piloted and brought to use in the next phase. The new structure based on the star data model allows presenting different "countables" (such as numbers of samples or donors) for various combinations of variables (such as material types or data types or diseases). The model is backwards compatible while providing a fundamentally new flexibility for services like Directory. BBMRI-ERIC's Interoperability Forum, a vendor-neutral platform for consensus seeking on interoperability between application programming interfaces and related data models, has been restarted. A new scoping of BBMRI-ERIC's Interoperability Forum has been proposed and practical work focused on the Federated Platform architecture and relevant protocols and data models.

Further development of the provenance standards in ISO (standard series 23494 led by BBMRI-ERIC in ISO TC/276) has been funded exclusively from external projects, namely EOSC-Life and BY-COVID

FEDERATED PLATFORM

BBMRI-ERIC has organised an international IT Symposium in January 2021, with the aim to provide a state-of-the-art overview of tools available for both biobank management (biobank and laboratory information management systems) and federated querying of availability of samples and data in biobanks. The Symposium has attracted a broad range of participants from BBMRI-ERIC member states and solution providers from academia and industry on global scale. Utilizing the outcomes of the Symposium, BBMRI-ERIC has formulated its strategy on a federated platform in Q1/2021 and set up the Federated Platform Task Force (FP TF) in order to proceed with its implementation together with BBMRI-ERIC's National Nodes and biobank community. After consulting BBMRI-ERIC's Management Committee which includes all National Nodes, a Call for Tender has been published to select a solution provider for the Platform. The tender resulted in selection of two solutions, one based on BC|Platforms' RQuest system and the other being open-source Locator solution based on developments of DKFZ as a part of German National Node. The FP TF has been co-led by Drs. Zdenka Dudová from BBMRI.cz and Phil Quinlan from BBMRI.uk.

As a part of the FP TF, the initial integration of two solutions into BBMRI-ERIC IT infrastructure has been developed and the solutions have been deployed centrally in BBMRI-ERIC. FP TF proceeded in parallel with onboarding the biobanks into the initial pilot phase, where 16 biobanks from Germany, Czech Republic, UK, Finland, Austria, Malta, Sweden, and Switzerland participated, enabling federated availability querying on more than 250,000 donors. The platform is expected to move out of the pilot phase during 2022 with further onboarding of biobanks. Beside FP TF further taskforces were identified as mechanisms for inter-National-Node collaboration and two out of them – one for Biobank Data Quality & Certification and the other for Expedited Access Procedure for Samples & Data – shall become operative in the coming year.

ACIEVEMENTS OF BBMRI-ERIC'S ELSI SERVICES & RESEARCH

In 2021, thanks to our solid structure comprising of the cornerstones research, services and trainings, our ELSI team of multidisciplinary experts from bioethics, data protection or science and technology studies from both the Headquarters and National Nodes could excel again on its achievements. The strategy to gain new knowledge via research (projects) whilst sharing it further via trainings (esp. webinars, workshops, conferences) and service provisions (especially Knowledge Base, Helpdesk Network) paid off, resulting in more than 1000 participants attending live events with an ELSI focus that BBMRI-ERIC (co-)organised with National Nodes or in the context of a research project. This includes more than 20 webinars and conference sessions led by BBMRI, including a session on the ethics of AI at Europe Biobank Week congress 2021 (EBW2021).

The digital International Conference "Biosamples & Biodata in Medical Research - ELSI Challenges", for instance, aimed at an interdisciplinary reflection from physicians, diagnosticians, lawyers, philosophers, ethicists, political scientists, sociologists on regulatory, normative, and axiological problems related to biosamples and biodata. Jointly realised by the Department of Humanities and Social Medicine, Medical University of Lublin, Poland, BBMRI.PL, and BBMRI-ERIC, the conference aimed for best practices that respect human dignity, fundamental rights, legal norms, social expectations, and cultural beliefs in management of biosamples and biodata. It attracted more than 200 participants across 20 countries (Poland, Italy, Spain, Portugal, France, Belgium, Turkey, Germany, Austria, Czech Republic, Estonia, Latvia, Lithuania, Sweden, Finland, Romania, Switzerland, Hungary, Greece, Australia).

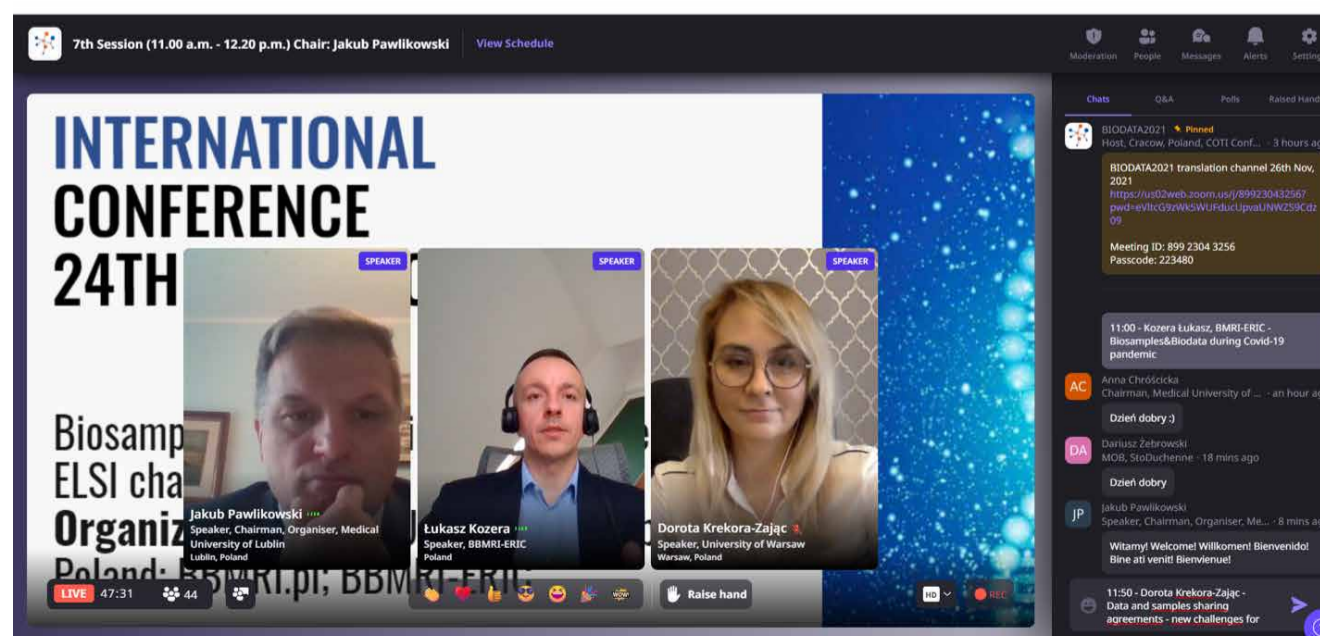


Figure: International Conference "Biosamples & biodata in Medical Research - ELSI Challenges"

Furthermore, the ELSI Helpdesk received 93 requests to date since 2017, thereof 61 requests in 2021 equaling 470 person hours of expertise provided on multidisciplinary topics reaching from GDPR compliance, access procedures, risk assessment to IP rights and gender aspects in research. Whereas some requests can be solved in less than an hour, substantial requests took up to 40 hours, requiring research and consultation among the ELSI Helpdesk Network experts.

Furthermore, improvements in design and content have been implemented for the ELSI Knowledge Base, our open-access resource platform. A graphically appealing design and a simple structure based on topics, common challenges and guidelines to good research promote know-how on legal, ethical and societal issues. Exemplarily, the article "Biobanking with Children" allows to learn why and how to engage with minors and involve them in biobanking as a best-practice in a participatory and dynamic way.

Moreover, our ELSI experts from both Headquarters and National Nodes as Linked Third Parties (LTPs) continue to steadily provide their expertise in more than 20 research projects and proposals, among them B1MG, EOSC-Life, CY-Bio-bank, CINECA, BigPicture, EUCanImage, or Healthy Cloud. Most notably, research is conducted on the ethics of AI, risk typologies, translational data transfer leading to 5 publications in 2021.

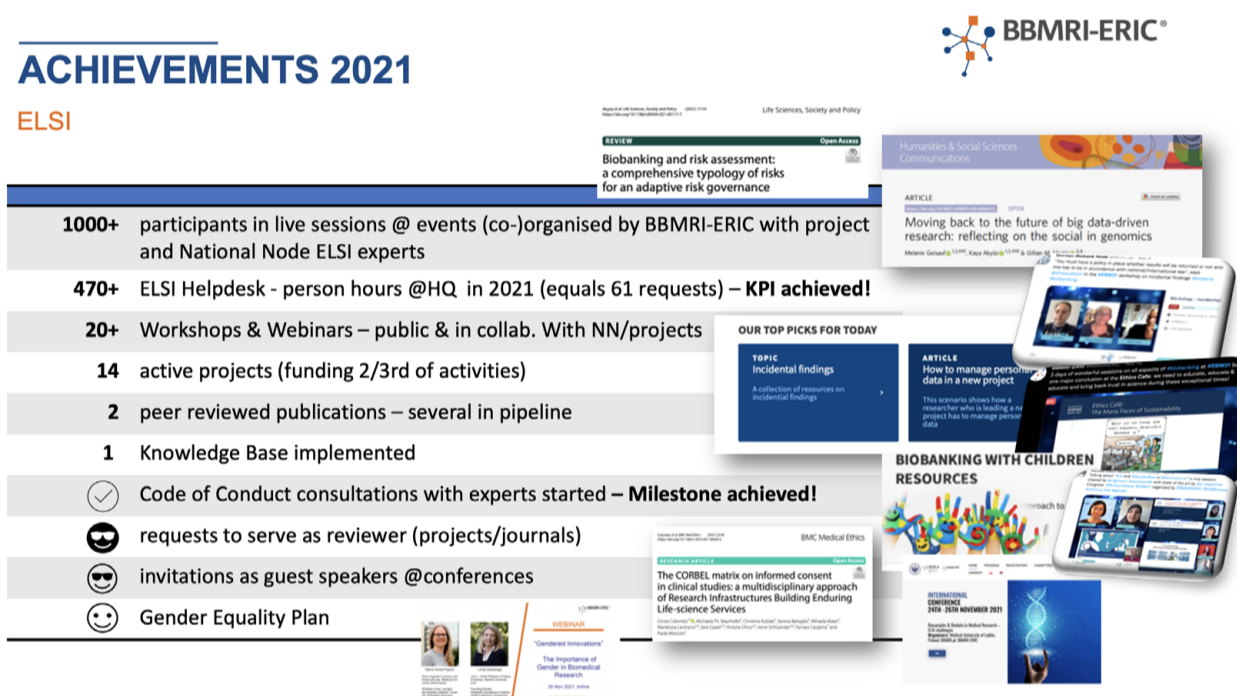


Figure: ELSI Key Achievements 2021

ACHIEVEMENTS OF BBMRI-ERIC'S QUALITY MANAGEMENT

In the year 2021, BBMRI.QM was pleased to have an exceedingly large community engagement within member and observer countries and beyond.

The BBMRI.QM webinar training series on the biobank standard ISO20387:2018 reached a significant part of the community with over 280 participants (live participation and watching recordings) and laid the foundation for the community to take further ambitious steps in the implementation of the new standard in the biobanks.

BBMRI.QM has continued to promote and make available to the community the extensive range of biobank-relevant BBMRI-ERIC Self-Assessment Surveys (SAS). These assessment forms support biobanks in self-assessment to determine the implementation of quality requirements according to international standards. Subsequently, the biobanks have the possibility to receive a Quality Label on the biobank or collection level through the BBMRI.QM audit program, after a positive assessment. In 2021, access to the BBMRI-ERIC SAS was requested and processed a total of 71 times. Finally, 17 BBMRI-ERIC SAS reports were submitted to BBMRI.QM and based on a positive evaluation, Quality Labels were issued to 13 collections and 2 biobanks.

It is a great success that the first biobank within our community, the Wrocław Medical University Biobank (WMU Biobank) of the Polish National Node BBMRI.pl, underwent the BBMRI-ERIC audit program and was able to successfully demonstrate that the WMU Biobank has implemented a quality management system (QMS) according to the principles of ISO 20387:2018 and performs and maintains its processes according to the requirements of the international standard.

The Polish Stem Cells Bank (PBKM - Polski Bank Komórek Macierzystych) followed this success story and - based on strict audit criteria - was also successfully awarded a Quality Label according to the biobanking standard in the BBMRI-ERIC directory. Other Polish biobanks, such as the Biobank Fahrenheit'a in Gdansk and the Port Biobank of the Łukasiewicz Research Network have completed the on-site audit, which was performed on behalf of BBMRI-ERIC, and are in the final phase of the audit program.

<p>▶ PL - Polski Bank Komórek Macierzystych S.A.</p> <p>Quality mark(s): BBMRI audited ISO 20387:2018 ✓</p>	<p>Collection types: Sample collection, Birth cohort, Population-based</p> <p>Juridical person: Polish Stem Cells Bank</p> <p>Covid-19: BSL-2 laboratories available, Ability to set up clinical trials</p>
<p>▶ Wroclaw Medical University Biobank</p> <p>Quality mark(s): ISO-9001:2015 ✓ BBMRI audited ISO 20387:2018 ✓</p>	<p>Collection types: Disease specific, Sample collection, Hospital, Cohort, Longitudinal, Population-based, Cross-sectional</p> <p>Juridical person: Wroclaw Medical University</p> <p>Covid-19: Laboratories doing PCR-based diagnosis, Ability to set up prospective collections</p>

Figure: Visualization of Quality marks in the BBMRI-ERIC Directory

In addition, 5 biobanks indicated the possession of 3rd party certificates (4x ISO 9001, 1x ISO 17025) which were registered accordingly in the BBMRI-ERIC Directory.

BBMRI-ERIC Expert Centres are our trusted partners who integrate pre-competitive public and private research and development activities by providing access not only to biological samples and medical data but also to the broad spectrum of medical and scientific expertise related to the samples, data, and their analysis. The fulfilment of the defined QA/QC requirements for these centres was reviewed and for CBmed and CNAG-CRG during an audit confirmed.

Our QM community, which has grown over the years to more than 140 quality and biobank experts, has been invited to meet three times in 2021 as part of the "Working Group QMS" for an in-depth exchange on experiences in implementing the biobanking standard in their biobank QMS and to take further steps towards standardisation and harmonisation to enhance sample quality. Determining user satisfaction was identified as an important, overarching action point that we will jointly work on in 2022.

Under the motto "Get insights from the outside", the brand-new, quarterly virtual format of consultation hours on quality-related topics in the field of biobanking and biomedical research and development was successfully launched. With the short presentation of the QM activities from the National Nodes (EE, PL, AT, CH, TR, NO, CY, DE, LT) and IARC, outstanding guest speakers and the possibility to exchange with the community, we were not only able to attract a total of 287 participants from our member and observer countries, but also from France, India, Portugal and Egypt.

Designated QM tasks in projects such as the IMI projects ConcePTION and European Platform for Neurodegenerative Diseases (EPND) or the H2020 projects SPIDIA4P, EDIRex, CliniMARK, CY-Biobank, IC2PerMed have been conducted and the project results mark a milestone in knowledge gain to benefit the entire BBMRI-ERIC community. This consists of access to and exchange of project results like biobank QM specific document templates, process descriptions, audit programs, standards and guidelines and tailored training concepts.



Figure: SPIDIA4P Standards + Innovation Award 2021

In addition, new projects such as EPND and the ongoing DIAMONDS project were added to the BBMRI.QM portfolio. The kick-off of the EPND project marked the start of comprehensive QM activities in the field of biobanking to facilitate biomarker research for neurodegenerative diseases.

BBMRI.QM has been involved in the DIAMONDS project to monitor the biobank processes established as part of the study in 2022, using the biobank of the Medical University of Graz as an example.

The CY-Biobank project deserves special mention. A QM- and Document Management system were setup as part of the WP3 tasks in the framework of the project. QMS trainings for ISO 9001:2015 implementation in the biobank.cy Centre of Excellence administration were performed. To evaluate the QMS, an internal audit in a hybrid format with on-site and remote presence of BBMRI.QM team members was carried out in 2021. A comprehensive Management Review and an external audit for ISO 9001:2015 certification by the Cyprus Organisation for Standardisation is planned to be performed in 2022. In parallel the biobank.cy is build up according to the international biobanking standard ISO 20387:2018.

The four-part series of Virtual Round Tables in the IC2PerMed project focusing on biobanking, data, ELSI and quality as well as the common intersections was initiated. Renowned European and Chinese experts presented and discussed the European and Chinese perspectives/challenges and future trends in Personalised Medicine (PM). This series strongly supports the project objective of fostering common approaches on PM research, development, innovation, and policies by collaboration.

In the EDIReX project, seven audits at the participating consortium partner sites (BE, FR, IT, NL, SP, UK) were successfully conducted by BBMRI.QM, with the aim to monitor the compliance and local implementation of standards developed for health monitoring, biobanking and quality control in patient-derived cancer xenografts.

The four-year SPIDIA4P project was completed in 2021 with great success. In the last year, 8 new standards, addressing the pre-analytical workflows applied to PM, were published on the European and international level. In addition, the in-depth trainings on the "pre-analytical standards" were continued and completed with 16 virtual sessions and 122 registrants from 23 countries in total. The European Committee for Standardisation CEN / CENELEC also acknowledged the important contribution of research and innovation to standardization of the project and rewarded the Standards + Innovation Award 2021 (in the category "European research/innovation project").

The new training format BBMRI.QM Academy was kicked off with a virtual three-part series about the "pre-analytical phases of biobanking". It attracted 406 participants from 31 countries and was very well received. The participants' efforts towards continuous medical education (CME) and professional development could be rewarded for the first time with CME Certificates for full participation in the live educational webinars by BBMRI-ERIC. In total 159 European CME Certificates, accredited by the European Accreditation Council for Continuing Medical Education (EACCME®), were issued.

Liaisons with ISO and CEN were continued and liaisons with national accreditation bodies of Germany (DAkks), UK (UKAS) and Turkey (TURKAK) were intensified. A virtual 3-day training for more than 40 assessors on the accreditation standard was successfully conducted for TURKAK in 2021.

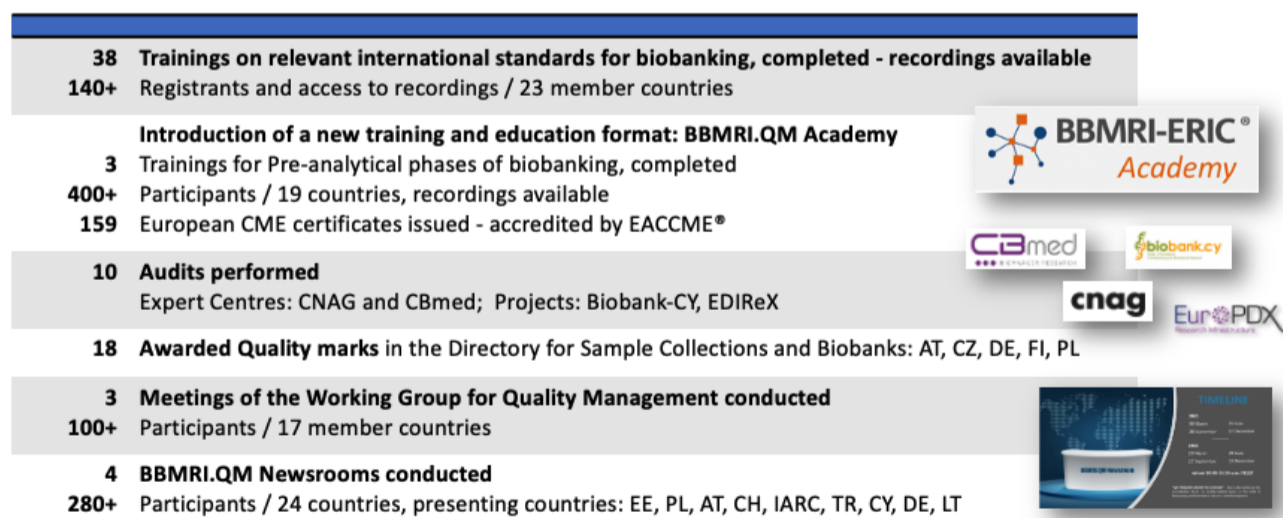


Figure: QM highlights 2021

BBMRI-ERIC'S COOPERATIONS WITH MEMBER STATES AND KEY PARTNERSHIPS

BBMRI-ERIC's membership continues to grow

In 2021 BBMRI-ERIC continued to grow in its membership. Hungary joined as full members and Spain as an Observer. With these countries BBMRI-ERIC counts 23 Members and Observers in 2021, thus being one of the biggest European Infrastructures in terms of membership. BBMRI-ERIC also drove forward discussions with other countries in Europe and there has been an interest towards memberships also from non-EU countries. In this respect BBMRI-ERIC has started to prepare a policy exploring membership of third countries in BBMRI-ERIC. Also in 2021, we have started the official onboarding process for new members/observers of BBMRI-ERIC. As part of this process, we analyze the needs of each newly admitted country and organise a special workshop for the biobanking community to ensure that new members and observers can start developing their national infrastructure and competences based on the targets for the entire research infrastructure. In 2021, such workshop was organised for Hungary, and in the following year it will be organised for those countries that joined at the later time.

Relations with existing MS and observers

Despite the pandemic, the Director General and BBMRI-ERIC senior staff took part upon invitation in several national meetings of the biobanking communities. For example, the Director General addressed the meetings of the Belgian, Finish, German, Lithuanian, Norwegian, Polish, and Turkish communities. Prof. Habermann also discussed with key UK actors, such as the leadership of the UK Biobank and the Health Data UK, how to strengthen the relationship between the health and biobanking communities post-Brexit.

Stakeholder Forum

During 2021, BBMRI-ERIC's efforts were focused on fully reviving the relations with patient organizations. In this respect, three meetings of the Patient and Citizens Pillar took place, as well as the participation of patient organizations was key in organizing the workshop on trusted research environments as well as two sessions focused on the role of patient organizations in biobanking during the Europe Biobank Week. Besides these two priorities, another important focus of the group's work was on cancer, in particular pediatric cancer, as well as tackling cancer on the policy level through the EU Mission on Cancer.

ERIC Forum

As the coordinator of the ERIC-Forum project, BBMRI-ERIC continued to ensure timely and qualitative implementation of project activities. We organised the annual meeting of the ERIC Forum community and key external stakeholders, such as ESFRI, EU Presidencies, EC and EOSC, and brought together over 170 participants in an on-line venue. Moreover, BBMRI-ERIC was fully engaged in working on the long-term sustainability of the ERIC Forum and was supporting the ERIC Forum and its Chair as the secretariat. BBMRI-ERIC was also fully engaged as a partner in the RI-VIS project, which explored international links of European RIs. These activities not only raised the profile of BBMRI-ERIC within the community, but also with the key external stakeholders listed above, which are key also for BBMRI-ERIC's bilateral relations in the overall European arena.

Key partnerships

In particular, BBMRI-ERIC became a member of the EOSC Association in 2021. With this membership BBMRI-ERIC gets to fully participate and co-build this key European partnership in Europe, that will set the ecosystem for hosting and exchange of research data. BBMRI-ERIC continued to build a close partnership with other life-science RIs, successfully conducted its coordinating role of the ERIC Forum project, entered into EOSC Association membership, and maintained its fundamental role in the EOSC-Life project; thereby overall significantly contributing and sharing of its expertise to the rest of the community. BBMRI-ERIC also increased its engagement with the EU AMRI partners, conducting three retreats while preparing for the EU-AMRI launch event which had to be postponed to 2022 due to the COVID pandemic. The EU-AMRI partners published several position papers on pertinent EU policy issues and launched a joint website of the alliance. New venues for partnerships were explored with ESBB (European, Middle Eastern & African Society for Bio-preservation & Biobanking), EVAg (European Virus Archive), ECRAID (European Clinical Research Alliance on Infectious Diseases), the Trisomy 21 Cluster of EBRA (European Brain Research Area), and EUHA (European University Hospitals Alliance) within its GRAIN group (strateGic pRojects Accelerator fundIng eNgine). Close relationships with these will continue to be further defined in 2022 while a Memorandum of understanding has been signed with EORTC (European Organization for Research and Treatment of Cancer) in spring 2021. Last but not least, BBMRI-ERIC continued to be an active member of the European Health Coalition.

MAGNIFYING THE MESSAGES FROM OUR MEMBERS

Accelerating the achievements from our National Nodes and new Members through social media, our website and the monthly newsletter as well as continued outreach and dissemination activities as WP leads in the H2020 projects RI-VIS and EOSC-Life - including management of social media and websites for EOSC - was our key focus in 2021. We completed and promoted many ELSI and Quality webinars focusing on our BBMRI community. We also completed a deep reset of some of our BBMRI-ERIC website pages: the ELSI Knowledge Base, the IT section and the Jobs page are the best examples. Early 2021, we strongly supported our International IT Symposium conducted in partnership with ESBB. Due to COVID-19 related travel restrictions in 2021, most conferences took place in the virtual space; we focused on bringing our expertise in supporting these virtual meetings on social media and in providing efficient and professional technical support.

EUROPE BIOBANK WEEK

In autumn 2021, the most important biobanking event remained the Europe Biobank Week (EBW), which was co-organised with our long-time partner ESBB, the European, Middle Eastern & African Society for Biopreservation and Biobanking. With the theme "Biobanking for our Future - Opportunities Unlocked", our annual biobanking conference attracted 420 attendees and 16 sponsors from 42 countries to the virtual space. With 29 sessions on a variety of topics from animal, plant and human biobanking, covering key areas ranging from ethical, quality management and machine learning aspects to data protection, participants were able to expand and deepen their knowledge. The EBW 2021 conference platform, Swapcard, remains accessible for 12 months following the end of the conference for registrants, who will find all session recordings and e-posters available on-demand.

COVID-19 SPECIFIC

Capturing Availability of Samples and Data in the Directory

Given the world-wide implications of the pandemic, BBMRI-ERIC had extended its global scope of the Directory beyond rare diseases and continued also in 2021 cataloging resources also from non-Member States, advertising this opportunity on a regular basis. BBMRI-ERIC's directory captures now the availability of COVID-19 samples and data from 60 biobanks with existing COVID-19 samples and data. In addition, 33 biobanks are listed offering capability to set up prospective collections with COVID-19 samples/data, based on tailored user needs. Lastly, the Directory captures information on specific capabilities of biobanks related to infectious diseases such as availability of BSL-2/3 laboratories.

Providing Guidance on Ethical, Legal and Societal Issues

Public health ethics, personal data protection, ethics of data sharing, protection of consent and vulnerability as well as compliance issues within international data sharing have remained topics relevant for COVID-19 research. Against this background, BBMRI.ELSI continued to engage in research proposals (e.g., BC-COVID) and provide trainings and support on a case-by-case basis (e.g., Helpdesk requests).

Participating in COVID-19 Calls

BBMRI-ERIC substantially contributed to the BY-COVID and ISIDORE proposals with our core services and developments in ELSI, Quality, IT and BBMRI biobanks providing COVID-19 related samples and/or data. Both proposals were selected for funding in 2021 and will further enable our biobanking community to showcase its fast response capabilities and scientific expertise beyond service provision for samples and data.

Responding in Collaboration with other LS RIs

Under the umbrella of the Alliance of Medical Research Infrastructures (AMRI), the COVID-19 Fast Response Service had been set up and has been continued as a coordinated effort to accelerate procedures for researchers to access the academic facilities, services and resources of the three medical research infrastructures: the European Research Infrastructure for Translational Medicine (EATRIS), the European Clinical Research Infrastructure network (ECRIN) and BBMRI-ERIC. Research requests are handled via a single point of contact, with a targeted turnaround time of three working days or less.

CORE BUDGET EXPENDITURES AND ALLOCATED COMPETITIVE RESEARCH GRANTS

COVID-19 has required us to navigate and constantly monitor changes that impacted the financial forecasts and adjust resources wherever necessary. Deviations from the forecasts were reported, as expected, predominantly on travel and meetings budgets across all services and active projects, since a significant part of our activities were moved online. However no major deviations were recorded, and the financial impact of COVID-19 is ultimately not material for the overall financial health of BBMRI-ERIC.

In addition, five new proposals received funding, officially starting in 2021 (BY-COVID, EOSC Future, EPND, HealthyCloud and) Intervene, securing roughly 1.400,000€ in competitive research grant funding for BBMRI-ERIC with project duration between three to five years.

In conclusion, 2021 further showcased that BBMRI-ERIC successfully adapted to the prolonged challenges of the COVID-19 pandemic whilst further advancing scientifically and ensuring financial and organizational sustainability.

Sincerely,

The BBMRI-ERIC Headquarters Team

May 2022

Services

DIRECTORY

618

biobanks
connected

3172

collections

32

countries contributing
collections

648

average users
per month

NEGOTIATOR

2151

collections
represented

959

total
users

QUALITY

17

Self-Assessment
Survey completions in 2021

13

additional collections
with Q-mark in 2021

2

Additional biobank
with Q-mark in 2021

ELSI

Milestone Q3/2021: Code of Conduct Consultation starts with draft sections among experts

109 of Ethics Checks, ELSI Helpdesk requests and consultations (2017 - 2021)

61 requests in 2021 equaling 470 person hours in 2021.

KEY FIGURES

17

member states

6

observers

22

projects underway
in 2021

7.8M

overall budget

SOCIAL MEDIA

409

new followers
twitter

240

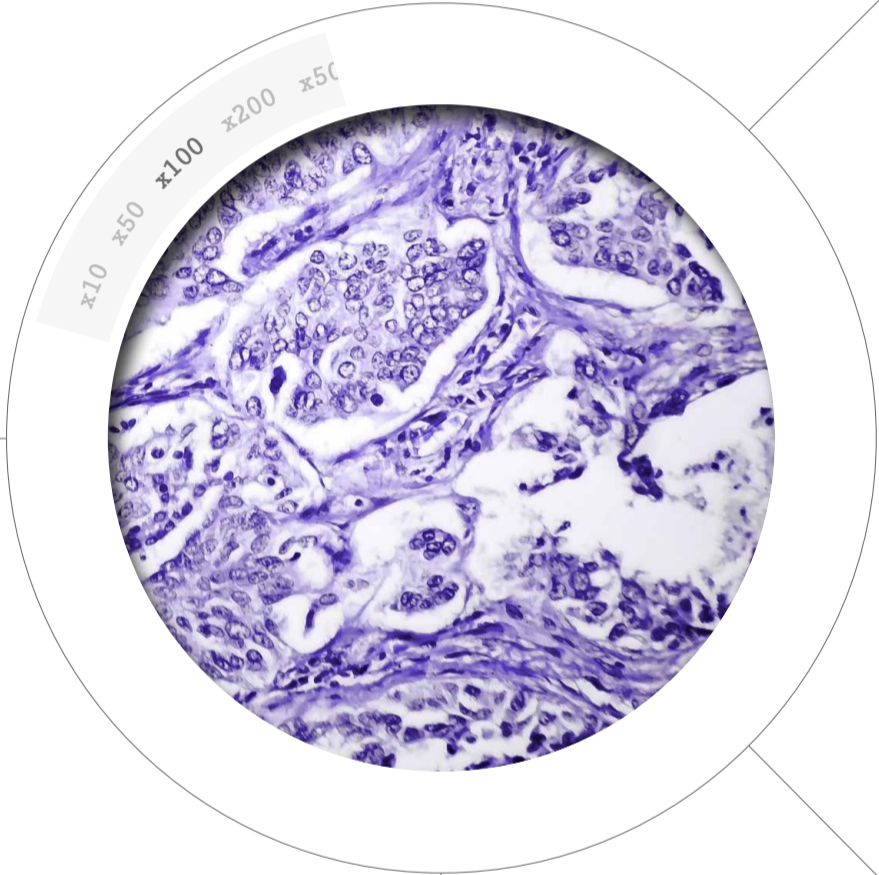
new followers
linkedin

380.000

impressions for social media
over the year 2021

PART 2

FINANCIAL INFORMATION



CONNECT BIOBANKS,
INCREASE VISIBILITY,
FACILITATE ACCESS.

Profit & Loss Statement

In EUR	2015	2016	2017	2018	2019	2020	2021
Turnover	3,631,636	888,860	2,892,951	3,050,231	4,091,202	3,305,108	3,292,908
Other operating income	62,137	-	629	1,068	10,882	8,907	7,441
Material Expenses	-	-	-	-	-	-	-
Staff expenses	(887,215)	(1,554,036)	(1,689,010)	(1,647,023)	(1,840,023)	(2,143,081)	(2,477,511)
Amortization	(30,454)	(30,020)	(29,518)	(35,896)	(31,683)	(30,000)	(54,819)
Other operating expenses	(687,764)	(1,172,010)	(1,367,820)	(1,464,964)	(1,676,029)	(847,735)	(758,648)
Operating result	2,088,340	(1,867,207)	(192,768)	(96,584)	554,348	293,198	9,371
Other interest and similar income	16	-	-	-	-	-	-
Interest and similar expenses	-	(58)	(30)	(41)	-	(54)	(204)
Financial result	16	(58)	(30)	(41)	-	(54)	(204)
Loss from operating activities, Earnings before taxes	2,088,356	(1,867,265)	(192,798)	(96,626)	554,348	293,144	9,167
Taxes on income and revenue	(4)	-	-	-	-	-	-
Profit of the year	2,088,352	(1,867,265)	(192,798)	(96,626)	554,348	293,144	9,167
Reversal of profit reserves	-	1,867,265	(192,798)	(96,626)	-	-	-
Allocation to profit reserves	(2,034,352)	-	-	-	(554,348)	293,144	(9,167)
Profit carried forward from the previous years	313,775	367,775	367,775	367,775	367,775	367,775	367,775
Balance sheet profit	367,775	367,775	367,775	367,775	367,775	367,775	367,775

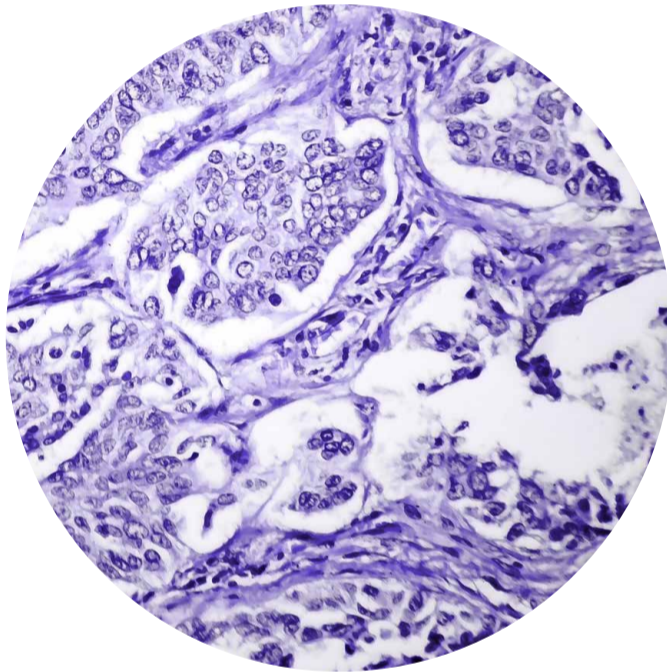
Balance Sheet

In EUR	2015	2016	2017	2018	2019	2020	2021
Intangible Assets	3,840	2,560	1,280	8,459	5,639	2,820	91,920
Tangible Assets	112,120	87,759	73,274	55,924	66,339	54,414	41,891
Fixed Assets	115,960	90,320	74,554	64,382	71,978	57,233	133,811
Receivables and other Assets	93,179	145,488	199,669	1,164,191	343,225	299,341	439,425
Receivables arising from deliveries services	130	9,249	126,626	134,301	86,743	93,001	254,117
Other receivables and assets	93,049	136,239	73,043	1,029,890	256,482	206,340	185,308
Cash on hand and Bank deposits	3,625,026	1,970,135	2,189,624	1,645,101	2,916,641	2,491,713	2,667,526
Current Assets	3,718,204	2,115,623	2,389,293	2,809,292	3,259,867	2,791,055	3,106,951
Prepaid expenses, deferred charges	250	3,581	5,919	13,332	5,031	2,811	3,923
Assets	3,834,415	2,209,523	2,469,766	2,887,006	3,336,876	2,851,099	3,244,685
Reserves pursuant to the articles of association	2,193,362	326,097	133,300	36,674	591,022	884,166	893,333
Balance sheet profit	367,775	367,775	367,775	367,775	367,775	367,775	367,775
Investment grants	-	-	-	-	-	-	13,189
Capital and Reserves	2,561,137	693,872	501,075	404,449	958,797	1,251,941	1,274,297
Other accruals	24,669	52,800	128,178	832,308	157,473	68,792	127,273
Accruals	24,669	52,800	128,178	832,308	157,473	68,792	127,273
Liabilities arising from deliveries and services	31,407	54,179	58,187	164,723	226,636	30,026	246,162
Other liabilities	24,823	204,924	157,418	131,022	385,357	396,798	221,866
Liabilities	56,230	259,104	215,604	295,745	611,993	426,824	468,027
Deferred income	1,192,378	1,203,748	1,624,910	1,354,505	1,608,612	1,103,541	1,375,087
Liabilities and Owner's Equity	3,834,415	2,209,523	2,469,766	2,887,006	3,336,876	2,851,099	3,244,685

Cash Flow

In EUR	2016	2017	2018	2019	2020	2021
Profit of the year	(1,867,265)	(192.798)	(96.626)	554,348	293,144	9,167
Amortization	29,955	28.096	31.878	31,683	30,000	54,819
Cash Flow from the Result	(1,837,309)	(164.702)	(64.748)	586,031	323,144	63,986
Δ Receivables arising from deliveries services	(9,119)	(117.377)	(7.675)	47,559	(6,258)	(161,116)
Δ Other receivables and assets	(43,190)	63.196	(956.847)	773,407	50,142	21,032
Δ Liabilities arising from deliveries and services	22,772	4.007	106.536	61,913	(196,610)	216,136
Δ Other liabilities	180,102	(47.507)	(26.396)	254,335	11,441	(174,932)
Δ Prepaid expenses, deferred charges	(3,331)	(2.337)	(7.414)	8,301	2,221	(1,113)
Δ Accruals	39,500	496.540	433.725	(420,727)	(593,752)	330,027
Δ Investement grants					-	13,189
Δ Working Capital	186,733	396.523	(458.070)	724,789	(732,817)	243,223
Cash Flow from Operations	(1,650,576)	231.820	(522.817)	1,310,820	(409,672)	307,209
Investing / Deinvesting	(4,315)	(12.331)	(21.706)	(39,280)	(15,256)	(131,397)
Cash Flow from Investing Activities	(4,315)	(12.331)	(21.706)	(39,280)	(15,256)	(131.397)
Δ Capital and Reserves						
Cash Flow from Financing Activities	-	-	-	-	-	-
Total Cash Flow	(1,654,891)	219.490	(544.523)	1,271,540	(424,928)	175,813
Cash Beginning	3,625,026	1.970.135	2.189.624	1,645,101	2,916,641	2,491,713
Δ	(1,654,891)	219.490	(544.523)	1,271,540	(424,928)	175,813
Cash End	3,625,026	1,970,135	2.189.624	1.645.101	2,916,641	2,667,526

Report on the Audit of the Financial Statements as of December 31, 2021
(see end of this Annual Report)





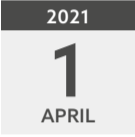


PART 3

PROJECTS

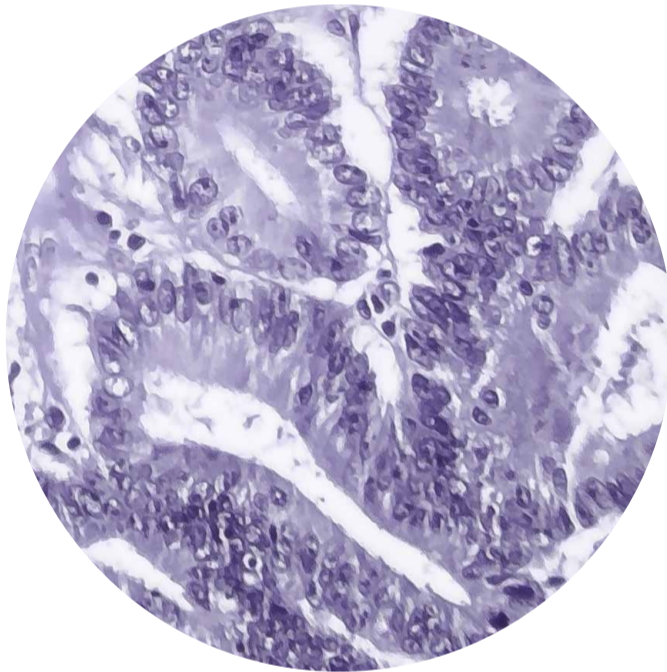


CONNECT BIOBANKS,
INCREASE VISIBILITY,
FACILITATE ACCESS.

Projects Launched in 2021

INTERVENE	HealthyCloud	EOSC-Future	BY-COVID
BBMRI-ERIC Budget* € 349,975.00	BBMRI-ERIC Budget € 311,875.00	BBMRI-ERIC Budget € 68,312.50* (+LTP 93,750.00)	BBMRI-ERIC Budget € 312,868.75 (+LTP 739,079.00)
Start Date 	Start Date 	Start Date 	Start Date 
International consortium for integrative genomics prediction	Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research	Integration and consolidation of the existing pan-European access mechanism to public research infrastructures and commercial services through the EOSC Portal	FAIR and open data sharing in support to European preparedness for COVID-19 and other infectious diseases
EPND			
BBMRI-ERIC Budget* € 313,875.00			
Start Date 			
A platform for accelerating biomarker discovery and validation to support therapeutics development for neurodegenerative diseases			

* Budget figure doesn't include linked third parties

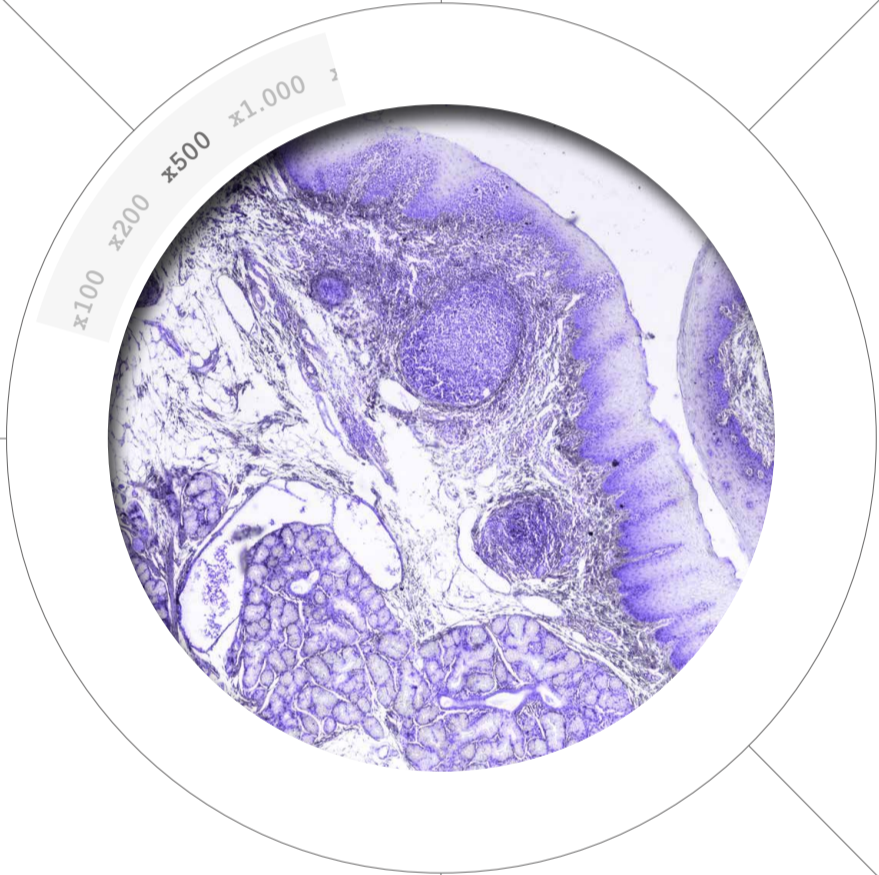


“

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,
FACILITATE ACCESS.

AUSTRIA

ABOUT THE NODE

4

Number of biobanks and stand-alone collections (2 under construction)

>23,000,000

Number of samples / size of collections (listed in BBMRI-ERIC Directory by Dec 2021)

>30,000

Number of samples/ data used for research

BBMRI.at comprises as partners all public, one private Austrian Medical University, and a University of Veterinary Medicine with their biobanks, and two other universities (bringing in IT and ELSI expertise). BBMRI.at was established in 2013 and is funded by the Federal Ministry of Education, Economy and Research (BMFWF GZ 10.470/0016-II/3/2013). More at www.bbMRI.at.

TOP 3 AREAS OF EXPERTISE

1. Quality management(QM) and analytical technologies: Development and implementation of ISO & CEN pre-analytics standards; Regulatory requirements for IVDs; QM cross-audits; QM trainings/webinars; BSL-3 facility build-up/operation; spatial transcriptomics; NGS; biobanking of material containing high risk pathogens

2. Data management: Data quality; High-capacity digitalization process & facility for tissue slides; Innovative privacy preserving technologies; Trusted data environment for biobanks and new data access model; BBMRI.at Catalog/Biobank Editor development; Input to BBMRI-ERIC Directory/ Negotiator development; BiBoX; Digitalization/whole slide imaging & AI;

3. Stakeholder and user engagement: discussion groups/interviews with stakeholders (on value of biobanking, data-citizenship); Education/training (e.g. on standards & IVDR; Biobanking MSc, and courses); Translational Science Forum with industry; Public engagement (e.g. biobank tours, children courses); Conference organization; Online portal for donors;

TOP 3 KEY SUCCESSES IN 2021

- 1. Harmonization & standardization:** Contribution to ISO & CEN standards & publication of ISO 20166-4 FFPE in situ detection, CEN/TS 17626 human specimen microbiome DNA; Organization of joint events on IVDR & QM with Austrian Life Science Clusters, Notified Bodies & Austrian Standards Institute;
- 2. Data Management:** Establishing concepts for new data access models and "trusted environment for patient data" & discussion at United Nations level; Complementing Biobank samples with digital whole slide images; Start of pilot projects for Animal Model Biobank;
- 3. Stakeholder and user information and engagement:** Several collaborations with industry and biobank contribution to COVID-19 studies incl. numerous publications; Implementation of biobanking and research technologies around high-risk pathogens; Strong presence in public media; Awareness raised on need for high-quality samples and biobanks at Austrian funding bodies/networks; Biobanking education (e.g. Biobanking MSc, courses (Med Uni Graz));

ADDITIONAL COMMENTS

Specific strengths of BBMRI.at:

- Solid community of BBMRI.at partners
- SARS-CoV-2: i) Contribution to development and validation of diagnostic SARS-CoV-2 tests (MedUni Wien Biobank); ii) Virus cultures from patient samples established, iii) 25 projects related to new antiviral drugs, diagnostics and decontamination procedures performed in BSL-3 facility (Med Uni Graz); iii) Research using SARS-CoV-2 cohorts (Med Uni Graz)
- Project leader of and expert contributions to the development of CEN/TS and ISO standards (in CEN/TC 140, ISO/TC 212, ISO/TC 276)
- Pioneering role for QM activities of BBMRI-ERIC (cross-audits, Self-Assessment Surveys, pre-analytic quality standards and courses)
- Biobank Graz – one of the largest biobanks in Europe awarded with several prizes
- VetBioBank – one of few BBMRI animal biobanks – with quality-marked samples and profound expertise in animal (model) biobanking
- High-throughput tissue slide digitalization facility (Med Uni Graz: up to 3800 slides/day in 6 slide cleaning stations, 9 slide scanners, 2 PB storage)
- Professional strategy development process at certain biobank partners;
- Developing the role of biobanks as key resource provider for developing AI algorithms
- Animated biobanking video for patients (Med Uni Graz)
- Biobanking university workshops for children
- Engagement in context of UN Sustainable Development Goals
- Central access point for sample/data/collaboration requests
- Biobank tours

BBMRI.be



BELGIUM

18

Number of biobanks

29

stand-alone collections

3 collections with
<1000 samples

11 collections with
1000-10,000 samples

10 collections with
10,000-100,000 samples

5 collections with
100,000-1000,000 samples

87,983

Number of samples
used for research

ABOUT THE NODE

The scientific participation of Belgium in BBMRI-ERIC was initiated by uniting the three existing Belgian network biobank initiatives i.e. Belgian Virtual Tumourbank project assigned to the Belgian Cancer Registry (BVT-BCR), Biothèque de la Fédération Wallonie-Bruxelles (BWB) and the Flemish Biobank Network (CMI). Since 2019, BBMRI.be invites all officially recognized Belgian biobanks with translational research potential to join the BBMRI.be network as well as users seeking structural research collaborations with the BBMRI.be network. Currently, our network connects 18 biobanks that are linked to public institutions such as hospitals, universities and research centers and two biobank user partners.



TOP 3 AREAS OF EXPERTISE

1. Clinical biobanks
2. Healthcare integrated biobanking
3. Quality management of samples and data

TOP 3 KEY SUCCESSES IN 2021

1. **New biobank (user) partners:** In 2021, two new biobanks ([Biobank of the Institute of Tropical Medicine \(ITM\)](#) and the [Central Biobank Platform of Sciensano](#)) and two biobanks users ([Stibion & Plasma Industries Belgium](#)) have joined the BBMRI.be network. The biobanks of ITM and Sciensano host collections from human material but also collections from animals (including insects) and microorganisms. The addition of these biobanks to our network has significantly broadened the scope of our biobank network that was before mainly focusing on clinical oriented biobanks with human biobank collections. [Stibion](#) and [Plasma Industries Belgium](#) are the two first biobank users that have joined our network, thereby setting up a structural collaboration with our biobanks. We hope many companies/institutes will follow in their footsteps so we can further enrich the collaborations between our biobanks and (industrial/academic) researchers.
2. **B3-ISO project granted:** In July 2021, BELSPO launched the ESFRI-FED call to support the participation of Belgian Federal Scientific Institutions (FSI) and federal departments in ESFRI distributed and virtual research infrastructures, through the funding of R&D projects based on scientific excellence and European anchorage. BBMRI.be received funding for a project entitled High quality BioBanking in Belgium: the road towards ISO 20387 accreditation (B3-ISO). Within this project, BBMRI.be will develop a stepwise quality improvement program that can be implemented at the individual biobanks. This quality improvement program will facilitate the road towards ISO 20387 for the BBMRI.be biobanks by guiding them step by step. At the same time, an accreditation program will be established together with BELAC, ultimately leading to ISO accreditation for our biobanks
3. **Setup new Governance Boards:** On July 8th 2021, Prof. Elke Smits was officially appointed as the next president of BBMRI.be from 1/09/2021- 31/08/2023. She will be responsible for the strategic management of BBMRI.be in close collaboration with the new Board of Directors and the National Node Director. For the first time, also an Advisory Board was set up with representatives from different organizations and stakeholders (patient organizations, government, industry, researchers, BBMRI-ERIC, ...) to give external advice to the Board of Directors of BBMRI.be. An [Action Plan](#) for the next two years was defined with continuation of the activities in the earlier established Working Groups (IT, ELSI, Quality, Stakeholder Involvement, Networking) and the startup of activities in the new Working Group on Sustainability of Biobanks.

ADDITIONAL COMMENTS

Publication list:

1. Extracellular HMGB1 blockade inhibits tumor growth through profoundly remodeling immune microenvironment and enhances checkpoint inhibitor-based immunotherapy. Hubert P, Roncarati P, Demoulin S, Pilard C, Ancion M, Reynders C, Lerho T, Bruyere D, Lebeau A, Radermecker C, Meunier M, Nokin MJ, Hendrick E, Peulen O, Devenne P, Herfs M. *J Immunother Cancer*. 2021 Mar;9(3):e001966. doi: 10.1136/jitc-2020-001966.
2. Metastatic colorectal cancer cells maintain the TGF β program and use TGFBI to fuel angiogenesis. Chiavarina B, Costanza B, Ronca R, Blomme A, Rezzola S, Chiodelli P, Giguelay A, Belthier G, Doumont G, Van Simaey G, Lacroix S, Yokobori T, Erkhem-Ochir B, Balaguer P, Cavailles V, Fabrizio E, Di Valentin E, Gofflot S, Detry O, Jerusalem G, Goldman S, Delvenne P, Bellahcène A, Pannequin J, Castronovo V, Turtoi A. *Theranostics*. 2021 Jan;11(4):1626-1640. doi: 10.7150/thno.51507. eCollection 2021.
3. Treatment algorithm and prognostic factors for patients with stage I-III carcinoma of the anal canal: a 20-year multicenter study. Bruyere D, Monnier F, Colpart P, Roncarati P, Vuitton L, Hendrick E, Lepinoy A, Luquain A, Pilard C, Lerho T, Molimard C, Maingon P, Arnould L, Bone-Lepinoy MC, Dusserre L, Martin L, Reynders C, Ancion M, Peiffert D, Leroux A, Hubert P, Delhorme JB, Ghnassia JP, Woronoff AS, Delvenne P, Prétet JL, Bosset JF, Peulen O, Mougou C, Valmary-Degano S, Herfs M. *Mod Pathol*. 2021 Jan;34(1):116-130. doi: 10.1038/s41379-020-0637-6. Epub 2020 Jul 29.
4. Potential Role of Epithelial Endoplasmic Reticulum Stress and Anterior Gradient Protein 2 Homologue in Crohn's Disease Fibrosis. Vieujean S, Hu S, Bequet E, Salee C, Massot C, Bletard N, Pierre N, Quesada Calvo F, Baiwir D, Mazzucchelli G, De Pauw E, Coimbra Marques C, Delvenne P, Rieder F, Louis E, Meuwis MA. *J Crohns Colitis*. 2021 Oct 7;15(10):1737-1750. doi: 10.1093/ecco-jcc/jjab061.
5. Tumor resistance to ferroptosis driven by Stearoyl-CoA Desaturase-1 (SCD1) in cancer cells and Fatty Acid Binding Protein-4 (FABP4) in tumor microenvironment promote tumor recurrence. Luis G, Godfroid A, Nishiumi S, Cimino J, Blacher S, Maquoi E, Wery C, Collignon A, Longuespée R, Montero-Ruiz L, Dassoul I, Maloujahmoum N, Pottier C, Mazzucchelli G, Depauw E, Bellahcène A, Yoshida M, Noel A, Sounni NE. *Redox Biol*. 2021 Jul;43:102006. doi: 10.1016/j.redox.2021.102006. Epub 2021 May 14.
6. GABARAPL1 Inhibits EMT Signaling through SMAD-Targeted Negative Feedback. Jacquet M, Hervouet E, Baudu T, Herfs M, Parratte C, Feugeas JP, Perez V, Reynders C, Ancion M, Vigneron M, Baguet A, Guittaut M, Fraichard A, Despouy G. *Biology (Basel)*. 2021 Sep 24;10(10):956. doi: 10.3390/biology10100956.
7. Mapping the human genetic architecture of COVID-19. COVID-19 Host Genetics Initiative. *Nature*. 2021 Dec;600(7889):472-477. doi: 10.1038/s41586-021-03767-x. Epub 2021 Jul 8.
8. Post-intensive care syndrome after a critical COVID-19: cohort study from a Belgian follow-up clinic. Rousseau AF, Minguet P, Colson C, Kellens I, Chaabane S, Delanaye P, Cavalier E, Chase JG, Lambermont B, Misset B. *Ann Intensive Care*. 2021 Jul 29;11(1):118. doi: 10.1186/s13613-021-00910-9.
9. Circulating Nucleosomes as Potential Markers to Monitor COVID-19 Disease Progression. Cavalier E, Guiot J, Lechner K, Dutsch A, Eccleston M, Herzog M, Bygott T, Schomburg A, Kelly T, Holdenrieder S. *Front Mol Biosci*. 2021 Mar 18;8:600881. doi: 10.3389/fmolb.2021.600881. eCollection 2021.
10. Triest D, Geebelen L, De Pauw R, De Craeye S, Vodolazkaia A, Verbrugghe M, Magerman K, Robben LL, Pannus P, Neven K, Ramaekers D, Van Gucht S, Dierick K, Van Loon N, Goossens ME, Desombere I. Performance of five rapid serological tests in mild-diseased subjects using finger prick blood for exposure assessment to SARS-CoV-2. *J Clin Virol*. 2021 Sep;142:104897. doi: 10.1016/j.jcv.2021.104897.
11. Noël G, Fontsa ML, Garaud S, De Silva P, de Wind A, Van den Eynden GG, Salgado R, Boisson A, Locy H, Thomas N, Solinas C, Migliori E, Naveaux C, Duvillier H, Lucas S, Craciun L, Thielemans K, Larsimont D, Willard-Gallo K. Functional Th1-oriented T follicular helper cells that infiltrate human breast cancer promote effective adaptive immunity. *J Clin Invest*. 2021 Oct 1;131
12. Tarabichi M, Demetter P, Craciun L, Maenhaut C, Detours V. Thyroid cancer under the scope of emerging technologies. *Mol Cell Endocrinol*. 2022 Feb 5;541:111491.
13. Boisson A, Noël G, Saiselet M, Rodrigues-Vitória J, Thomas N, Fontsa ML, Sofronii D, Naveaux C, Duvillier H, Craciun L, Larsimont D, Awada A, Detours V, Willard-Gallo K, Garaud S. Fluorescent Multiplex Immunohistochemistry Coupled With Other State-Of-The-Art Techniques to Systematically Characterize the Tumor Immune Microenvironment. *Front Mol Biosci* 2021 Sep 21;8:673042
14. De Caluwé A, Buisseret L, Poortmans P, Van Gestel D, Salgado R, Sotiriou C, Larsimont D, Paesmans M, Craciun L, Stylianos D, Vandekerckhove C, Reyaf F, Isabelle V, Eiger D, Piccart M, Romano E, Ignatiadis M. Neo-CheckRay: radiation therapy and adenosine pathway blockade to increase benefit of immunotherapy in early stage luminal B breast cancer, a randomized phase II trial. *BMC Cancer*. 2021 Aug 6;21(1):899.D33

BBMRI.bg



BULGARIA

ABOUT THE NODE

1

Number of biobanks

3

stand-alone collections

> 23,500

Number of samples/ size of collections

> 2000*

Number of samples/ data used for research

59*

Number of projects supported

Since 2019 the Ministry of Education and Science has supported the establishment of the National Node and biobanking network in Bulgaria in the frame of the National Roadmap of Research Infrastructures. The National Node is based at Molecular Medicine Center, Medical University of Sofia, hosting the biggest biobank with various clinical research collections. The aim of the NN is to establish national biobanking network and integrate it in BBMRI-ERIC, increasing the international visibility and further use of the available collections, supporting high quality technical and ethical standards, and contributing to health research and precision medicine. At present the biobanking network involves biobank and collections in two of the biggest Medical Universities in Sofia and Plovdiv.

TOP 3 AREAS OF EXPERTISE

1. **Research biobanking in oncology**
2. **Clinical biobanks for research in rare diseases**
3. **Activities related to QM and ELSI on national level**

TOP 3 KEY SUCCESSES IN 2021

1. Funding of 1,27 M Euro was provided in 2021 by the Ministry of Education and Science to the National University Complex for Biomedical and Translational Research (NUCBTR). Part of the funding is to support the BBMRI.bg National Node and capacity building in Biobanking and Genomics at Medical University of Sofia and Medical University of Plovdiv. The rest of the funding supports a pilot 1000 Bulgarian Genomes project to contribute to the Genome of Europe project.
2. Two COVID19 related sample and data collections were established in the Medical Universities of Sofia and Plovdiv, including more than 400 DNA samples of patients and more than 200 Sars-CoV-2 RNA samples in collaboration with leading university hospitals. The collections are supported by research projects on COVID19, funded by the National Science Fund, Ministry of Education and Science.
3. Multidisciplinary team of gastroenterologists, microbiologists, and geneticists established the first stool biobank in Bulgaria at University Hospital "Tsaritsa Yoanna", Medical University of Sofia in collaboration with the National Node and Molecular Medicine Center

ADDITIONAL COMMENTS

Due to the increased efforts of the NN and biobanks for high quality sample and data collection, access and coordination support to research teams, more than 40 papers were published in 2021 using data and human samples stored in the biobank as well as the collections of cell cultures and microorganisms.

* The numbers refer to patients whose samples were included in projects active in 2021 at Medical University of Sofia and Medical University of Plovdiv, funded by institutional, national and international projects.

CYPRUS

ABOUT THE NODE

2

Number of biobanks and
stand alone collections

>5000

Number of samples/ size of collections

~2000

Number of samples/ data used for research

>5

Number of Projects supported

The BBMRI.CY infrastructure is coordinated by Ms. Carolina Stylianou from the Ministry of Health, Cyprus Government. Currently there are two registered biobanks, that collect, maintain, and process samples, including blood, serum, plasma, DNA and associated clinical and demographical data. The collections are enriched with extended inclusion of biological material from different participant segments: diseased, population-based, and healthy volunteers.

More specifically:
biobank.cy

- Biobanking of a general population cohort (CY-Biobank, MITOS) (approx. 2.500 samples)
- Eye diseases cohort (CY-Biobank_Opth) (approx. 800 samples)
- Kidney diseases cohort (CY-Nephron) (approx. 300 samples)
- Cardiovascular diseases cohort (CY-GenCardio) (approx. 400 samples)
- COVID-19 cohort (COVID-19 Cyprus) (approx. 2700 samples)

CING

- Neurogenetics cohort
- Hemoglobinopathies cohort

TOP 3 AREAS OF EXPERTISE

- 1. Kidney disorders**
- 2. Neurogenetics and other diseases**
- 3. General population**

TOP 3 KEY SUCCESSES IN 2021

1. The creation of the only COVID-19 cohort on the island.
2. Success in Joint project with BBMRI-ERIC (ISIDORE project) – participation in cohort preparation (Integrated Services for Infectious Diseases Outbreak Research Fostering Africa-Europe cooperation in high-consequence pathogen research).
3. Collaboration with BBMRI-ERIC on ELSI - Ethical, Legal, and social issues and trainings.

BBMRI.cz



CZECH REPUBLIC

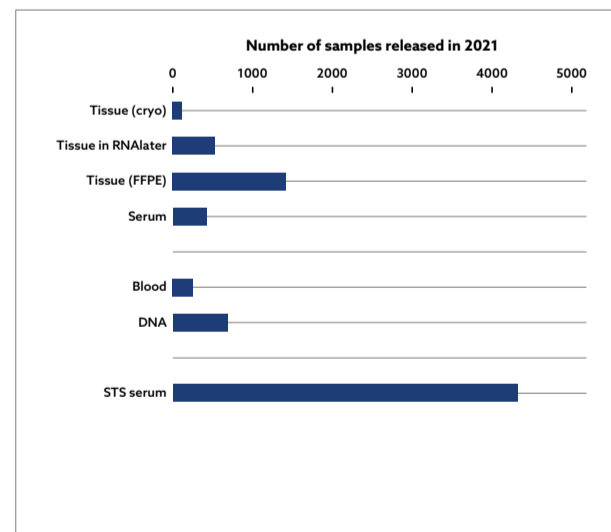
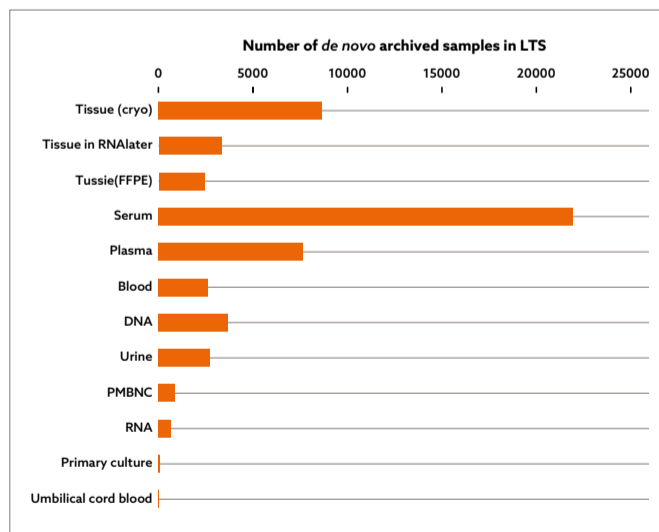
6

Number of biobanks

- BBM at Masaryk Memorial
 - Cancer Institute – MMCI
 - BBM at 1st Faculty of Medicine, Charles University – 1FM CU
 - BBM at Faculty of Medicine in Hradec Králové, Charles University – FM HK CU
 - BBM at Faculty of Medicine in Pilsen, Charles University – FMCU Pilsen
 - BBM at Faculty of Medicine, Palacký University in Olomouc – FM PU Olomouc
 - BBM at Institute of Rheumatology
- + 4 AFFILIATE MEMBERS/COLLABORATING PARTNERS
- Research Centre for Toxic Compounds in the Environment– Recetox MU & Medical data repository CERIT-SC (Masaryk University)
 - Institute of Hematology and Blood Transfusion (IHBT)
 - St. Anne’s University Hospital – FNuSA
 - University Hospital Brno – FN Brno

ABOUT THE NODE

BBMRI.cz is the Czech National Node of European biobank infrastructure BBMRI-ERIC and it is supported by the Ministry of Education through the project BBMRI-CZ. It is a network of individual biobanks of human biological samples. The primary task of these biobanks is the acquisition, processing and long-term storage of human biological material and data (HBM/D) from healthy volunteers and patients with a broad spectrum of socially important diseases for future research. We also store data related to the samples, such as digitalized histological images of the tissue along with results from specific biomarker analyses not only from tumor tissue, blood or urine, but also other biomolecular resources that can be used in biomedicine research. However, our efforts are not limited to storage of selected types of human biological samples (e.g. blood, urine, tissue, cells or DNA), but we also provided many specialized services and tools, which are offered to the wide range of users.



TOP 3 AREAS OF EXPERTISE

1. Offering high-quality human-derived clinical material within the currently applicable European legal landscape for an eligible researcher and eligible industrial collaborator.
2. Expert knowledge on preparation, cryostorage, and handling of human-derived biospecimens, derivation of biobanking specimens from diagnostic pathways, modeling specimen and data workflows for new users/participants.
3. Expert knowledge on the usability of material stored in biorepositories to make the best use of precious biological specimen collections, thus preventing irreproducible or meaningless research.

TOP 3 KEY SUCCESSES IN 2021

1. In March 2021, the Biobank Network in the Czech Republic covered by BBMRI-CZ project has been expanded with a new member - Institute of Rheumatology in Prague, thus samples portfolio expanded in the field of rheumatology diseases as well as expertise in this field.
2. BBM 1FM CUNI already installed robotic system for cryopreservation, managed personnel trainings and successfully passed the audit of the quality system according to ISO 9001:2015. And BBM MMCI and BBM FM Pilsen CUNI are preparing for installation of robotic cryopreservation system in near future.
3. BBM MMCI has expanded its services with the possibility of booking samples, which can facilitate prospective research and clinical trials. In cooperation with the team of Dr. Novák from MMCI we have conducted research in the field of natural language processing and applied computational algorithms (machine learning) to medical reports. In the prototype, we focused on CRC diagnoses and preliminary results show that the chosen methodology is sufficiently successful.

ADDITIONAL COMMENTS

- We have employed Dr. Nováková as a communications and external relations manager (PR) at BBM MMCI in order to raise awareness of the existence of BBMRI-CZ within both the academic and industrial sectors.
- Dr. Dudová serving as a key expert responsible for IT issues in frame of whole BBMRI-CZ went to maternity leave in a mid of 2021 with an expected return in March 2022. After her return, she is expected to continue in coordination of the pilot phase of BMRI-ERIC Task Force 1 focused on federated sample and data search.
- At the end of the year, the project team in FM Pilsen CUNI had expanded due to new technical staff recruited in connection with the increased activities in collecting and registration of COVID samples.
- We have been actively involved in Horizon Europe Programme HORIZON-INFRA-2021-EMERGENCY-02 with ISIDORE project (Research Infrastructure Services for Rapid Research Responses to COVID-19 & Other Infectious Diseases Epidemics) and HORIZON-INFRA-2021-SERV-01-01 with canSERV project (Providing cutting edge cancer research services across Europe).

BBMRI.de



GERMANY

ABOUT THE NODE

35

Number of biobanks and stand-alone collections (21 partners, 14 observers)

36,000,000

Number of samples/size of collections (13.5 M Tissues; 20.5 M liquid; 2 M derivatives)

442,000

Number of samples/data used for research

The German Biobank Node (GBN) is the umbrella organisation of academic biobanks handling human biospecimens and associated data in Germany. GBN coordinates a powerful network of 35 biobanks with harmonised quality management and a networked IT infrastructure: the German Biobank Alliance (GBA). Of all German medical faculties, 84% are represented within the GBA. GBN is the German partner and national node of BBMRI-ERIC.

TOP 3 AREAS OF EXPERTISE

1. Further education: GBN is continuously developing a comprehensive further education and training programme for biobank staff, with specific offers for technicians. In 2021, a web forum for technicians has been added to the e-learning platform. In the same year, GBA members had the opportunity to participate in the online course "Biobanking - theoretical and practical basics" (aimed at all biobank employees). This course will be integrated into four German Master's programmes as of 2022. Last but not least, GBN has held nine webinars in 2021.

2. Quality management: GBN offers a comprehensive quality programme which includes proficiency tests, internal audits, training courses and various services such as a [QM manual](#). In 2021, two proficiency tests (with tissue and liquid samples) have been conducted to increase sample quality. Moreover, a second round of internal audits was initiated and remote audits performed due to the ongoing pandemic. An insightful webinar on best practices for preparation and downstream analyses of PBMC led by national experts was attended by more than 90 participants.

3. IT network: The IT network of GBA biobanks facilitates the search for biosamples and associated data across locations in real time without restrictions ("[Sample Locator](#)"). In 2021, the establishment of this IT network was [published in PLoS ONE](#) while establishing central and local technical monitoring to help improving the entire system. In the same year, a joint project of GBN, GBA biobanks and the German Medical Informatics Initiative was launched: "ABIDE_MI", aiming at the enrichment of biosamples with comprehensive clinical information to enable a more focused search for research purposes.

TOP 3 KEY SUCCESSES IN 2021

- 1. Observer status in GBA:** GBN introduced the observer status in 2021 to support "younger" biobanks in the development phase and prepare them for a later GBA partnership. A full 14 biobanks were newly admitted to the GBA in the same year and have since benefited from the broad support and exchange of experience in the network.
- 2. Strategic development:** GBN/GBA have committed themselves to set the course for a "cultural change" in the interaction between biobanking and research. Several working groups are striving to advance the sharing of samples and data by biobanks locally and in the network. By appealing to funding agencies, they aspire to improve the framework conditions for biobanks and to promote their use more strongly. At the same time, cooperation with other research infrastructures is being strengthened in order to unleash the full potential of the biobanking structures created by GBN/GBA.
- 3. Animated film for patients:** To inform patients about biobanking and to motivate them to provide biospecimens for medical research, GBN has released an [explanatory film for specimen donors](#). The production of this film is also a success story of European cooperation: originally created by Biobank Graz, GBN adapted the animated film and now offers it to all GBA biobanks for use.

ADDITIONAL COMMENTS

"We are deeply impressed by your philosophy of open science and your aim to go beyond the frontiers of Germany, which is mirrored in your close interaction with BBMRI-ERIC. Your infrastructure is a model that other national nodes should copy", said Dominic Allen, former COO of IBBL, at the 2021 meeting of the GBN/GBA Scientific and Ethical Advisory Board.

BBMRI.ee

ESTONIA

ABOUT THE NODE

Number of biobanks and stand-alone collections:

In 2021 EstBB obtained the ISO 17025:2017 certificate.

Estonian government is supporting the Estonian Biobank, but there are some other sample collections from research projects or from clinical work.

Number of samples / size of collections: EstBB has 205 000 gene donors in the biobank with DNA and plasma samples. All are genotyped with Illumina GSA array and by the end of 2022 all will be analyzed by NMR (Nightingale). All have longitudinal clinical data and 75% have answered the questionnaire.

Number of samples or data used for research: The entire StBB is open for research. In 2021 EstBB released:

- 133 224 plasma samples
- 4 664 DNA samples
- 360 062 gene donor's genotype data
- 3 509 294 phenotypes

In total EstBB processed 74 data/sample release applications with ethical approval.

TOP 3 AREAS OF EXPERTISE

1. High quality samples, genotypes, and health data from ca 20% of the Estonian population available for research and introduction of the personal medicine in Estonia.
2. Professional IT team and world class biostatistics group working in close collaboration with Institutes of Computer science and mathematical statistics of Uni. Tartu.
3. Recontacting of gene donors with a prior consent to find study participants, a service for which an electronic platform was constructed and returning the data from the EstBB to people.

TOP 3 KEY SUCCESSES IN 2021

1. Biobank data transfer into OMOP data model.
2. IT group was growing and has now 16 experts on big data, software and biobank data management including ability to contact 200 000+ gene donors instantly and genotype data release to more than 10 000 gene donors.
3. Several good research grants and long list of publications where EstBB data, people and expertise was used.

ADDITIONAL COMMENTS

EstBB is active member of the 1+MG and EU project B1+MG. In addition, the EstBB also participates in the global network of large biobanks International Hundred K + Cohorts Consortium (IHCC), which operates together with the Global Genomic Medicine Collaborative community and Nordic Society of Human Genetics and Personal Medicine.

BBMRI.es



SPAIN

ABOUT THE NODE

57

Number of biobanks

3.459

stand-alone collections

1.069.872

Number of samples / size of collections

226.678

Number of samples / data used for research

1.597

Number of projects supported

The ISCIII Biobanks and Biomodels Platform (P_ISCIII_BB) is an initiative of the Carlos III Health Institute. The P_ISCIII_BB is the National Node (NN) in BBMRI. The P_ISCIII_BB is organized into four scientific-technological HUBS, which include: Biobanks, Organoids, Animal Models and 3D Printing. This structure makes it possible to manage and supply biological samples and associated clinical data. In the interest of promoting and incrementing scientific-technological resources in biomedical research, the P_ISCIII_BB's services include organoids, animal models and 3D printing. Furthermore, the Coordination of the P_ISCIII_BB is working in the development and implementation of measures to establish the Spanish virtual biobank and thus generate an electronic database of biological specimens and other related clinical information allowing to bring together the existing collections and repositories of biospecimens and associated genetic and other background data into one virtual location for ease of access by clinicians and researchers.

KEY PERSONS INVOLVED

BBMRI Assembly of Member (AoM) delegate: Elena María Doménech (ISCIII) and Marina López (ISCIII).

Scientific Direction: Nuria Montserrat (Coordinator of the P_ISCIII_BB, Institute for Bioengineering of Catalonia-IBEC) and Eva Ortega-Paño (Coordinator of the HUB of Biobanks within the P_ISCIII_BB and National Node-Scientific Coordinator, Spanish National Cancer Research Centre-CNIO (Madrid)).

TOP 3 KEY SUCCESSES IN 2021

1. **More than a million** samples have been generated in the biobanks of the P_ISCIII_BB for research.
2. Number of **donors** in 2021: 109.052
3. Number of **patient associations** collaborating with the P_ISCIII_BB: 52

OTHER HIGHLIGHTS

A total of 536 publications citing the biobanks of the P_ISCIII_BB.

Participation of the P_ISCIII_BB in the European project Respiratory Host-Pathogen Interaction-REACT (call HORIZON-HLTH-2021-DISEASE-04-07) through IBEC and CNIO.

Participation of the P_ISCIII_BB in the project Advanced Therapies (TERAV) from the Results-Oriented Cooperative Research Networks in Health (RICORS) within the Strategic Health Action 2017-2020 from ISCIII through IBEC.

FINLAND

Number of biobanks and stand-alone collections: 10 biobanks (all the academic biobanks in Finland) are members of the BBMRI network, one private biobank is an observer. Total 28 stand-alone collections

- 8 of the biobanks can be considered one stand-alone collection each
- THL Biobank has 16 stand-alone collections
- Arctic Biobank has 4 stand-alone collections

Number of samples / size of collections:
Total number of samples in Finnish biobanks: ~13 million samples from ~4 million sample donors. The samples include both legacy samples collected before 2013 and transferred to the biobanks as well as samples collected with a biobank consent (~300 000 sample donors).

Number of samples/data used for research: 123,227 samples were used for research and datasets from ~1.4 million non-unique sample donors

ABOUT THE NODE

Since January 2021 Finnish Biobank Cooperative-FINBB (www.finbb.fi) has been the national coordinator of the European level BBMRI-ERIC infrastructure (www.bbMRI-ERIC.eu) in Finland. FINBB is cooperative owned by six of the largest hospital districts and six universities and Finnish Institute for Health and Welfare (THL). FINBB was appointed as the national coordinator by Ministry of Education and Culture.

All eleven Finnish biobanks are involved in the biobank network activities. Ten public and academic Finnish Biobanks are hosted by universities, hospital districts, Finnish Red Cross Blood Service and THL. Private Terveystalo Biobank is a close collaborator of the network. The biobanks participate actively in implementation of the BBMRI-ERIC Work Program with specific emphasis in IT, Quality and Ethical and Legal Issues.

The shared vision of the biobank network is to have next-generation sustainable biobank services for researchers enabling the introduction of personalized and preventive medicine first in the world. To achieve this vision the mission is to build an integrated, sustainable, state-of-the-art biobank network in Finland. This will increase high-impact research projects in Finland leading to new breakthroughs enabling routine personalized and preventive medicine, eventually reducing human suffering and improving health. The mission is implemented by reaching the specified goals with detailed concrete deliverables, such as obtaining the ISO 20387 accreditation.

TOP 3 AREAS OF EXPERTISE

- 1. High quality samples with refined sample collection and handling procedures, detailed sample associated clinical data and genome data returned to the biobanks from the FinnGen biobank study.**
- 2. Real world data retrieval from healthcare registries and high-end data analytics within hospital districts' data lake infrastructure.**
- 3. Recontacting of sample donors with a prior consent to find study participants, a service for which an electronic platform was constructed.**

TOP 3 KEY SUCCESSES IN 2021

1. In 2021 149 feasibility requests and 80 biobank studies were initiated via the one-stop Fingenious® digital service covering seven of the Finnish public biobanks. Thirty-five percent of the projects were oncology related.
2. Successful execution of the large FinnGen public-private biobank study, with over 500 000 samples collected. Of these genome data from approximately 392 000 participants have been returned back to the biobanks (in March 2022) where it is available for biomedical research projects.
3. Successful continuity of biobank consents (e.g. by a national consent collection campaign www.annatkoluvan.fi), sample collections and research studies despite COVID-19.

ADDITIONAL COMMENTS

Number of Projects supported in 2021
621 projects, including both new projects initiated and ongoing projects. In 2021 total of 247 new projects were initiated

BBMRI.gr



GREECE

ABOUT THE NODE

12
Number of biobanks
and stand-alone collections

45,000
Number of samples/
size of collections

19,000
Number of samples/
date used for research

BBMRI-GR, the Greek National Node of BBMRI-ERIC, coordinates the biobanks within Greece and actively participates in numerous research projects and the provision of medical diagnostic services and various diagnostic projects within the country. BBMRI-GR led the support to the Greek State and other national Biobanks for COVID-19 samples collection. A COVID-19 dedicated section of the BBMRI.GR has been established containing 62.000 viral DNA samples and the associated DNA sequences (genotyping of SARS-COV-2).

TOP AREAS OF EXPERTISE

- 1. Cancer, Parkinson, Infectious Diseases, Hematological Malignancies**
- 2. Population biobanks**
- 3. Genomics, Deep Immune Phenotyping, Single-Cell -Omics**
- 4. ELSI**

TOP KEY SUCCESSES IN 2021

1. Implementation of BBMRI.GR SOPs; ELSI matrices: informed consent, MTA, DTA
2. Secure common IT infrastructure for the operation of the biobanks members of BBMRI.GR for managing of big data and personal data protection.
3. BRFAA/BBMRI.GR coordinates 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.
4. BRFAA/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.
5. BBMRI-GR supports the Greek research community by facilitating knowledge exchange, compliance with regulatory requirements, promoting best practices and ensuring guidance on ethical, legal and societal (ELSI) issues. Dr. Olga Tzortzatou, lawyer at the Biomedical Research Foundation of the Academy of Athens legal office, provides legal services to BBMRI-ERIC ELSI 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.



BBMRI.hu

HUNGARY

ABOUT THE NODE

6
Number of
institutional biobanks

400,000
Number of samples/
size of collections

50-2500
Number of samples/
subcollections

The Hungarian National Node was established in 2021 and consists of 6 major biobanks of the largest healthcare providers in Hungary. The coordinator of the National Node is Semmelweis University. Our biobanks are collecting several types of biospecimens and associated data elements. We are harmonizing quality standards within our Node and establishing federated data sharing within the network, aiming to implement FAIR principles as the foundation of the process. Our Node believes that biobanks have a strategical importance in the future of data driven precision medicine. We are engaging all stakeholders relevant to biobanks – from researchers to patients. To facilitate the research we provide beside biological samples large clinical data sets and in some disorders longitudinal follow-up data as well.

TOP AREAS OF EXPERTISE

- 1. Oncology/Oncohaematology**
- 2. Rare disorders**
- 3. Pancreatic Disorders**

TOP KEY SUCCESSES IN 2021

Our node did not exist in 2020, our success in 2021 the establishment of the Hungarian Node.

BBMRI.it



ITALY

Number of biobanks and stand-alone collections: 55 BBs (including 148 collections) in BBMRI-ERIC Directory. They meet the quality and ELSI requirements. They signed the BBMRI-ERIC Partner Charter. They grant transnational access. 42 BBs are improving their Quality System and are assisted by the Quality Common Service. Total 97 BBs.

Number of samples / size of collections: 43% of BBs store > 10.000 samples.

Number of samples:

- Diseases oriented BBs 2.1 M case collected.
- Rare Diseases BBs 175.000 case collected.

Archived Tissue BBs >250M case collected.

Number of samples/data used for research: The number of samples/data used for research varies according to the type of biobank (i.e. RD BBs, diseases oriented BB) ranging from 0,5% to 15%.

ABOUT THE NODE

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 involved 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 97 biobanks, Biological Resources Centers and Collections organised in thematic networks and regional networks with a matrix architecture. BBMRI.it has developed a web portal, a Help Desk and Common Services for ICT, Quality and ELSI have been set up to support the network. Annually, BBMRI.it Help Desk process a median of 250 request related to ethical and legal issues and 300 request related to quality matters. 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 offer services and support to 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.

TOP 3 AREAS OF EXPERTISE

- 1. Quality Management (QM): QM trainings and support to biobanks. Support to implementation of ISO 20387 standard. Healthcare integrated biobanking**
- 2. Stakeholder and user engagement. Working groups, dissemination and communication activities were carried out to involve the key 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. ELSI with a specific focus on co-production of knowledge as well as on engagement processes.**
- 3. Data management: secure IT solution for managing big data and sensitive data. BBMRI.it directory development and input to BBMRI-ERIC Directory**

TOP 3 KEY SUCCESSES IN 2021

1. Establishment of a joint ELSI & Quality Working Group for translational biobanking of samples/data from clinical activities with biobanks and their institutions. Development of best practices and tools and later to allow the biobanking for research purposes, of historical collections or collections of biological materials stored for non-scientific research purposes. Support to the National Healthcare Institute for the development of the policy document "Guidelines for the use of residual biological or clinical material for research purposes" in the frame of the Implementation of the reorganization and reform of the legislation on clinical trials of medicinal products for human use (DECRETO LEGISLATIVO 14 maggio 2019, n. 52.).
2. Biobanking with minors (what tools, what pathways) as a pilot for engaging vulnerable individuals together with the extended biobanking community including Schools. Development of a Matrix for Informed Consent for minors.

3. Population biobanks. Four additional biobanks in BBMRI.it network. Development of a White Paper: scientific and ethical aspects, cost recovery and sustainability, translational biobanking, case studies (elderly population, minors, genetically isolated population, institutional collaborations).

ADDITIONAL COMMENTS

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

BBMRI.lv



LATVIA

ABOUT THE NODE

3

Number of biobanks
and stand-alone collections

> 60,000

Number of samples/
size of collections

> 2,500

Number of samples/
data used for research

The aim of BBMRI.LV is to provide resources for biomedicine research in Latvia and collaborate with institutions abroad, ensuring knowledge circulation, development and setting of new goals, that will encompass international standards, best practices, and promote scientific excellence. Institutions: Latvian Biomedical Research and Study centre, Institute of Clinical and Preventive Medicine of University of Latvia, Laboratory of Personalized Medicine of University of Latvia, Institute of Biology of University of Latvia, Riga Stradins University Institute of Oncology and Scientific Laboratory of Molecular Genetics.

TOP 3 AREAS OF EXPERTISE

- 1. Biological samples of population-based and disease-specific collections, survey data and information retrieval from health care system**
- 2. Large-scale sequencing and digitalization of biological samples in national scale "omics" projects**
- 3. Activities in ELSI and quality management on national and international level**

TOP 3 KEY SUCCESSES IN 2021

1. Establishment of national framework of European 1+Million Genome initiative implementation in Latvia in collaboration with Ministry of Health of the Republic of Latvia, that will ensure funding and framework for sequencing of 3500 whole genomes from Latvian population as a part of European initiative. Development of Latvian Microbiome project a citizen science project, recruiting over 500 participants in the biobank with generated dietary, health information, microbiome sequencing and genotyping data.
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 in into force in Latvia participation in the working group for development of national regulation for secondary data use for research.
3. Participation in development of more than 25 national-level and more than 5 international-level research projects; proposals include areas of diabetes, tumor research, rare disease, ELSI and other.

ADDITIONAL COMMENTS

Latvian National Node of BBMRI-ERIC are actively participating in internationally significant projects and initiatives: European 1+Million Genome initiative, Million Microbiome of Humans Project, The COVID-19 Host Genetics Initiative and nationally important projects: Pediatric Cancer Initiative, Latvian Microbiome project and National Research Program to mitigate consequences of COVID-19 in Latvia.

LITHUANIA

ABOUT THE NODE

2

Number of biobanks
and stand-alone collections

> 80,000

Number of samples/
size of collections

~7,000

Number of samples/
data used for research

27

Number of projects
supported

The BBMRI.It infrastructure is coordinated by the Lithuanian National Biobank Node (LBN) at the National Cancer Institute. LBN is the umbrella organisation of biobanks in Lithuania that represents the interests of Lithuanian biobanks within BBMRI-ERIC network. Currently, national biobank gathers, maintains and processes wide collection of oncological, hematological, and infectious disease samples, including tissue, blood, serum, plasma, viable cells, DNA and RNA and associated clinical, demographical data. The collection will be enriched with extended inclusion of biological material from different participant segments: diseased, population-based and healthy volunteers.

TOP 3 AREAS OF EXPERTISE

1. Clinical biobanks for research in cancer and other diseases
2. Activities in ELSI on national level
3. Genomics

TOP 3 KEY SUCCESSES IN 2021

1. Sequencing of 1000 SARS-CoV-2 samples led to National virus sequencing project. Currently, 5-15 % of all positive COVID-19 cases in Lithuania are being sequenced..
2. Onco-hematological patient collection, with more than 1300 donors was used to study immunogenicity of the BNT162b2 COVID-19 mRNA vaccine and results were published high impact journal - The Lancet Haematology.
3. Lithuania and Japan have started the joint project "Radiogenomic patterns of BRCA1/2 breast cancer" for the harmonization of Biobanks, the comparison of cohorts and the development of diagnostic tools.

BBMRI.mt



MALTA

ABOUT THE NODE

15

Number of biobanks
and stand-alone collections
1 biobank, 14 collections

~90,000

Number of samples / size of
collections. Approx. 90,000 samples,
14 collections

~ 1,000

Number of samples/
data used for research

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 and chair 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 - hereditary blood disorders, mitochondrial disorders**
2. **Population Genetics**
3. **Cancer**

TOP KEY SUCCESSES IN 2021

1. PI elected chair of EuroBioBank.
2. First Maltese mtDNA (N=300) and Y chromosome (N=292) haplotypes uploaded to the European DNA profiling Mitochondrial DNA PoPulation database (EMPOP) and the Y Chromosome Haplotype Reference Database (YHRD).
3. Connected to the BBMRI-ERIC Finder (BC-Platforms) - dataset of 533 Colo-rectal cancer samples.

ADDITIONAL COMMENTS

The NN intends to pursue further development of a clinical biobank in the main hospital and a social co-operative for partners that lend samples and data for research and biobanking. It seeks to improve sustainability of funding and governance beyond research grant mechanisms. Within BBMRI the Malta NN shall promote further interest in:

- Organization of consortia for competitive funding in Bio-Bank-Led Research
- Rare Disease Bio-Banking
- The Euro-Mediterranean Platform.

Note: The above information was compiled by the previous national node/biobank manager. Since November 2021, BBMRI.mt has undergone a major reshuffle in its management, with replacement of Professor Alex Felice (BBMRI.mt national node representative) and Dr Joanna Vella (Biobank Manager) by Dr Nikolai Pace and Dr Lydia Ryabova as national node representative and biobank manager respectively. At the present, we are seeking to restructure the operation of the University of Malta Biobank. Specifically, plans are in place to audit and validate existing collections and respective consent forms, and to relaunch the biobank as DWARDNA-BIO, with the aim of establishing a nationally-representative cohort collection for longitudinal follow-up using dynamic consent procedures.

NETHERLANDS

ABOUT THE NODE

N/A

Number of biobanks

N/A

Number of stand-alone
collections

N/A

Number of samples/
size of collections

In the Netherlands we aim to achieve better health outcomes for patients in the future in comparison with today. Reaching this ultimate goal necessitates international connection and coordination. Therefore, research infrastructure in itself is not a goal, but a means to establish efficient and effective international alignment on an organizational, content, and communicative level.

In the Netherlands, Health-RI is building a national integrated health data infrastructure to support the research and innovation process, with the goal to ultimately result in a learning healthcare system. Health-RI builds on national initiatives, including Dutch regional nodes and the ESFRI programs in the personalized medicine domain, being BBMRI, EATRIS, ELXIR and (to a lesser extent) EURO-BIOIMAGING. Health-RI collaborates with BBMRI.nl to ensure FAIRification of data- and biomaterial-collections deriving from biobanks. Health-RI aims to formalize its function as 'national node coordinator' in collaboration with BBMRI-ERIC.

TOP 3 AREAS OF EXPERTISE

1. IT-services

2. ELSI

3. National Health research infrastructure

TOP 3 KEY SUCCESSES IN 2021

1. Health-RI is building a national integrated health data infrastructure to support the research and innovation process. Health-RI collaborates with BBMRI.nl to ensure FAIRification of data- and biomaterial-collections deriving from biobanks.
2. National Findability and Accessibility of Metabolomics data (BIOS), pathology tissues, and cohort data.
3. National ELSI Service desk.

ADDITIONAL COMMENTNS

We in the Netherlands are pleased to hear that the AMRI-initiative is developing further. We do believe that this helps to align the work program of BBMRI, EATRIS, and ECRIN on an organizational and content-level. A clearly defined plan how to establish the interaction between the RIs and the involved stakeholders (researchers, biobanks, patients, industry, etc.) will help to bring AMRI a step further.

Community engagement with users (both data requesters as providers) and developers is crucial to further develop a European research infrastructure for biobanking to boost biomedical research. Ultimately, aiming for a one-stop-shop (one front office) will facilitate researchers to find us. Therefore, the idea of AMRI resonates with the ideas in the Netherlands. Increasing the visibility how the infrastructure developed in collaboration with BBMRI-ERIC contributes to their research outcomes promotes widespread interest in and use of the infrastructure.

BBMRI.no



NORWAY

ABOUT THE NODE

80

Number of biobanks
and stand-alone collections

15,500,000

Number of samples/
size of collections

>60,000

Number of samples/
data used for research

Biobank Norway (bbmri.no) is a large-scale national research infrastructure for clinical and population-based biobanks, established in 2011. Over the last 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 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 of sensitive, big data.**

TOP 3 KEY SUCCESSES IN 2021

1. Biobanks were involved in several Covid-19 related projects.
2. The Research Council of Norway granted bbmri.no for a new project period – Biobank Norway 4 (2022-2026).
3. The infrastructure supported 125 projects and 1197 users in 2021.

ADDITIONAL COMMENTNS

Biobank Norway will be centrally placed in a revised strategy for precision medicine in Norway, offering close to 500 000 genomwide, genotyped samples from population biobanks. Based on recent funding, a biobank data archive will be established with one access-point to the collection.

BBMRI.pl

POLAND

52

Number of biobanks

>50

Number stand-alone
collections

> 1,000,000

Number of samples/
size of collections

3

Number of biobanks
with quality marks

2

Number of biobanks with
BBMRI audited ISO 20387:2018

ABOUT THE NODE

BBMRI.pl National Node has been a member of BBMRI-ERIC since 2016 and was formed by seven institutions: Łukasiewicz Research Network - PORT Polish Center for Technology Development, Medical University of Gdansk, Medical University of Warsaw, Wrocław Medical University, Medical University of Lublin, University of Łódź and Regional Science and Technology Centre in Chęciny. The Node is financed by the Ministry of Education and Science of Poland.

Polish Biobanking Network, formed as a result of BBMRI.pl activities, is a unique national research infrastructure with a main goal to map and harmonize biobanking units and biomolecular resources throughout the country. In 2021 the Network gathered 52 units biobanking human biological material and data (29 Members and 23 Observers). Most of the Polish biobanks collect biological material of human and animal origin and are located in universities, research institutes and hospitals. Collections stored within the Network are population-based and disease-specific with oncology and rare/genetic diseases being the most prominent areas. The activities of BBMRI.pl adhere to the BBMRI-ERIC Workplan and are focused on introducing and harmonizing quality standards in the biobanks, developing common IT infrastructure and providing expertise in ELSI. Resources of Polish biobanks are presented on www.biobanks.pl website and in BBMRI-ERIC Directory

TOP 3 AREAS OF EXPERTISE

1. Code of Conduct, ELSI Expert Centre.
2. Quality Expert Working Group in BBMRI.pl, QMS Expert Centre.
3. IT Expert Centre.

TOP 3 KEY SUCCESSES IN 2021

1. Project of Polish Code of Conduct (GDPR) - finished and sent for approval to National Authority of Data Protection.
2. First biobank quality mark in the BBMRI-ERIC Directory according to ISO 20387:2018.
3. Organization of national proficiency tests in the fields of cell number and viability and DNA quantification and purity.

BBMRI.se



SWEDEN

ABOUT THE NODE

450²

Number of biobanks

~160,000,000

Number of samples

508 764 / 225 686

Number of samples/
data used for research

Healthcare providers and universities with medical faculties are working together towards national harmonisation at the strategic and operational levels, with input from patient organizations and industry representatives. With six regional biobank centres managing more than 450 biobanks and approximately 160 million samples, Sweden stands to benefit substantially from increased harmonisation, and a more formalised integration of university biobanks and their regional healthcare counterparts. Thanks to funding from the Swedish Research Council, a strengthened research infrastructure focusing on coordination, efficiency and sustainability in terms of biobank samples and associated healthcare and molecular analysis data, is an integral part of Biobank Sweden's activities.

TOP 3 AREAS OF EXPERTISE

- 1. National organisation and collaboration:** Sweden's national infrastructure is characterised by clear contact points at all levels.
- 2. Clinical biobanks:** A standardised process for collecting, handling and storing samples for research has been implemented across Sweden, and is integrated in the routine healthcare system. Currently 25 hospitals can provide healthcare-integrated biobanking for blood and other liquid samples for research purposes, and more than 120 studies collect samples using the process.

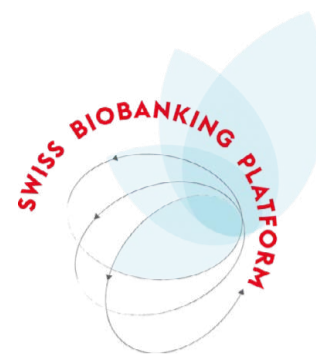
3. Interconnected sample collections and registries: Sweden has a long tradition of creating, maintaining and making available national registries. Together with the practice of issuing national personalised identity numbers, allowing researchers to link data from various registries to a specific individual, and the rich diversity of sample collections, this makes Sweden a unique biobanking research environment.

TOP 3 KEY SUCCESSES IN 2021

- 1. The Swedish Biobank Registry (SBR):** A new biobank registry was a highly prioritised aspect of Biobank Sweden's national IT strategy that was formulated in 2019. A national sample registry is essential to ensure new diagnostics and treatments will be made available to patients, such as in the context of precision medicine. Development of the registry started in 2020, and was launched during the fall of 2021. SBR is crucial for Biobank Sweden's fundamental goal to give Sweden the best prerequisites for healthcare and research within the biobank area.
- 2. Strengthening the Swedish ELSI platform:** During 2021, Biobank Sweden established a new national council for legal and ethical biobanking issues, as well as a national legal working group, in order to better address complex issues in need of further ethico-legal discussion and analysis. In accordance with BBMRI-ERIC's Patient Pillar initiative, steps have also been taken towards a reevaluation and enhancement of Biobank Sweden's patient engagement strategies.
- 3. Launching a major communication and education initiative:** After significant foundational activities during 2018-2020, Biobank Sweden was ready to launch core initiatives for communication and education during 2021. Tools and platforms for both internal and external communication were improved and expanded, and national coordination was intensified. In terms of education, a long-term initiative that will kick off during 2022 was developed.

TOP 3 KEY SUCCESSES IN 2021

The Swedish Research Council-funded Covid-19 project carried on throughout 2021, and a comprehensive report will follow later in 2022.



Swiss Biobanking Platform

SWITZERLAND

28

Number of biobanks
and stand-alone collections

ABOUT THE NODE

In Switzerland, biobanks operate with heterogeneous processes, are not registered, making the usability and comparability of samples difficult. Moreover, biobanking practices have greatly evolved over the last ten years, from the individual collection of biological material to professional infrastructures dealing with ethical and legal issues, accessibility and data sharing, interoperability, data protection and quality leading to a huge increase in the costs of biobanking activities. In 2013, the SNSF launched a competitive call for concepts for constituting a national biobanking platform. Swiss Biobanking Platform (SBP) concept was selected by an international panel of experts in biobanking activities. Today, SBP is the national coordination platform for human and non-human biobanks which supports biomedical and biological research to address questions around quality, access, transparency and the interconnectedness of biobanks and their related data.

TOP 3 AREAS OF EXPERTISE

1. **Quality.**
2. **IT / Interoperability.**
3. **Visibility and Networks.**

Together with its monitoring and evaluation tool called SBP Biobank SQAN and its overall quality strategy, SBP maps, supports and provides biobanks in Switzerland up-to-date technical know-how with specific expertise for the management of their daily biobanking activities. Moreover, SBP links Swiss biobanks with the European Biobanking and Biomolecular Research Infrastructure (BBMRI-ERIC) through its Directory to foster biobank networks and increase sharing of information on biological resources. This link with BBMRI Directory is key for Swiss researchers willing to create new partnerships and collaborations with the European network or other BBMRI nodes.

TOP 3 KEY SUCCESSES IN 2021

1. **SBP Next:** An interactive map to increase the visibility of Swiss biobanks through a directory highlighting their main features with an innovative search interface focusing on their hosted biological resources. This new tool is part of SBP strategy to foster SBP network and increase access, visibility and sharing of biological samples for research.

The Swiss Directory of biobanks, SBP NExT, has now been expanded for biobanks willing to increase their visibility and to feature sample-related data. This E-platform connects biobanks with researchers willing to access available samples based on defined inclusion criteria.

2. **SBP HARMONIZED DOCUMENTATION:** Harmonized documentation (e.g policies, SOPs, templates) in compliance with the European and international requirements and the applicable professional standards. This documentation is the first pillar in SBP Quality strategy to increase the overall quality of research and set the foundation of an harmonized Swiss biobanking practice.

Main documentation development:

- **Quality Manual:** The Quality Manual template is the reference deliverable guiding the biobank in the definition of its quality strategy. The template is easily adaptable to each biobank practice making it a practical document supporting biobanks or biobank infrastructures to set up and document their quality management system (QMS). Describing all elements of a quality management system allows to have an efficient overview of the biobank operational procedures and helps identifying and addressing potential gaps. Documentation of the quality management system is a requirement for the ISO 20387-General requirements for biobanking and for the obtention of SBP OPTIMA Label.





 <p>Chapter 2 ORGANIZATIONAL REQUIREMENTS</p>	<p>2.1. Governance</p> <p>2.2. Roles and responsibilities</p> <p>2.3. Communication</p>
 <p>Chapter 3 QUALITY REQUIREMENTS</p>	<p>3.1. Quality policy and objectives</p> <p>3.2. Quality plan</p> <p>3.3. Document management</p> <p>3.4. Improvement</p> <p>3.5. Risk and Opportunities Management</p>
 <p>Chapter 4 RESOURCES</p>	<p>4.1. Sustainability</p> <p>4.2. Personnel</p> <p>4.3. Facilities</p> <p>4.4. Equipment</p> <p>4.5. IT and data</p> <p>4.6. Support services</p>
 <p>Chapter 5 PROCESSES</p>	<p>5.1. Quality control of sample and data</p> <p>5.2. Consent</p> <p>5.3. Collection</p> <p>5.4. Transport and reception</p> <p>5.5. Sample processing</p> <p>5.6. Storage</p> <p>5.7. Transfer of biological material and data</p>

Figure 1: Structural content of the Quality manual, highlighting the hierarchy of organizational requirements applying to all chapters, quality requirements applying to resources and processes and finally the resources required to operate the processes.

SOP risk management: This SOP provides insights into the biobank risk and opportunities management as a basis of decision-making in the biobank at all stages of the biobanking processes. In this document, Failure Mode and Effect Analysis (FMEA) method was adapted to meet the ISO 20387 standard ("Biotechnology – Biobanking – General requirements for biobanking") requirements regarding risk management.

Service Level Agreement template: This Service Level Agreement (SLA) template details in the format of a written contract the services provided and the expectations between the service provider and the biobank. The document describes the scope, the procedure for modification, the services controls and audits, the responsibilities, the duration and termination terms of the contract, and the expectations in term of quality for all services covered by the agreement.
SLAs are developed to satisfy a requirement from the ISO 20387 standard ("Biotechnology – Biobanking – General requirements for biobanking") regarding subcontractors.

- 3. INCREASE OF SBP NETWORK:** Through SBP Biobank SQAN, different labels validate the compliance of SBP partner biobanks with minimal governance (VITA), process (NORMA) and quality (OPTIMA) requirements.
SBP network is increasing over time with new biobanks coming from cantonal institutions, Universities, ETH / EPF or from the private sector.


	BIOBANKS		BIOBANK INFRASTRUCTURES	
	2020	2021	2020	2021
Registered	46	70	12	19
Vita label	28	46	N/A	N/A
Norma label	8	11	3	7
Optima label	3	3	2	2

Figure 2: In 2021, SBP enriched the BBRMI Directory with additional Swiss entities: 26 collections and 2 biobanks.

TURKEY

ABOUT THE NODE

5

Number of biobanks/
stand-alone collections

31,093

Number of samples/
size of collections

2,477

Number of samples/
data used for research

The BBMRI.tr infrastructure is coordinated by the National Node at Izmir Biomedicine and Genome Center (IBG) and the regulatory organization for BBMRI.tr is Ministry of Industry and Technology (via its secretariat at The Scientific and Technological Research Council of Turkey (TUBITAK) R&D Support and Process Management Services Group -ARGES). The Biobank Node of Turkey is the umbrella organization of biobanks in Turkey, and the partner biobanks of BBMRI.tr are Hacettepe University Center for Biobanking and Genomics, Istanbul University, Aziz Sancar Institute of Experimental Medicine Biobank Facility, Acibadem University Rare Disease Biobank Unit (ACU-RDB), Ankara University Brain Research and Application Center Cell Line Biobank and Izmir Biomedicine and Genome Center Biobank. BBMRI.tr aims to create a collaborative research infrastructure between biobankers, biomedical researchers, clinicians, and patient organizations in Turkey to increase the biobanking capacity in rare diseases, cancer and infectious diseases. Furthermore, the BBMRI.tr seeks to expand the scope of biobanking in the Euro-Mediterranean region and MENA countries. BBMRI.tr established QM, IT and ELSI teams to support the network and developed strategies to accelerate Biomedical research via increasing close collaboration, integration, and harmonization between biobanks in Turkey to facilitate access to high-quality biospecimens and related data. Briefly, BBMRI.tr team has implemented CEN and ISO standards for the accreditation and certifications of biobanks to Turkish Biobanks in collaboration with the Turkish accreditation body TURKAK and organised training sessions on quality management. It has been working to adopt the BBMRI-ERIC standards to Turkish Biobanks.

TOP 3 AREAS OF EXPERTISE

- 1. Rare and undiagnosed diseases: Clinical expertise on rare diseases and repositories of large consanguineous families.**
- 2. Rare cancers and cancers: Clinical expertise on hereditary & sporadic solid and hematological cancers and repositories of FFPE, tissue and blood samples of cancer patients.**
- 3. Education and training for biobanks.**

TOP 3 KEY SUCCESSES IN 2021

1. Several local, and international education and training activities were held to increase awareness on the importance of Biobanking to create a comprehensive and sustainable biobanking ecosystem in Turkey.
2. With the support of BBMRI.tr standardized informed consents and quality strategies were developed and sample/data quality and capacity in Turkish Biobanks were increased. BBMRI.tr QM, ELSI, Rare Diseases (RD) working groups were established and regular meetings were held. First international industrial collaboration agreements for biobanking of clinical samples were signed, and a BBMRI.tr partner biobank is certified for biobanking of clinical samples.
3. National Accreditation Standards for Biobanking with the General Requirements for Biobanking, ISO 20387 and accreditation experts were trained in collaboration with Turkish accreditation agency (TURKAK).

BBMRI.uk



UNITED KINGDOM

ABOUT THE NODE

834

Number of biobanks
and stand-alone collections

N/A

Number of samples/
size of collections

N/A

Number of samples/
data used for research

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 an "honest broker". The sole remit is to make sure existing resources can be discovered and accessed, with a revived drive for transparency across the whole ecosystem. Therefore, 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 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 misuse 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 2021

1. Biobank Alliance project scoping the feasibility of a governance framework which would enable a single access application model across institutions.
2. *State of Biobanking in the UK* report, culmination of assessment of node activities, stakeholder interviews and focus groups and subsequent public consultation.
3. UKCRC Tissue Directory and Coordination Centre API to allow bulk upload of biobank collection data to the Tissue Directory.

International Agency for Research on Cancer

International Agency for Research on Cancer



IARC

ABOUT THE NODE

1

Number of biobanks and stand-alone collections

6,030,521

Number of samples/size of collections

1,810,389

Number of samples/data used for research

The Biobank is part of the International Agency for Research on Cancer (IARC/WHO), an executive research Agency of the World Health Organization. The IARC Biobank is one of the largest and most varied international collections of clinical samples in the world, focusing on gene-environment interactions and disease-based collections. This WHO infrastructure supports multinational research efforts and delivering those to resource-restricted settings.

Additionally, the IARC Biobank coordinates the Biobank and Cohort Building Network (BCNet; <https://bcnet.iarc.fr/>), a network aimed to support the establishment of laboratory infrastructure in LMICs with appropriate sample and data management. BCNet incorporates 34 institutions from 21 countries as of 2020.

The WHO commitment to global education is also reflected on the IARC Biobank activities, with the support to a number of biobanking courses internationally and the continuous development of the eLearning platform dedicated to biobanking (<https://learning.iarc.fr/biobanking/>).

TOP 3 AREAS OF EXPERTISE

1. Longitudinal population cohort studies
2. Low- and Middle- Income Countries (LMIC)-related studies
3. Combining research evidence to support guidelines and policies

TOP 3 KEY SUCCESSES IN 2021

1. Partner in the key EU-funded project CanSERV (Providing cutting edge cancer research services across Europe).
2. Publishing the key findings and guidelines from the G20 Digital Health summit (Riyadh) and participating in the G20 Indonesia, T20 Healthcare Taskforce for 2022 through policy briefs.
3. Participation in the ASEAN biobank feasibility study.

ADDITIONAL COMMENTS

The ongoing pandemic presented a number of challenges to the IARC Biobank, as well as to our collaborators and BCNet members alike. Many biobanks and laboratory facilities that collaborate with IARC on research in LMICs have been asked to stop their normal operations in order to process samples for COVID-19 testing – and that still remains the case. As such the long-term sustainability of these biobanks remains in question.

IARC has significant experience in providing safety training to laboratory technicians, and the Agency provides training on mitigating the risks of handling potentially pathogenic samples. For example, IARC organised webinars to train BCNet members in Egypt, Kenya, Philippines, Mali and Indonesia using its online Biobanking learning platform (<https://learning.iarc.fr/biobanking/>).



BBMRI-ERIC, Graz

Report on the Audit of the
Financial Statements
as of December 31, 2020 (Translation)

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.

non-binding electronic copy



BBMRI-ERIC, Graz

**Report on the Audit of the
Financial Statements
as of December 31, 2020 (Translation)**

Duplicate

**Ernst & Young
Wirtschaftsprüfungsgesellschaft m.b.H.
1220 Wien, Wagramer Straße 19, IZD-Tower**

**Tel.: [43] (1) 211 70
Fax: [43] (1) 216 20 77
E-Mail: ey@at.ey.com
URL: www.ey.com/austria**

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TRANSLATION

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<u>Appendix 1</u>	Financial Statements as of December 31, 2020
<u>Appendix 2</u>	General Conditions of Contract for the Public Accounting Professions

Note:

Due to rounding differences, figures in tables and cross-references may differ slightly from the actual figures (units of currency, percentages, etc.).

BBMRI-ERIC, Graz

December 31, 2020

TRANSLATION

To the Director General of
BBMRI-ERIC,
Graz

We have completed the audit of the financial statements as of December 31, 2020 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, 2020, 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.

TRANSLATION

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, from April to May 2021 mainly in a remote manner due to the current COVID-19 pandemic. 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 Director General in the notes to the financial statements.

TRANSLATION

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 Director General and the Company's employees provided all evidence and explanations requested by us. We obtained a representation letter signed by the Director 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 Director 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).

TRANSLATION

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, 2020, 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, 2020 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 until the date of this auditor's report is sufficient and appropriate to provide a basis for our opinion by this date.

Our responsibility and liability as auditor is guided by Section 275 (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.

TRANSLATION

Responsibilities of the Director General for the Financial Statements

The Director General is 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, the Director General 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.

TRANSLATION

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.

TRANSLATION

Comments on the Management Report

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

Vienna, May 12, 2021

Ernst & Young
Wirtschaftsprüfungsgesellschaft m.b.H.

Mag. Erich Lehner mp ppa Mag. 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

Director General

Jens K. Habermann, M.D., Ph.D.

Legal Address

BBMRI-ERIC
Neue Stiftingtalstrasse 2/B/6
8010 Graz, Austria
Phone: +43 316 34 99 17-0
Fax: +43 316 34 99 17-99
Email: contact@bbmri-eric.eu

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 Euro-
pean 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 opera-
tion 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 resour-
ces, their expertise and services on a
non-economic basis. BBMRI-ERIC is
established for an unlimited period
of time.

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:

<http://bbmri-eric.eu/>
<https://twitter.com/BBMRIERIC>
<https://www.linkedin.com/company/bbmri-eric>
<https://www.youtube.com/channel/UCL2n13WcvK4jLg6AkFner4Q>

Court Jurisdiction

Court of Justice of the European Union

Liability

Members of BBMRI-ERIC

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, Italian Repub-
lic, 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, Republic of Lithuania, 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.



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INCREASE VISIBILITY,
FACILITATE ACCESS.


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Neue Stiftingtalstrasse 2/B/6
8010 Graz I AUSTRIA
+43 316 3499170
contact@bbmri-eric.eu

 www.bbmri-eric.eu
 @BBMRIERIC
 BBMRI-ERIC

