BBMRI-ERIC®

CONNECT BIOBANKS,
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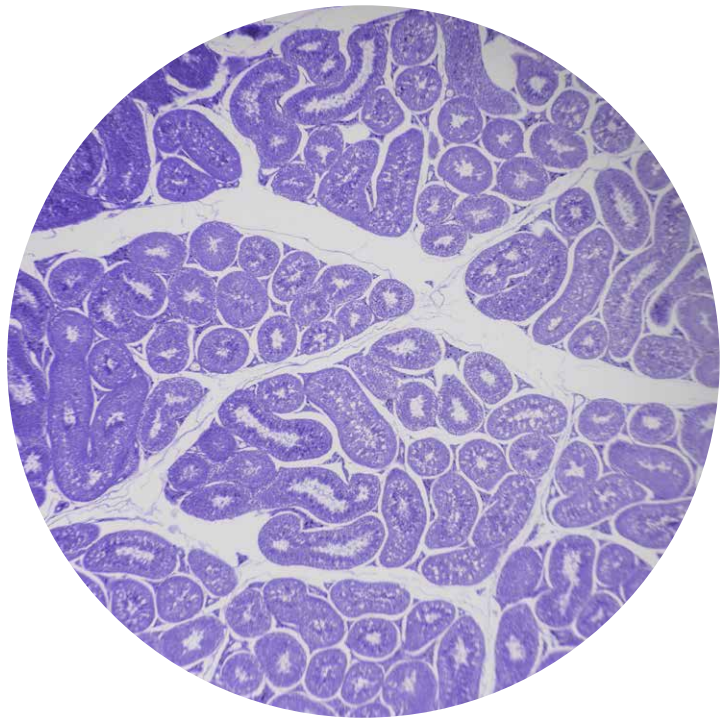
ANNUAL REPORT 2020



“

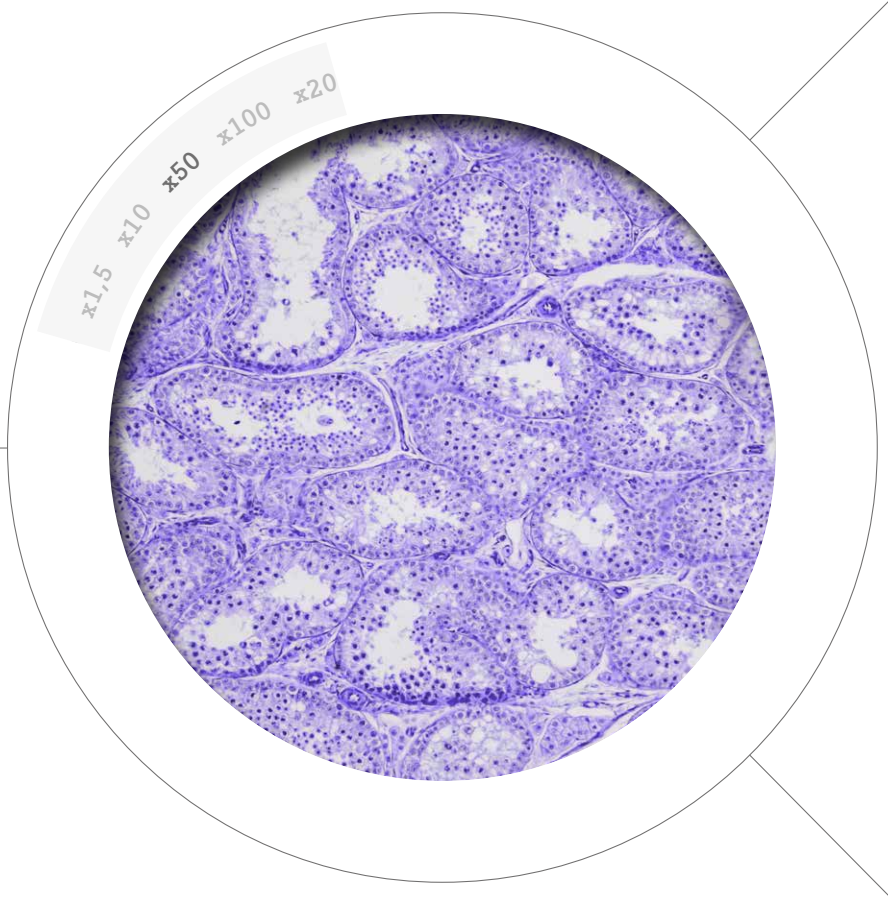
Biobanks (and Biomolecular Resources Centres) mean collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and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

BBMRI-ERIC Statutes, Article 1(1)

BBMRI-ERIC®

PART 1

EXECUTIVE SUMMARY



CONNECT BIOBANKS,
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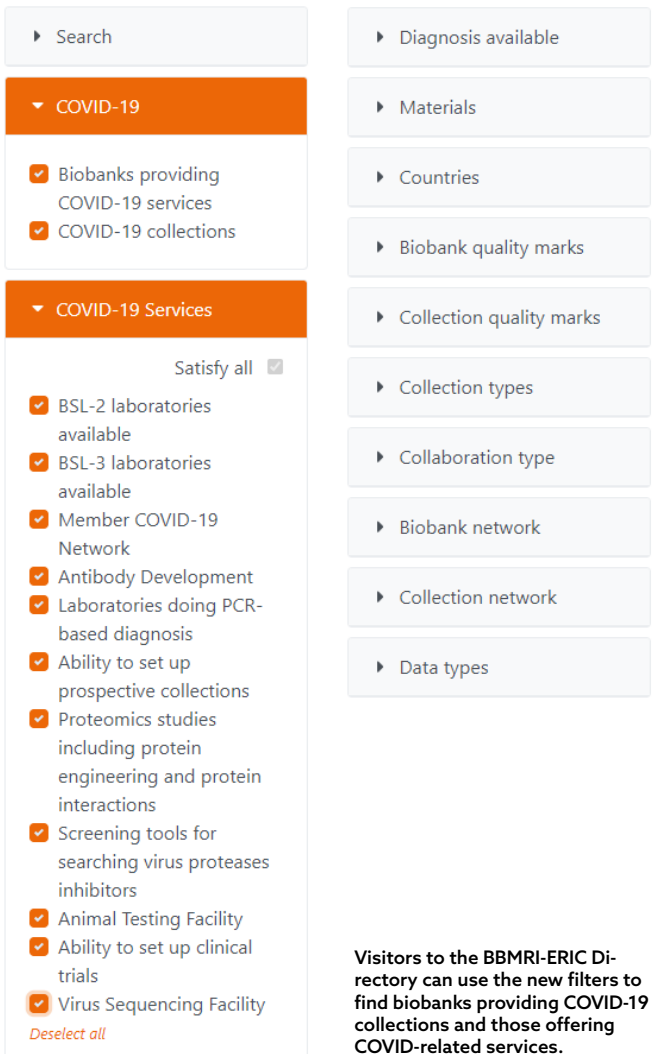
The past year has been dominated by the COVID-19 pandemic, which has not only influenced planned activities but also stimulated rapid responses from the scientific community for contributing to the acceleration of transnational research, ultimately for the benefit of patients and society at large. 2020 will be remembered as a year that impacted all aspects of our professional and personal lives. As an organisation, BBMRI-ERIC was able to rapidly adjust to remote working conditions and new scientific challenges—until September 2020 under the leadership of Interim Co-DGs Michaela Th. Mayrhofer (scientific) and Carmen Cristea (finance & human resources), thereafter under DG Jens K. Habermann.



Visitors to the BBMRI-ERIC Directory can use the new filters to find biobanks providing COVID-19 collections and those offering COVID-related services.

Together with our National Nodes, representing 20 Member States and one international organization, we not only delivered on the Work Programme 2020 but also ensured organisational stability and successfully participated in several research proposals. It is thus with some pride that we present our key achievements.

COMMON SERVICE IT

The new Common Service IT was launched in April 2020. The main change is to strengthen the focus on core services such as the BBMRI-ERIC Directory, Negotiator, Authentication and Authorization Infrastructure and Interoperability Services – MIABIS (Minimum Information About Biobank Data Sharing) and the Interoperability Forum. Other services are expected to be further developed by the National Nodes and their alliances; an assessment mechanism will be developed in the coming years to allow such BBMRI-endorsed status.

Beyond rapid reaction to COVID-19, most of the efforts in IT have been focused on the improved access facilitation to quality-defined samples and data. A new version of the Negotiator has been released with detailed tracking of access requests and improved support of performance monitoring of biobanks including many usability-related improvements. A new major release of the Directory has been prepared with a focus on improving the user experience when selecting biobanks for access negotiation, which is scheduled for early 2021. In addition, substantial efforts have been put into supporting the National Nodes in curating data into the Directory. The interoperability focus lay on extending the MIABIS CORE model to support the sharing of more detailed but still aggregated information on the availability of data and samples; this model will enable the enriching of data published in catalogue services such as the Directory. Major progress has been achieved in developing international standards for provenance of data and biological material in order to improve reproducibility of biomedical research; both parts 1 and 2 of the ISO 23494 standard have successfully proceeded to the next phases. Designated IT tasks in H2020 projects such as EJP RD or EOSC-Life are mainly on track and largely complement as well as promote the achievements of our IT services.

ELSI SERVICES & RESEARCH

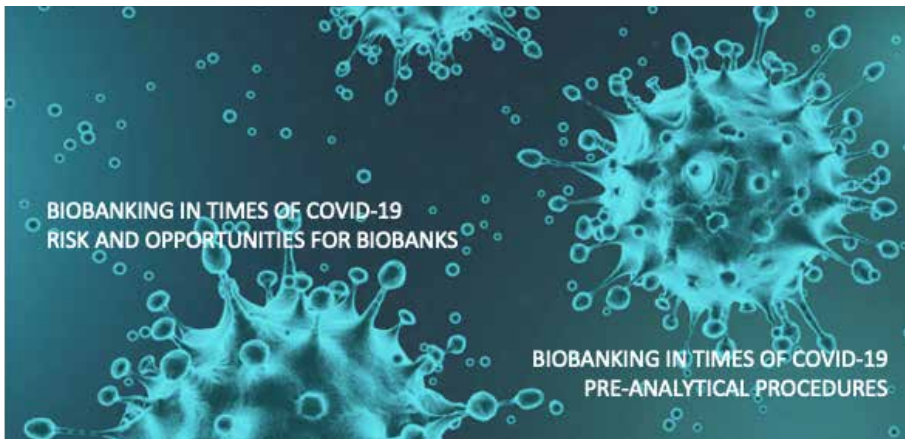
By the end of 2020, we had developed a solid structure for our ethical, legal and societal activities comprising the cornerstones research, services and trainings. Whilst new knowledge is gained via research, it is shared via trainings and sustainably promoted via our services for the benefit of the life sciences community, which include the following:

The ELSI Knowledge Base is an open-access resource platform offering a first orientation and practical know-how for responsible research in general. The ELSI Helpdesk Network operates in partnership with a network of ethical and legal experts coming from both academia and practice from our Member and Observer Countries and provides advice for a specific, typically project-related question. The Ethics Check is a support service for researchers who apply for H2020 research projects or similar initiatives during a proposal's application phase (Ethics Self-Assessment).

Currently, our ELSI experts from both Headquarters and National Nodes as Linked Third Parties (LTPs) are involved in more than 20 research projects and proposals allocating the highest return in external funding, among them CINECA, EUCAN-Connect, EOSC-Hub, EOSC-Life, CY-Biobank or BigPicture. Through this involvement BBMRI-ERIC is able to provide services and, through research, stay on top of the game. Most notably, know-how has been provided in relation to GDPR compliance, societal implications of artificial intelligence, and practical ethics management.

QUALITY MANAGEMENT

In 2020, we continued with the training on the international standard "General Requirements for Biobanking, ISO 20387:2018". This joint BBMRI-ERIC training and education programme was presented as an online course, split into 22 sessions in which the individual chapters of the standard were discussed. The comprehensive presentations given by renowned experts on requirements, definitions and the practical application were joined by 258 registrants from nearly all our Member and Observer countries.



Our COVID-19 webinars attracted hundreds of viewers in Spring 2020.

Due to the SARS-CoV-2 outbreak, the urgent needs of biobanks for information were addressed by two virtual conferences with more than 900 participants from 56 countries, titled "Biobanking in times of COVID-19". The topics of risk management, biosafety, laboratory handling and shipping of COVID-19 samples, as well as the collection and storage of infectious material were discussed. In-depth training on the "pre-analytical standards" took place between Q4/20 - Q1/21 in cooperation with partners of the project SPIDIA4P. The training included 16 virtual sessions and attracted 122 registrants from 23 countries. All QM trainings have been recorded and archived and can be accessed at any time for further study or for refreshing individual standard chapters.

Designated QM tasks in projects like the IMI Project ConcePTION or the H2020 Projects SPIDIA4P, EDIReX and CliniMARK, CY-Biobank, and IC2PerMed have been delivered according to plan. The BBMRI-ERIC Self-Assessment Surveys (SAS) have been updated from European (CEN) to international (ISO) standards. In 2020, 88 SAS were requested and processed. In addition, 27 biobanks (3rd Party Certificates, thereof 20x ISO 9001, 4x ISO 15189, 3x ISO 17025) and 37 collections (BBMRI-ERIC audited) are Q-Marked in the Directory. Liaisons with ISO and CEN were continued and liaisons with national accreditation bodies of Germany (DAkks), UK (UKAS) and Turkey (TURKAK) were intensified. A 3-day training for more than 40 assessors and biobanks on the accreditation standard was successfully held for TURKAK.

STAKEHOLDERS & PARTNERSHIPS

New Members

In April 2020, BBMRI-ERIC welcomed Lithuania as its 21st Member country. Lithuania, joining in the midst of the pandemic, showed outstanding vision for the future of its own national health research capabilities. We have also laid the groundwork for future expansions to BBMRI-ERIC membership, presenting the added value of joining BBMRI-ERIC, whilst initiating negotiations with several other EU and non-EU countries.

The ESFRI Panorama and ERIC Forum

While BBMRI-ERIC and other RIs were demonstrating their worth during the pandemic, we have maintained engagement with ESFRI beyond the crisis. In 2020, we contributed to shape the new ESFRI Monitoring System, designed to measure the impact of each ESFRI RI in the future. This is an important milestone towards a more harmonised EU RI panorama. In parallel, BBMRI contributed via the ERIC Forum to the review of the European Research Area, with the objective of creating a more connected, coherent ERA that builds on the investments already made by EU countries, such as those to establish ERICs. In 2020, the ERIC Forum reached its maturity under the coordination of BBMRI-ERIC, by approving and implementing a new governance structure including a revised rule of procedures or a newly elected Executive Board and a well-functioning Secretariat (in which BBMRI is represented). The stability brought to the Forum in terms of internal organisation raised the profile of the Forum outside the ERIC community. At the 2020 Annual Meeting, we enjoyed and highly appreciated the participation of the European Commission, the Croatian Minister of Research and other high-level decision makers.

Stakeholder Forum

The BBMRI-ERIC Stakeholder Forum remained the main interface for European patients' organisations, civil society, industry and academia to interact with the biobanking universe. The patients' pillar especially contributed to the success of our Europe Biobank Week (EBW) and cooperated together with National Nodes on autonomous collaborations such as in the context of the ERASMUS+ proposal. The Stakeholder Forum's industry pillar continued the dialogue to create a long-term, sustainable, equitable space where industry and biobanks can exchange ideas for the benefit of patients across Europe—and beyond. Through our collaboration with EFPIA, BBMRI-ERIC is continuously shaping the future of EU public-private partnerships, sharing our perspectives on the new Innovative Health Initiative.

BBMRI was represented at the AAAS Conference in Seattle from February 13th to 16th, 2020.

MAGNIFYING THE MESSAGES FROM OUR MEMBERS

Accelerating the achievements from our National Nodes through social media, our website and the monthly newsletter was our key focus in 2020, alongside continued outreach and dissemination activities as Work Package leads in the H2020 projects RI-VIS, EOSC-Life and CORBEL. We completed two promotional videos, among them one animation on our ELSI Services & Research. In early 2020, three public webinars on communications were conducted and were highly attended by representatives from the National Nodes. Due to the travel restrictions, most conferences took place in the virtual space, including Austria's "Lange Nacht der Forschung" (Long Night of Science), where BBMRI-ERIC was promoted as an infrastructure for research and outreach to the general public was achieved.

EUROPE BIOBANK WEEK

In autumn 2020, the most important event remained 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 Global Challenges", our annual biobanking conference attracted 670 attendees and 28 sponsors from 45 countries to the virtual space. With 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 in 31 live and on-demand sessions. The EBW 2020 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

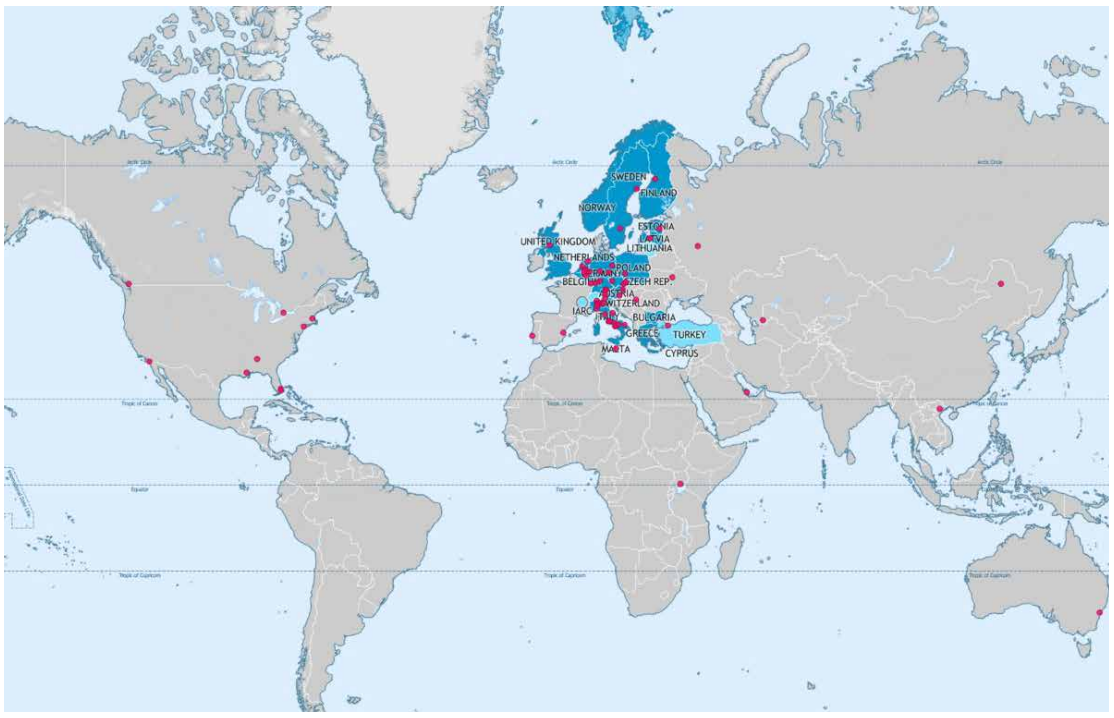
Capturing Availability of Samples and Data in the Directory

Given the world-wide implications of the pandemic, BBMRI-ERIC extended its global scope of the Directory beyond rare diseases and started cataloging resources also from non-Member States that were COVID-relevant, advertising this opportunity on a regular basis. Now, a specific extension captures the availability of COVID-19 samples and data from 55 biobanks with existing COVID-19 samples and data within the BBMRI-ERIC Directory. In addition, 38 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.

Ensuring Knowledge Transfer on Quality Management Aspects

BBMRI.QM attracted close to 900 participants from 56 countries to the "Biobanking in Times of COVID-19" web conference series: "Risks and Opportunities for Biobanks" and "Pre-Analytical Procedures" on April 1st and April 7th, respectively.

Besides representatives from all National Nodes, participants included representatives from Armenia, Australia, China, Demark, Egypt, Faroe Islands, French Guyana, Ghana, Hong Kong, Hungary, India, Ireland, Japan, Lithuania, Luxembourg, Mexico, Peru, Philippines, Portugal, Puerto Rico, Qatar, Saudi Arabia, Singapore, Slovakia, South Africa, the United Arab Emirates and the United States.



COVID-19 resources in the BBMRI-ERIC Directory

Transferring Knowledge 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 gained urgency in COVID-19 research. Against this background, BBMRI.ELSI held a webinar that took a closer look at these issues. The webinar took place on April 24th, 2020; the recording is available online and has attracted 207 viewers to date.

Questions raised during the webinar further resulted in a Q&A document that ventures into much detail on those topics. It also showcases two examples from Germany and Italy, as well as a detailed commentary on contact-tracing apps from a legal perspective. The document thus laid the foundation for further discussion on ELSI and COVID-19 in the context of biobanking.

Participating in Emergency Calls

In June 2020, BBMRI-ERIC and most of the National Nodes participated in three proposals under the Innovation Action SC1-PHE-CORONAVIRUS-2020-2: deCovid (2B), C-Cure (2D) and CoCoNet (2E). Although the proposals were not selected for funding, our biobanking community was able to showcase its fast response capabilities and scientific expertise beyond service provision for samples and data. The lessons learned are instrumental for current and future emergency response calls.

Responding in Collaboration with other LS RIs

Under the umbrella of the Alliance of Medical Research Infrastructures (AMRI), the COVID-19 Fast Response Service was set up 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.

In the context of the H2020 project CORBEL, the LS RIs prioritized COVID-19 research not only individually, but jointly produced an animation video showcasing how nine of the LS RIs can be used to advance research on coronavirus and other diseases.

Animated video "Accelerate your SARS-CoV-2 and COVID-19 research with European Life Science Research Infrastructures"

Deviation from Planned Activities

With reasonable effort, most activities were successfully adapted for the virtual space, leading to only few cancellations of planned events or minor delays of deliverables. In relation to the Code of Conduct for Health Research Initiative, however, the process almost came to a halt. The focus of legal experts shifted to the assessment of the ethical and legal frameworks regulating the pandemic. This deviation was mitigated by committing to the Code of Conduct as a key activity of the 2021 Work Programme.

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 immaterial to the overall financial health of BBMRI-ERIC. Several EU-funded grants scheduled to end in 2020 were granted extensions, moving the due dates of their final reports to 2021. At the same time, six new proposals received funding, officially starting in 2020 (i.e., CETOCOEN Excellence Teaming Phase II, IC2PerMed, Diamonds, EuCanImage, B1MG, Rabbit 2), securing roughly 600,000€ in competitive research grant funding for BBMRI-ERIC for the following three years.

In conclusion, 2020 showcased that BBMRI-ERIC is able to quickly and successfully adapt to a diverse set of challenges whilst thriving both scientifically and financially, as well as in organisational aspects.

Sincerely,
The BBMRI-ERIC Headquarters Team
May 2021

Members of the Headquarters team 2020 from left to right: Jens K. Habermann, Michaela Th. Mayrhofer, Carmen Cristea, Petr Holub, Andrea Wutte, Luc Deltombe, Francesco Florindi, Łukasz Kozera, Ulrike Rohrer, Viridiana Beltrán Venegas, Daniela Krasser, Robert Reihs, Fereniki Ioakeimidou, Nadja Palko, Barbora Halmová, Joanna Vella, Caitlin Ahern, Ayodeji Adeniran, Melanie Goisauf, Rudolf Wittner, Jasjote Grewal, Kaya Akyüz, Mónica Cano Abadía, Alexander Fürbass.
Not pictured: Sara Casati, Heimo Müller, Irene Schlünder

Services

DIRECTORY

687
biobanks connected

2514
collections

31
countries contributing collections

651
average users per month

NEGOTIATOR

1317
collections represented

646
total users

QUALITY

88
Self-Assessment Survey completions

3
additional collections with Q-mark

1
Additional biobank with Q-mark

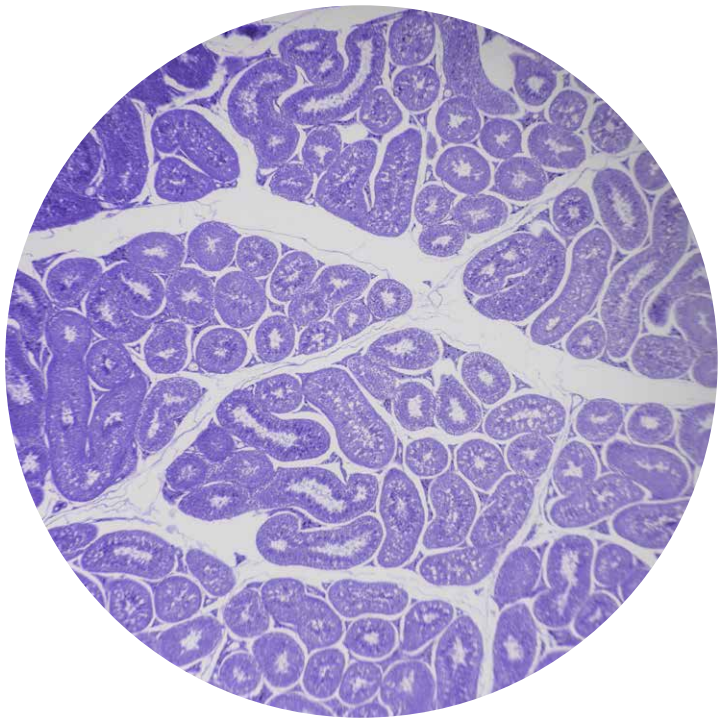
ELSI

18
Helpdesk requests completed

6
Ethics Checks for H2020 EU projects

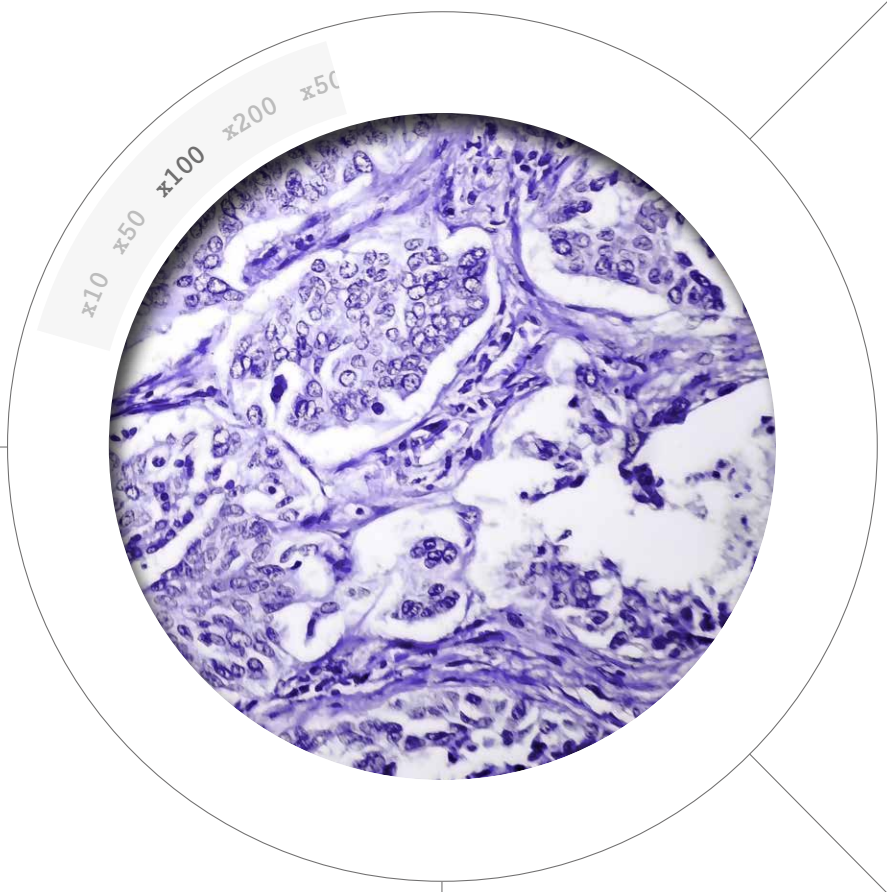
PART I

EXECUTIVE SUMMARY



PART 2

FINANCIAL INFORMATION



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Profit & Loss Statement

In EUR	2017	2018	2019	2020
Turnover	2,892,951	3,050,231	4,091,202	3,305,108
Other operating income	629	1,068	10,882	8,907
Staff expenses	(1,689,010)	(1,647,023)	(1,840,023)	(2,141,081)
Amortization	(29,518)	(35,896)	(31,683)	(30,000)
Other operating expenses	(1,367,820)	(1,464,964)	(1,676,029)	(847,735)
Operating result	**(192,768)**	**(96,584)**	**554,348**	**293,144**
Other interest and similar income	-	-	-	-
Interest and similar expenses	(30)	(41)	-	(54)
Financial result	(30)	(41)	-	(54)
Loss from operating activities, Earnings before taxes	**(192,798)**	**(96,626)**	**554,348**	**293,144**
Taxes on income and revenue	-	-	-	-
Profit of the year	**(192,798)**	**(96,626)**	**554,348**	**293,144**
Reversal of profit reserves	**(**192,798**)**	**(**96,626**)**	-	-
Allocation to profit reserves	-	-	(554,348)	293,144
Profit carried forward from the previous years	367,775	367,775	367,775	367,775
Balance sheet profit	**367,775**	**367,775**	**367,775**	**367,775**

Balance Sheet

In EUR	2017	2018	2019	2020
Intangible Assets	1,280	8,459	5,639	2,820
Tangible Assets	73,274	55,924	66,339	54,414
Fixed Assets	**74,554**	**64,382**	**71,978**	**57,233**
Receivables and other Assets	199,669	1,164,191	343,225	299,141
Receivables arising from deliveries services	126,626	134,301	86,743	93,001
Other receivables and assets	73,043	1,029,890	256,482	206,340
Cash on hand and Bank deposits	2,189,624	1,645,101	2,916,641	2,491,916
Current Assets	**2,389,293**	**2,809,292**	**3,259,867**	**2,791,055**
Prepaid expenses, deferred charges	5,919	13,332	5,031	2,811
Assets	**2,469,766**	**2,887,006**	**3,336,876**	**2,851,099**
Reserves pursuant to the articles of association	133,300	36,674	591,022	884,166
Balance sheet profit	367,775	367,775	367,775	367,775
Capital and Reserves	**501,075**	**404,449**	**958,797**	**1,251,941**
Other accruals	128,178	832,308	157,473	68,792
Accruals	**128,178**	**832,308**	**157,473**	**68,792**
Liabilities arising from deliveries and services	58,187	164,723	226,636	30,026
Other liabilities	157,418	131,022	385,357	396,798
Liabilities	**215,604**	**295,745**	**611,993**	**426,824**
Deferred income	1,624,910	1,354,505	1,608,612	1,103,541
Liabilities and Owner´s Equity	**2,469,766**	**2,887,006**	**3,336,876**	**2,851,099**

Cash Flow

In EUR	2017	2018	2019	2020
Profit of the year	(192.798)	(96.626)	554,349	293,144
Amortization	28.096	31.878	31,683	30,000
Cash Flow from the Result	**(164.702)**	**(64.748)**	**586,031**	**223,144**
Δ Receivables arising from deliveries services	(117.377)	(7.675)	47,559	(6,258)
Δ Other receivables and assets	63.196	(956.847)	773,407	50,142
Δ Liabilities arising from deliveries and services	4.007	106.536	61,913	(196,610)
Δ Other liabilities	(47.507)	(26.396)	254,335	11,441
Δ Prepaid expenses, deferred charges	(2.337)	(7.414)	8,301	2,221
Δ Accruals	496.540	433.725	(420,727)	(593,752)
Δ Working Capital	**396.523**	**(458.070)**	**724,789**	**(732,817)**
Cash Flow from Operations	**231.820**	**(522.817)**	**1,310,820**	**(409,672)**
Investing / Deinvesting	(12.331)	(21.706)	(39,280)	(15,256)
Cash Flow from Investing Activities	**(12.331)**	**(21.706)**	**(39,280)**	**(15,256)**
Δ Capital and Reserves				
Cash Flow from Financing Activities	**-**	**-**	**-**	**-**
Total Cash Flow	**219.490**	**(544.523)**	**1,271,540**	**(424,928)**
Cash Beginning	1.970.135	2.189.624	1,645,101	2,916,641
Δ	219.490	(544.523)	1,271,540	(424,928)
Cash End	2.189.624	1.645.101	2,916,641	2,491,713

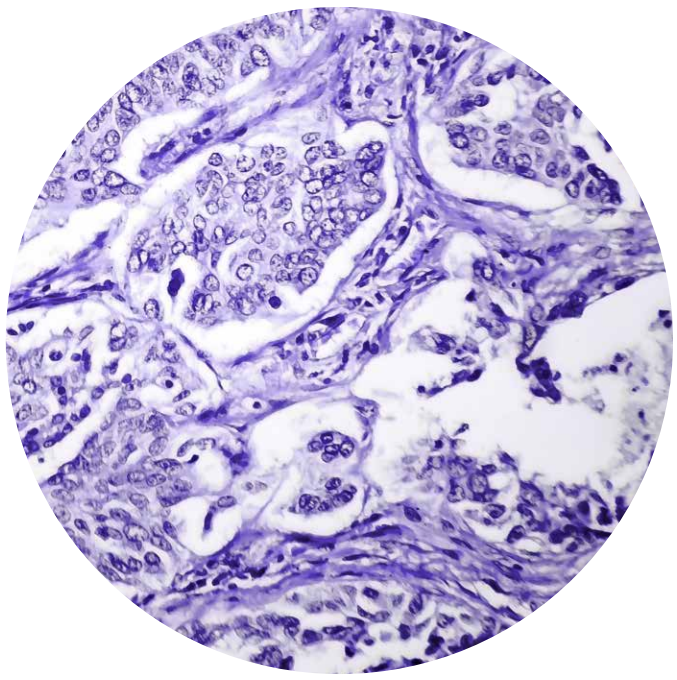
Key Facts & Figures

16

member states

18

projects underway in 2019



2.3 m

overall budget

5

observers

SOCIAL MEDIA

455

new followers

214

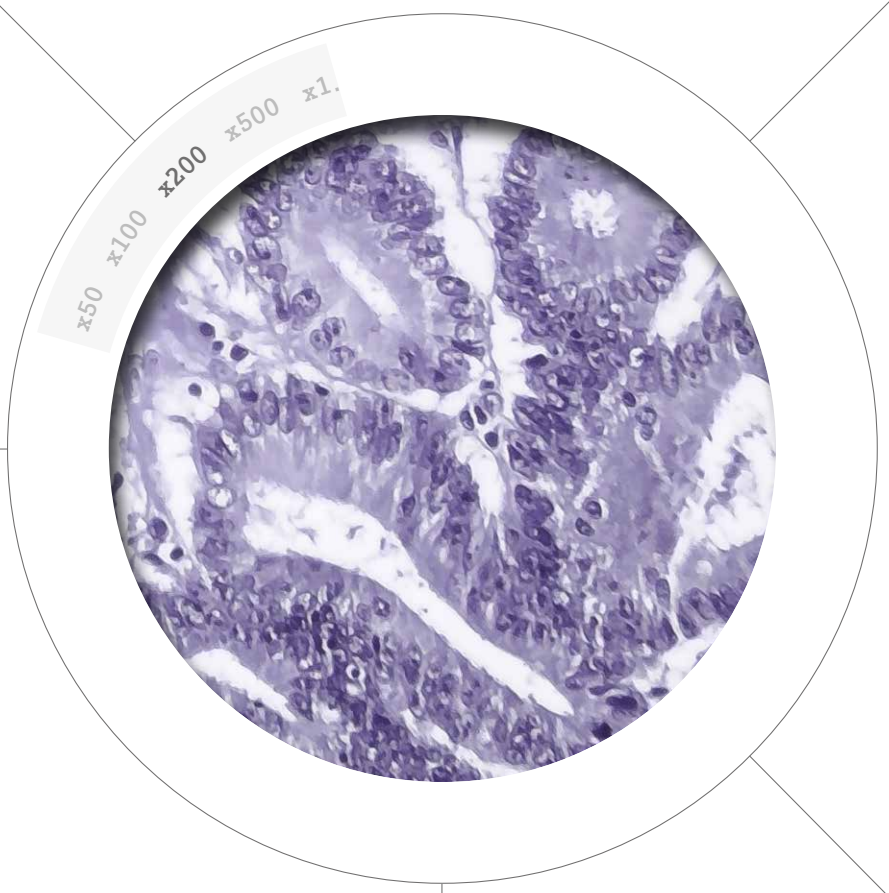
new followers

480,000

impressions

PART 3

PROJECTS



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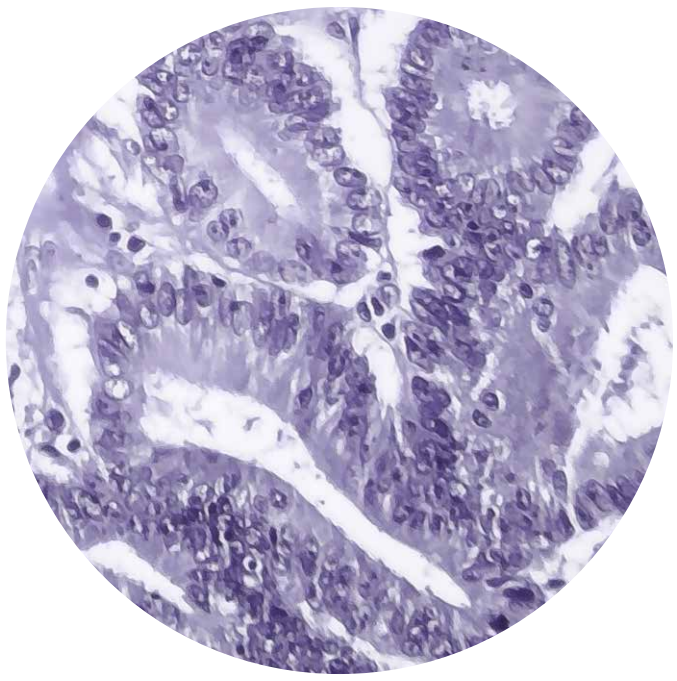
Projects Launched in 2020

CETOCOEN II	Diamonds	Rabbit 2	IC2PerMed
BBMRI-ERIC Budget* **€ 600,000.00**	BBMRI-ERIC Budget* **€ 130,000.00****	BBMRI-ERIC Budget* **€ 15,000.00****	BBMRI-ERIC Budget* **€ 219,687.50****
Start Date 2020 1 JANUARY	Start Date 2020 1 JANUARY	Start Date 2020 1 JANUARY	Start Date 2020 1 JANUARY
Establishing the European Centre of Excellence in Environmental Health Sciences	To bring personalised medicine into routine use in EU healthcare systems for diagnosis and treatment of common infectious and inflammatory diseases	To support EIT Health partners in simplifying access to biobanks and quality registries, and to help them leverage the assets available all over Europe.	Integrating China in the International Consortium for Personalised Medicine

	B1MG	EuCanImage	
	BBMRI-ERIC Budget* **€ 157,190.13**	BBMRI-ERIC Budget* **€ 310,425.00**	
	Start Date 2020 1 JUNE	Start Date 2020 1 OCTOBER	
	Towards access to at least 1 million sequenced genomes in the EU by 2022	Building a secure and federated imaging platform for next-generation artificial intelligence in oncology	

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

**Budget figure does not include linked third parties.



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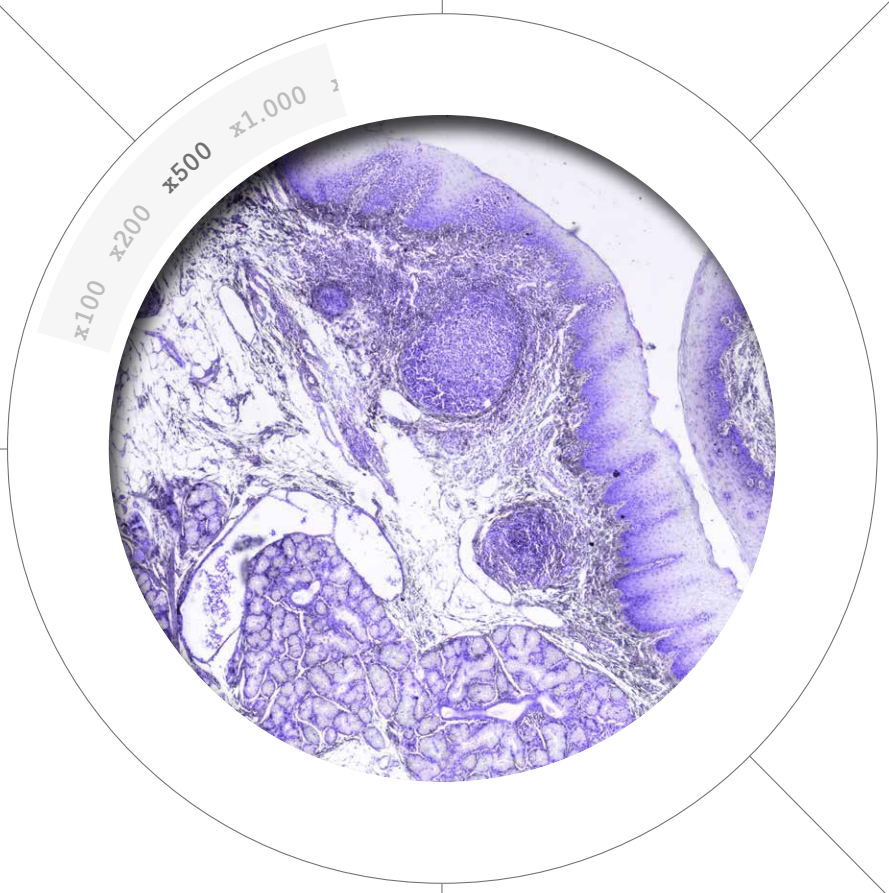
Our National and Organizational Nodes are the powerhouses behind the work we do. They coordinate the biobanks within their countries while actively contributing to research and growing our sample collections. Here is a snapshot of what makes each Node unique, and we encourage readers to see additional information on each Node’s individual website.”

BBMRI-ERIC®

PART 4

NODES



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BBMRI.at

BBMRI.at
Biobanking and
BioMolecular resources
Research Infrastructure
Austria

AUSTRIA

4
Number of biobanks and stand-alone collections (2 under construction)

20,000,000
Number of samples / size of collections (listed in BBMRI-ERIC Directory by Dec 2020)

150,000
Number of samples/ data used for research

140
Number of projects supported

ABOUT THE NODE

BBMRI.at comprises as partners four public medical universities, 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. 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; QM trainings/webinars; QM cross-audits; Regulatory requirements for IVDs; BSL-3 facility build-up/operation; NGS; spatial transcriptomics

2. **Data management and analytical technologies:** 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; BiBBoX

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

TOP 3 KEY SUCCESSES IN 2020

1. Harmonization & standardization: Lectures on pre-analytics standards in BBMRI-ERIC webinars; Contribution to ISO & CEN standard & development (e.g. ISO 20166-4, CEN/TS 17626); BBMRI-ERIC Self-Assessment-Tool Update to ISO standards supported;Organization of joint events with Austrian Life Science Clusters, Notified Bodies and Austrian Standards Institute; QM standard discount promotion initiated

2. Data Management: Biobank samples complemented with digital whole slide images; Development of involvement started; Establishing concepts for new data access models and trusted environment for patient data; Concept for Animal Model Biobank; VetBioBank: 1st animal biobank with quality-marked samples in BBMRI-ERIC Directory

3. Stakeholder and user information and engagement: Awareness of need for high-quality samples and biobanks raised at Austrian funding bodies/networks; Professional strategy development process at certain biobank partners; 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 and iii) 25 projects related to new antiviral drugs, diagnostics and decontamination procedures performed in BSL-3 facility (Med Uni Graz)
- Project leader of and expert contributions to the development of CEN/TS and ISO standards (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)
- Developing the role of biobanks as key resource provider for developing AI algorithms
- Animated biobanking video for patients developed (Med Uni Graz)
- Biobanking university workshops for children
- Biobank tours
- Engagement in context of UN Sustainable Development Goals and with large charity organizations

BBMRI.be

BBMRI.be
Biobanking and
BioMolecular resources
Research Infrastructure
Belgium

BELGIUM

16
Number of biobanks

27
stand-alone collections

3 collections with
< 1000 samples

10 collections with
1000-10,000 samples

8 collections with
10,000-100,000 samples

6 collections with
100,000-1000,000 samples

72,195
Number of samples/
data used for research

TOP 3 AREAS OF EXPERTISE

1. Clinicak biobansk

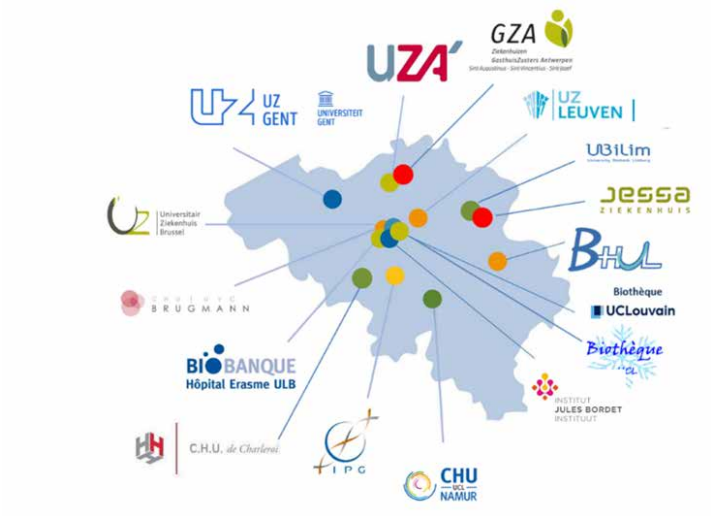
2. Healthcare integrated biobanking

3. Quality management of samples and data

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 2013, BBMRI.be has matured into a solid partner network on biobanks in Belgium and has proven to reach out to a broader community beyond the founding partners.

To allow further growth and activities, a new governance structure (BBMRI 2.0) has been worked out. All Belgian retrospective- and prospective-, individual or institutional biobanks with translational research potential can now apply to enter the BBMRI.be network. In contrast to BBMRI.be-1.0, BBMRI.be-2.0 also invites users seeking structural research collaborations with the BBMRI.be network aiming at accessing/building specific sample collections through research collaborations. Currently, our network connects 16 biobanks that are linked to public institutions such as hospitals, universities and research centers.



TOP 3 KEY SUCCESSES IN 2020

1. Release of the BBMRI.be Directory: A national version of the BBMRI-ERIC Directory has been released: the BBMRI.be Directory. From now on, the BBMRI.be biobanks can continuously update their data in the national platform that is daily synchronized with the Directory of BBMRI-ERIC. This guarantees a more up to date reflection of the available samples and data in our biobanks. Currently, 14 biobanks with 27 collections are included in the BBMRI.be Directory. When new biobanks join BBMRI.be, they will be included in the Directory as well. The BBMRI.be biobanks host a variety of collections ranging from oncological collections, several other disease specific collections (COVID-19, rheumatoid arthritis, inflammatory bowel disease, hepatitis, ...) and some population cohorts.

2. KPI's for BBMRI.be: In order to show the added value of BBMRI.be, we have defined Key Performance Indicators (KPI's) for BBMRI.be that will be collected from 2021 onwards. The KPI's have been defined in alignment with the Working Groups of BBMRI.be (IT, Quality, ELSI, Stakeholder Involvement and Networking & Organization). For each of these working groups at least one metric KPI and one specific milestone achievement per year have been defined. Next to the KPI's on the working group levels, some KPI's on the national (BBMRI.be) level were identified to showcase the results obtained by BBMRI.be as an organization. The full document with the KPI's that will be collected in 2021 can be found here. @viridiana.beltran@bbmri-eric.eu

3. Participation in COVID-19 studies: The BBMRI.be biobanks have been strongly involved in both the setup and support of COVID-19 related studies. Several biobanks collected residual tissue (blood, nasal swabs, post-mortem tissue, ...) from COVID-19 patients treated at the hospital linked to the biobank. Also several prospective collections were set up with longitudinal follow-up samples of COVID-19 patients. COVID-19 samples collected in these biobanks were provided to researchers, diagnostic companies and for research projects and IMP studies in Belgium and across Europe. More information about the Belgian biobanks with available COVID-19 collections can be found in the BBMRI-be Directory.

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

BBMRI.bg

BBMRI.bg
Biobanking and
BioMolecular resources
Research Infrastructure
Bulgaria

BULGARIA

1
Number of biobanks

2
stand-alone collections

> 21,500
Number of samples/ size of collections

> 1600*
Number of samples/ data used for research

24*
Number of projects supported

ABOUT THE NODE

Bulgaria joined BBMRI-ERIC in 2018. The Ministry of Education and Science supports the establishment of National Node and biobanking network as part of the leading biomedical research infrastructure on the National Road Map. 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 National Node is to establish the 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.

TOP 3 AREAS OF EXPERTISE

1. Research biobanking in oncology

2. Clinical biobanks for research in rare diseases

3. Neurological and psychiatric research biobanking

TOP 3 KEY SUCCESSES IN 2020

1. The National Node was set up and personnel recruited responsible for the key activities related to IT, ELSI and Quality Control.

2. Funding of 1.5 million Euro was received by the Ministry of Education and Science to support the BBMRI.bg National Node and capacity building in Biobanking and Genomics at Medical University of Sofia and Medical University of Plovdiv in the framework of National University Complex for Biomedical and Translational Research (NUCBTR).

3. Two COVID-19 related sample and data collections were set up, in collaboration with several leading university hospitals, including both human host biological samples and SARS-CoV-2 samples.

ADDITIONAL COMMENTS

Biobanking in Bulgaria and the activities of BBMRI.bg and BBMRI-ERIC were presented during the European Researchers' night and BioTech Atelier 2020.

* The numbers refer to patients' samples included in projects active in 2020 at Medical University of Sofia and Medical University of Plovdiv, funded by national grants and 2 international projects.

BBMRI.cy

BBMRI.cy
Biobanking and
BioMolecular resources
Research Infrastructure
Cyprus

CYPRUS

2

Number of biobanks

7

stand-alone collections at the Biobank of the biobank.cy Center of Excellence, University of Cyprus

2,235

Number of samples/ size of collections

Disease/condition	Number of donors
CY-Biobank-General population biobanking	**450**
CY-Nephron-chronic kidney disease, including monogenic conditions	**600**
Cardiogenetics (biological material is only DNA)	**200**
Eye disorders	**68**
COVID-19Cryptorchidism	**650**
Systemic lupus erythematosus	**38**
Celiac disease	**229**

50%*

Number of samples/ data used for research

ABOUT THE NODE

In Cyprus there are two biobanks approved by the Cyprus National Bioethics Committee. Perhaps the most active one, engaged in daily systematic enrolment of volunteers and collection of biological material, is the Biobank of the University of Cyprus, funded by the EC and supported with complementary funding by national sources. It is a new Biobank with several short-term and medium-term objectives. A primary short-term objective is the preparation of a general population cohort of 1000 volunteers with the aim to generate the first Cypriot reference genome (the DNA of Cypriots). Medium-term objectives include the preparation of cohorts for monogenic disorders as well as for complex conditions.

TOP 3 AREAS OF EXPERTISE

1. Medical and molecular genetics

2. Inherited kidney disorders

3. Bioinformatics

ADDITIONAL COMMENTS

We are a small growing Biobank, with still a lot to accomplish. Hopefully, in 2-3 years we will have worth-while achievements to report.

* In our case, including the COVID-19 project, a sample accompanies a clinical record which includes personal, demographic, body measurements and clinical data. The biological material usually includes DNA (6 aliquots), plasma (2 aliquots), serum (4 aliquots) and urine (5 aliquots).

BBMRI.cz

BBMRI.cz
Biobanking and
BioMolecular resources
Research Infrastructure
Czech Republic

CZECH REPUBLIC

5*

Number of biobanks
and stand-alone collections

120,000

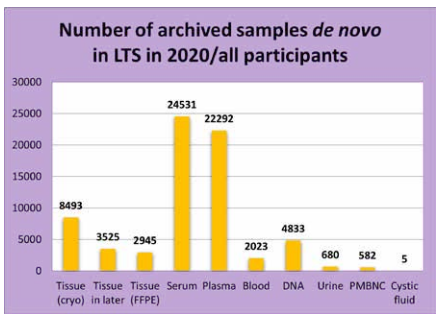
Number of samples/
size of collections

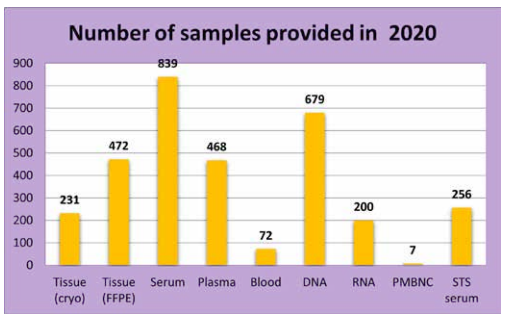
3,875

Number of samples/
data used for research

ABOUT THE NODE

BBMRI.cz is a Czech National Node of BBMRI-ERIC and it is supported by the Ministry of Education through the project BBMRI-CZ. It is designed as a network of individual biobanks responsible for storing samples obtained from associated healthcare providers. The primary task of the associated biobanks is the acquisition, processing and long-term storage of human biological material and data (HBM/D) from patients with a broad spectrum of socially important diseases for future research in the medical and biological sciences. These samples are otherwise irretrievably lost since medical institutions normally do not preserve this material and dispose of it as unused, in accordance with the law. However, our efforts are not limited to storage of selected types of human biological samples, such as blood, urine, tissue, cells or DNA. We also intend to store data related to the samples as well as other biomolecular resources that can be used in health research. Accordingly, we intend to develop an information system that will enable interoperability between biobanks at national level as well as with other European biobanks involved in BBMRI-ERIC.





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 2020

1. Biobanks of MMCI, 1FM CUNI and FM Pilsen CUNI have begun preparations and tenders for the planned acquisition of Robotic systems for LTS and sample dispensing.

2. Due to COVID-19 pandemic, all laboratory processes were reconstructed in BBM FM PU Olomouc to allow BSL3 laboratory handling of the primary material.

3. By depositing samples of patients with COVID-19, BBM MMCI participates in 2 studies: 1) Detection of antibodies in COVID-19 Cured Patients – SARS-CoV-2-CZ-Immunity ID: NCT04453280 and 2) COVID-19: Herd Immunity Study in the Czech Republic – SARS-CoV-2-CZ-Preval ID: NCT04401085.

ADDITIONAL COMMENTS

Personnel changes:

BBM MMCI: a deputy director of BBM MMCI, prof. Dalibor Valík, M.D., Ph.D., responsible for overall operations of the biobank and also serving as a coordinator of BBMRI-CZ project was replaced in September 18th by Assoc. prof. Roman Hrstka, M.Sc., Ph.D. (Ref. No. MSMT-33353/2019-24).

Quality manager, M. Mrkvicová, was replaced by J. Gottwaldová.

BBM 1FM CUNI: Executive manager, B. Staňková, was replaced by Libuše Nosková.

* 5 biobanks: BBM of Masaryk Memorial Cancer Institute – MMCI, BBM of 1st Faculty of Medicine, Charles University – 1FM CU, BBM of Faculty of Medicine in Hradec Králové, Charles University – FM HK CU, BBM of Faculty of Medicine in Pilsen, Charles University – FM CU Pilsen, BBM of Faculty of Medicine Palacký University in Olomouc – FM PU Olomouc

BBMRI.de

German Biobank Node
bbmri.de

GERMANY

22
Number of biobanks and stand-alone collections (20 sites)

31,500,000
Number of samples/ size of collections (13 M Tissues; 17 M liquid; 1.5 M derivates)

412,000
Number of samples/ data used for research

ABOUT THE NODE

The German Biobank Node (GBN) is the umbrella organisation of university/academic biobanks in Germany. GBN has provided the auspices for the development of a powerful partnership comprising a network of total of 22 biobanks: the German Biobank Alliance (GBA). Coordinated by GBN, the partners are harmonising their quality management processes and have established a linked-up sample level IT infrastructure in order to make biospecimens and associated data available for research. GBN represents the interests of German biobanks within BBMRI-ERIC.

TOP 3 AREAS OF EXPERTISE

1. **Stakeholder management:** GBN pursues various activities in the field of stakeholder management. In 2020, GBN conducted a focus group with patient representatives in cooperation with BBMRI-ERIC. The discussions focussed on framework conditions of collaborations between biobanks and partners from industry. The same question has been raised in qualitative interviews with representatives from pharmaceutical companies. Both measures have been evaluated extensively and build the basis for further dialogue and measures to be taken.
2. **Quality management:** An overarching QM system has been implemented for GBA biobanks by GBN. In 2020, four ring trials (with tissue and liquid samples) and eleven internal audits have been conducted to increase the standardisation of workflows and the quality of biosamples, data and services. An English version of the groundbreaking GBN QM manual for biobanks has been published Open Access.
3. **IT network:** GBN's Sample Locator (samplelocator.bbmri.de) enables researchers to search information from multiple biobanks online to locate specific samples and data. Following an evaluation carried out in 2020, the user interface was significantly improved. The search function is made possible by an infrastructure connecting local IT instances in the growing number of biobanks, but without central data storage. An implementation guide for biobanks was published in 2020.

TOP 3 KEY SUCCESSES IN 2020

1. New funding and long-term perspective: The German Federal Ministry of Education and Research (BMBF) will continue to support GBN's work for further three years, providing € 3.5 million in funding. In order to anchor GBN's position within the research environment and create a sustainable infrastructure, in 2024 GBN will become a permanent entity within the Berlin Institute of Health (BIH).

2. Crisis coordination and communication: GBN's coordination made it possible to clarify occupational safety issues at the beginning of the Corona pandemic and to quickly align study protocols between GBA partners. This enabled harmonised SARS-CoV-2 sample collection and the inclusion of samples from patients and controls from various biobanks in the Sample Locator. Building on this, GBN and GBA have since played a leading role in the National Pandemic Cohort Network (NAPKON) founded in the second half of 2020.

3. Quality management in response to the pandemic: As on-site audits were no longer possible, GBN has introduced additional remote audits for GBA biobanks in 2020. Due to the success of the format, GBN will continue to offer remote audits in the future. Furthermore, due to increased requests for PBMC and cfDNA samples, GBN has offered ring trials for GBA biobanks to check the quality of their samples and processes. In addition, an extended concept for the PBMC interlaboratory comparison for flow cytometry has been developed and implemented. Results of these measures are expected in 2021.

ADDITIONAL COMMENTS

"When evaluating the German Biobank Node and the German Biobank Alliance, the image of a long-distance runner comes to mind. There is an enormous strength in purpose within the organisation which is accompanied by an atmosphere and an approach of inclusiveness, openness and sharing", said Dominic Allen, former COO of IBBL, at the 2020 meeting of the GBN/GBA Scientific and Ethical Advisory Board.

BBMRI.ee

UNIVERSITY OF TARTU 1632

estonian genome center

ESTONIA

1

Number of biobanks and stand-alone collections

1,850,000

Number of samples/ size of collection

1,478,369*

Number of samples/ data used for research

26

Number of projects supported

ABOUT THE NODE

Estonian Biobanking Node is dealing mainly with Estonian Biobank, which is the only biobank supported by the law and state funding. The Estonian Biobank is a population-based biobank of the Estonian Genome Center at the Institute of Genomics of University of Tartu. The entire project is conducted according to the legislation given in the Human Genes Research Act of Estonia and all participants (gene donors) have signed broad informed consent. The cohort size is currently over 202,000 participants ("gene donors"), (≥18 years of age), which closely reflects the age, sex and geographical distribution of the Estonian population. All are genotyped with Illumina GSA array. Estonians represent 83%, Russians 14%, and other nationalities 3% of all participants. All subjects have been recruited randomly by general practitioners and physicians in hospitals and recruitment centres including one in the Estonian Biobank. Genomic GWAS analyses have been performed on all gene donors, and RNA samples from 2,100 individuals are available for gene expression studies, along with 45 biomarkers from serum and plasma. Currently available omics data is as follows: WGS (3 000), WES (2 500), metabolomics NMR (120 molecules, 11 000), clinical biochemistry (42 analysis, 2 700), telomere length (5 200), mRNA seq. (600), genome wide methylation arrays (700) and genome wide gene expression arrays (1 100). The health data of the participants is continuously updated through periodical linking to national electronic databases and registries. A part of the cohort has been re-contacted for follow-up purposes and resampling, and targeted invitations are possible for research project done on a specific diagnosis. Over 5000 individuals have been recontacted and health-related information based on genomic analysis and polygenic risk scores (PRS) have been returned in the framework of the research project. Early in 2021, a contract was signed with Finnish company Nightingale Health to produce the NMR analysis for ca 250 molecules from plasma (mostly lipidomics related) for the entire biobank of 200,000 individuals.

TOP 3 AREAS OF EXPERTISE

1. **High-volume recruitment and achieving public awareness of the biobanking and genomic medicine. We recruited in 9 months in 2018 over 100,000 new subjects into the EstBB and additional 50,000 in 2019.**

2. **Recontacting the subjects in the EstBB and IT infrastructure to support it**

3. **Implementing the polygenic risk score (PRS) technology into the real public health scenario as the "personal prevention" tool as our pilot study with 5000 subjects demonstrated (ms in preparation).**

TOP 3 KEY SUCCESSES IN 2020

1. EstBB joined actively into the COVID-19 projects

2. EstBB IT department made a strong step forward by initializing new developments

3. Based on EstBB samples and data over 60 scientific publications were published incl. journals like Nature*, Science, Cell, AJHG etc.

*In 2020 EstBB delivered 6315 DNA samples, 583 plasma samples, NMR results from 11 007 EstBB subjects and 1 471 471 phenotype & genotype data on EstBB subjects.

BBMRI.fi

BBMRI.fi
Biobanking and
BioMolecular resources
Research Infrastructure
Finland

FINLAND

11
Number of biobanks

27
stand-alone collections

~ 12.5m*
Number of samples

~ 114-115,000
Number of samples/
data used for research

ABOUT THE NODE

Since January 2020 Finnish Biobank Cooperative-FINBB (www.finbb.fi) is the national coordinator of BBMRI-ERIC infrastructure in Finland. FINBB is cooperatively 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 the 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 Programme with specific emphasis on 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 is being piloted.**

TOP 3 KEY SUCCESSES IN 2020

1. In 2020, 128 feasibility requests and 67 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 321,302 samples genetically analyzed by February 2021 (FinnGen Data Freeze 7). Of these genome data from approximately 230,000 samples have been returned back to the biobanks (in February 2021 / FinnGen Data Freeze 5), where it is available for further research studies.

3. Successful continuity of biobank consents (e.g. by launching a national consent collection campaign www.annatkoluvan.fi), sample collections and research studies despite COVID-19.

* 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.

BBMRI.gr

BBMRI.gr
Biobanking and
BioMolecular resources
Research Infrastructure
Greece

GREECE

14

Number of biobanks
and stand-alone collections

> 14,000

Number of samples/
size of collections

~5,000

Number of samples/
date used for research

ABOUT THE NODE

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 is coordinated by the Biomedical Research Foundation of the Academy of Athens (BRFAA). The members of BBMRI-GR actively participate in numerous research projects and the provision of medical diagnostic services and various diagnostic projects within the country.

TOP AREAS OF EXPERTISE

1. Disease and population biobanks

2. COVID-19 biobank

3. Genomics

4. ELSI

TOP KEY SUCCESSES IN 2020

1. The Internal Regulation of BBMRI-GR has been completed and agreed between partners.

2. The bioinformatics experts participating in the BBMRI-GR elaborated the roadmap of the implementation of common IT systems.

3. Standard Operating Procedures and existing guidelines were distributed to all participating nodes.

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

5. BBMRI-GR participates in the Greek Flagship Program on fighting the COVID-19 pandemic. BBMRI-GR coordinates and manages the national COVID-19 Biobank as a centralized resource to collect, store, and disseminate biological specimens and clinical data for researchers in Greece and elsewhere. SARS-CoV-2 viral genomes are being sequenced in parallel with patients' DNA samples to obtain a clearer picture of the spread, distribution, and scale of the epidemic in Greece and to investigate the dynamic interactions of the virus with human cells aiming to identify genes playing critical roles in the virus pathophysiology. 12,000 SARS-CoV-2 viral genomes have been sequenced. More than 1000 COVID-19 ICU patients' DNA samples and longitudinal RNA samples together with clinical and other laboratory information have been collected and are analyzed by genomics and deep immunophenotyping by mass cytometry.

6. ELSI expert Dr. Olga Tzortzatou, in collaboration with the partners of BBMRI-GR, organizes and coordinates the ELSI issues of the network e.g., common Consent Form, GDPR issues etc.

7. Special effort has been made in order to establish a stable connection with Patients Associations, although this task has been hampered by the pandemic.

BBMRI.it

BBMRI.it
Biobanking and
BioMolecular resources
Research Infrastructure
Italy

ITALY

47

Number of biobanks

43%

biobanks with > 10,000 samples

Archived tissue biobanks
>250 m case collected

Disease-oriented biobanks
1,700,000 samples

Rare disease biobanks
170,000 samples

0.5-15%

Number of samples/
data used for research

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 organized 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 requests related to ethical and legal issues and 300 requests 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 liaises the national node and the European infrastructure on the ELSI state of art.

Specific Strengths

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

TOP 3 AREAS OF EXPERTISE

1. **Healthcare integrated biobanking & ISO 20387 implementation**

2. **ELSI with a specific focus on co-production of knowledge and shared ELSI tools as well as on engagement processes**

3. **Secure IT solution for managing big data and sensitive data**

TOP 3 KEY SUCCESSES IN 2020

1. Support to biobanks for COVID-19 samples collection. COVID-19 dedicated section of the BBMRI.it portal set up to make tools and documents immediately available to the scientific community (Guide Lines for collection, storage, processing, transport and analysis of samples; safety requisite; database of publications; International Clinical Trials Registry Platform; in vitro diagnostics and laboratory technology).
   A Directory of COVID-19 collections has been created, including collections available in 18 Italian institutions: - Prospective clinical cohorts: adult patients; elderly patients; pediatric patients - Prospective cohorts from healthcare workers - Swab leftover samples from different Italian Regions - Post mortem tissue collections.

2. ELSI4COVID: Co-production of shared ELSI tools: from the simplified consent, to the glossary, to the regulatory framework tailored to the different COVID contexts. Currently the informed consent matrix for Covid research is part of the BBMRI-ERIC ELSI Knowledge Base.

   https://www.bbmri.it/en/nodo-nazionale/elsi-covid/

3. Implementation of BBMRI.it best practices (quality and risk management SOPs; of ELSI matrices: informed consent, MTA, DTA) in all the 52 IRCCS (research hospitals belonging to the Ministry of Health), to support healthcare integrated biobanking.

BBMRI.lv

BBMRI.lv
Biobanking and
BioMolecular resources
Research Infrastructure
Latvia

LATVIA

3
Number of biobanks
and stand-alone collections

> 50,000
Number of samples/
size of collections

> 2,500
Number of samples/
data used for research

> 30
Number of projects
supported

ABOUT THE NODE

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, which 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 form 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 levels**

TOP 3 KEY SUCCESSES IN 2020

1. Development of Latvian COVID-19 patients' cohort with expanded clinical characteristics and molecular data (genotypes, cytokine level, metabolites, RNA-seq, viral-seq, metagenome) from biological sample analysis. The obtained data are accessible for research via open COVID-19 data platform developed in Latvia (further information https://www.genomadatubaze.lv/en/covid-19-cohort).

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

ADDITIONAL COMMENTS

Latvian National Node of BBMRI-ERIC are actively participating in internationally significant projects an 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.

BBMRI.lt

BBMRI.lt
Biobanking and BioMolecular resources Research Infrastructure Lithuania

LITHUANIA

2
Number of biobanks and stand-alone collections

> 50,000
Number of samples/ size of collections

~4,500
Number of samples/ data used for research

14
Number of projects supported

ABOUT THE NODE

The BBMRI.lt 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 the BBMRI-ERIC network. Currently, the national biobank gathers, maintains and processes wide collection of oncological, hematological, and infectious disease samples, including tissue, blood, serum, plasma, nasopharyngeal swabs, saliva, viable cells, DNA and RNA with associated clinical, demographical data. The collection is constantly extending with inclusion of biological material from different participant segments: diseased, population-based and healthy volunteers.

TOP 3 AREAS OF EXPERTISE

1. Molecular and genetic cancer markers

2. Activities in ELSI on the national level

3. Initiation of new scientific projects and successful collaboration with industry

TOP 3 KEY SUCCESSES IN 2020

1. The project "Human Biological Resource Center", resourced from EU Structural Funds, was established to create a harmonized, efficient and leading biobank infrastructure. Consequently, Lithuania joined BBMRI-ERIC on 15th April 2020.

2. Partnership with Cancer Research UK in 'Grand Challenge' project (Mutographs).

3. Lithuanian biobanks helped in the fight against the SARS-CoV-2 virus pandemic. Our samples were used to validate existing and new serological and PCR testing techniques. Also, in response to the rising number of coronavirus variants of concern Lithuanian Biobanks have initiated a national SARS-CoV-2 sequencing project.

BBMRI.mt

BBMRI.mt
Biobanking and
BioMolecular resources
Research Infrastructure
Malta

MALTA

1

Number of biobanks
and stand-alone collections

~90,000

Number of samples/
size of collections in 14 collections

~ 1,000

Number of samples/
data used for research

5

Number of projects
supported

ABOUT THE NODE

The Malta National Node is the smallest within 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 the WHO. Biobanking continued to develop with support of particular collections with research grants and public or private sector funding. The PI is co-founder of EuroBioBank, the first European network of Rare Disease biobanking. The Malta Node 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 biobanking and a broader Euro-Mediterranean engagement.

TOP 3 AREAS OF EXPERTISE

1. Rare Diseases

2. Globin research

3. Mitochondria

TOP KEY SUCCESSES IN 2020

1. A reference Maltese Genome
2. Rare Disease events

ADDITIONAL COMMENTS

The Malta Node 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 Node shall promote further interest in:

1. Organization of consortia for competitive funding in bio-bank-led research
2. Rare Disease biobanking
3. The Euro-Mediterranean Platform

BBMRI.nl

BBMRI.nl
Biobanking and
BioMolecular resources
Research Infrastructure
The Netherlands

NETHERLANDS

113
Number of biobanks

970
Number of stand-alone collections

12,000,000
Number of samples/ size of collections

> 5,000
Number of Requested Pathology Tissue Blocks (yearly)

> 600
Number of users Omics dataset (total)

227
Number of Requests pathology portal, material + data (2019)

ABOUT THE NODE

It is the mission of BBMRI.nl to maximize the use of bio samples, images and data for health research on the prevention, diagnosis and treatment of diseases. For this, we make sure these resources are available in a FAIR way: Findable, Accessible, Interoperable and Reusable. We do this in compliance with ethical, legal and privacy demands, and with active participation of donors, citizens and patients. Without reinventing the wheel, we envision that samples and data will be exchanged and reused for various purposes in an efficient, effective and meaningful way, and in compliance with ethics, legislation and society's needs and wishes.

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

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

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

BBMRI.nl was one of the founding members of BBMRI-ERIC and has been a member since 2009.

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

TOP 3 AREAS OF EXPERTISE

1. Population omics/Imaging

2. IT for FAIR samples and data

3. ELSI

TOP 3 KEY SUCCESSES IN 2020

1. The Catalogue was extended with a COVID-19 filter and a multitude of COVID collections were added. The combination Catalogue-Podium (Find and Request) is in use and has facilitated 30+ data requests, for example for the Capacity Registry containing COVID data (https://capacity-covid.eu/for-professionals/).

2. The ELSI Helpdesk team organized very well attended online workshops regarding GDPR and observational research and the use of human data and material.

3. Under Health-RI the BBMRI.nl assets reach a broader audience and serve a larger and more diverse group of users.

BBMRI.no

BBMRI.no
Biobanking and
BioMolecular resources
Research Infrastructure
Norway

NORWAY

80
Number of biobanks
and stand-alone collections

15,000,000
Number of samples/
size of collections

> 300,000
Number of samples/
data used for research

ABOUT THE NODE

Biobank Norway (bbmri.no) is a large-scale national research infrastructure for clinical and population-based biobanks, established in 2011. Over the last 5 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-profile publications.

Digitization of biobank samples has been a major priority, focusing on large-scale genetic analyses (~ 400,000 study participants genotyped), metabolomics and proteomics.

The partners in Biobank Norway are the Norwegian University of Science and Technology (coordinator/Node director), the National Institute of Public Health, the University of Oslo, the University of Bergen, the University of Tromsø, the South-Eastern Norway Regional Health Authority, the Western Norway Regional Health Authority, the Central Norway Regional Health Authority, the Northern Norway Regional Health Authority, the Cancer Registry of Norway and Oslo University Hospital.

TOP 3 AREAS OF EXPERTISE

1. **Initiating and running some of the largest longitudinal, population-based biobanks worldwide**

2. **State-of-the-art clinical biobanks for research**

3. **Digitizing biobank samples and the establishment of secure solutions for storage and handling of sensitive, big data**

TOP 3 KEY SUCCESSES IN 2020

1. The Research Council of Norway granted BBMRI.no (https://bbmri.no) 4.3 M EUR for a third consecutive funding period (Biobank Norway 3, 2020-2024).

2. BBMRI.no has proven to be a highly valuable instrument for setting up COVID-19- related biobanks, also receiving several large grants from the Research Council of Norway.

3. Biobank Norway has launched a national initiative for precision medicine, bridging both population-based and clinical biobanks in this well received endeavor.

BBMRI.pl

BBMRI.pl
Biobanking and
BioMolecular resources
Research Infrastructure
Poland

POLAND

54
Number of biobanks

51
Number stand-alone collections

> 1,000,000
Number of samples/ size of collections

ABOUT THE NODE

Polish Biobanking Network (BBMRI.pl) is a unique research infrastructure in Poland with a main goal to harmonize biobanking units and biomolecular resources throughout the country. BBMRI.pl has been a member of BBMRI-ERIC since 2016. The consortium has been created by seven scientific partners: LUKASIEWICZ Research Network - PORT Polish Center for Technology Development (Consortium Leader, Leading National Research Center in Biobanking), Medical University of Gdansk, Medical University of Warsaw, Wroclaw Medical University, Medical University of Lublin, University of Lodz and Regional Science and Technology Centre in Checiny. So far 54 units biobanking biological material have joined the Network (29 Members and 25 Observers). Most of the Polish biobanks collect biological material of human and animal origin and are located at 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.

TOP 3 AREAS OF EXPERTISE

1. QMS Expert Centre

2. IT Expert Centre

3. ELSI Expert Centre

TOP 3 KEY SUCCESSES IN 2020

1. Launching the Polish National Node's Central IT Platform (polskasiecbiobankow.pl) with ability to export data to the BBMRI-ERIC Directory and compare biobank collections data previously uploaded with those currently presented on the Central Platform.

2. QMS BBMRI.pl expert group started audit process for compliance with Checklist 20387 in 5 Polish biobanks selected by BBMRI-ERIC QM. Wroclaw Medical University Biobank is the first biobank in BBMRI-ERIC awarded the Q-Mark in the BBMRI-ERIC Directory (BBMRI audited ISO 20387:2018). 5 units from Polish Biobanking Network have achieved Q-mark confirmation of compliance of QMS with the Quality Standards for Polish Biobanks.

3. BBMRI.pl has published a monography "The human body in scientific research and medical practice. A transdisciplinary approach" edited by Jakub Pawlikowski, Polish national ELSI expert and member of the BBMRI-ERIC ELSI Expert Network.

ADDITIONAL COMMENTS

Members of the Polish Biobanking Network in 2020 took an active part in the fight against the COVID-19 pandemic.

BBMRI.se

BBMRI.se
Biobanking and
BioMolecular resources
Research Infrastructure
Sweden

SWEDEN

450[2]
Number of biobanks

~160,000,000
Number of samples

371,575 / 278,583
Number of samples/
data used for research

470
Number of projects
supported

ABOUT THE NODE

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, building 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 2020

1. Addressing the COVID-19 pandemic head-on: Biobank Sweden was awarded additional funding amounting to 1 million Euros from the Swedish Research Council, as part of their major initiative to support COVID-19 related research efforts. A national working group was appointed in order to oversee the facilitation of sample collection, the safeguarding of standardisation matters in this context, and the distribution of funds. 17 out of Sweden's 21 healthcare regions were able to participate in the effort. At the end of the first stage, roughly half of the funding had been disseminated, the equivalent of around 30,000 COVID-19 samples made available for research. While facing several national pandemic-related challenges, Biobank Sweden embraced the opportunity to come together digitally: in addition to seamlessly switching nearly all national meetings over from physical to digital, no fewer than 145 Swedish participants joined Europe Biobank Week 2020, comprising more than 20% of all delegates at the European biobanking event of the year.

2. Further improving sample access: A main priority during 2020 has been facilitating access to samples for the scientific community. One project cluster has prioritised activities increasing output capabilities of regional joint biobank service facilities, aiming to improve sample access on a national scale. Focus areas include sample handling, reformatting, and improved sample data. In addition to making updates to the guide document put together in 2019, Biobank Sweden launched a web-based tool with the objective to facilitate access to samples for research and clinical trials, providing guidance for researchers and companies on getting access to existing samples in Swedish biobanks. These initiatives have remained highly successful, leading to steady sample output, even during the COVID-19 crisis.

3. Further strengthening national biobanking IT infrastructures: A pivotal step after the national IT strategy was finalised in 2019 was to address Sweden's National Biobank Registry (NBR). Development of the new iteration of the registry started after a period of significant technical delays and other challenges. The registry is crucial for Biobank Sweden's fundamental goal to give Sweden the best prerequisites for healthcare and research within the biobank area. 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.

[2] In 2020 EstBB delivered 6315 DNA samples, 583 plasma samples, NMR results from 11 007 EstBB subjects and 1 471 471 phenotype & genotype data on EstBB subjects.

Swiss Biobanking Platform

SWITZERLAND

58

Number of biobanks
and stand-alone collections

TOP 3 AREAS OF EXPERTISE

1. Quality **2. IT** **3. Networks**

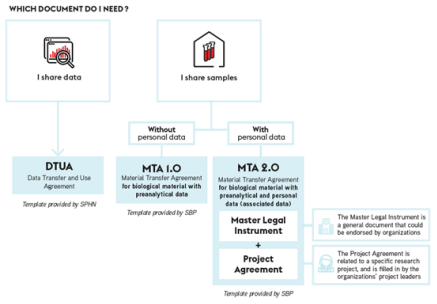
ABOUT THE NODE

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, Swiss Biobanking Platform (SBP) was selected by an international panel of experts in biobanking activities as the best concept to constitute a national biobanking platform. Today, SBP is the national coordination platform for human and non-human biobanks which supports biomedical research to address questions around quality, access, transparency and the interconnectedness of biobanks and their related data. With its newly developed tools (e.g. Biobank SQAN) and its overall quality strategy, SBP maps and monitors biobanks in Switzerland and provides them up-to-date technical knowhow and support for the management of their daily biobanking activities which includes IT management. Moreover, SBP links Swiss biobanks with BBMRI-ERIC through its Directory to foster biobank networks and increase sharing of information on biological resources and the related activities. This achievement is important for SBP as the Swiss Node of BBMRI. It gives Swiss researchers the opportunity to create new partnerships and collaborations within the European network and with other BBMRI nodes.

TOP 3 KEY SUCCESSES IN 2020

1. **SBP HARMONIZED DOCUMENTATIONS:** Harmonized documentations (e.g policies, SOPs, templates) in compliance with the European and international requirements and the applicable professional standards is key in SBP Quality strategy to increase the overall quality of research and lay the foundation of the Swiss biobanking practice in accordance with the highest and most relevant standards.

Main documentation development:
- SOP on Quality Control Implementation
This procedure provides a guidance on the developments to be implemented by the biobank to assess the quality of its biological material and related activities. This strategy focuses on measuring the performance of a biobank operational processes related to the objectives described in the future Quality Manual.



- MTA 2.0 to support researchers in the sharing of their biological material and health-related data

2. **BIOBANK SQAN:** An interactive tool to help biobanks become compliant with the minimal requirements in terms of governance, process and quality management. Through SBP Biobank SQAN, different labels validate their compliance with minimal governance (VITA), process (NORMA) and quality (OPTIMA) requirements.

Key success: SBP network is increasing over time with new biobanks as well as biobank infrastructures.

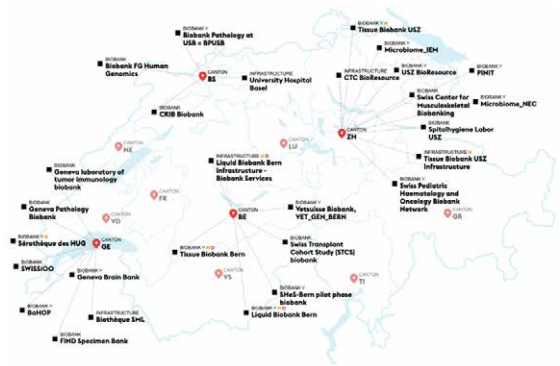
In 2020, SBP registered officially Swiss biobanks in the BBMRI Directory with 10 biobanks and 2 biobank infrastructures (https://directory.bbmri-eric.eu

SQAN 2020	Biobanks	Biobanks Infrastructure
Registered	46	12
Vita labe	28	N/A
Norma label	8	3
Optima label	3	2

C. **SBP NExT:** An interactive map to increase the visibility of SBP national biobanks through a directory highlighting their main features with an innovative search interface. This new tool is part of SBP strategy to foster SBP network and increase collaborations.

Main SBP development: SBP NExT as search tool to promote biobanks in SBP network and provide a national Directory

In 2020, SBP developed an interactive map with the possibility to make comparison between biobanks or to group biobanks around defined criteria. The list of criteria contains the following information and can be enlarged at any time: biobank type, species, canton, hosting organization, type of organization, purpose, research scope, SBP label, professional standards, services provided and type of entity.



BBMRI.tr

BBMRI.tr
Biobanking and
BioMolecular resources
Research Infrastructure
Turkey

TURKEY

5
Number of biobanks/
stand-alone collections

65,786
Number of samples/
size of collections

32,113
Number of samples/
data used for research

11
Number of projects supported:
1 international & 10 national

ABOUT THE NODE

The Turkish Node of BBMRI-ERIC aims to create a collaborative research infrastructure among biobankers, biomedical researchers, clinicians and patient organizations in Turkey to increase the biobanking capacity in rare diseases, cancer and COVID-19. BBMRI.tr actively participates in national activities to implement CEN and ISO standards in Turkish biobanks, and develops 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. Furthermore, BBMRI.tr seeks to expand the scope of biobanking in the Euro-Mediterranean region and MENA countries. The BBMRI.tr network has links with university biobanks, and actively participates in the establishment of the National Biobanking Research Infrastructure of the Health Institutes of Turkey (TUSEB). Currently, 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.

TOP 3 AREAS OF EXPERTISE

1. Rare Diseases

2. Cancer

3. Ethics

TOP 3 KEY SUCCESSES IN 2020

1. Establishment of COVID-19 Biobanks.

2. ISO 20387:2018 – Biotechnology – Biobanking training workshop with the Turkish Accreditation Agency accreditation experts, auditors and technical experts /managers of biobanks in Turkey.

3. Organization of a series of online training courses and preparing documents on the biobanking of COVID-19 samples and rare diseases biobanking.

BBMRI.uk

TISSUE DIRECTORY AND COORDINATION CENTRE

UK CLINICAL RESEARCH COLLABORATION

UNITED KINGDOM

834

Number of biobanks
and stand-alone collections

ABOUT THE NODE

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

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

TOP 3 AREAS OF EXPERTISE

1. Discovery processes, systems and best practice

2. Engagement of key stakeholders

3. Co-creation and collaboration with industry

TOP 3 KEY SUCCESSES IN 2020

1. Publication of researcher attitudes (https://www.liebertpub.com/doi/full/10.1089/bio.2019.0138)

2. Response to COVID - CO-CONNECT (https://www.nottingham.ac.uk/news/co-connect-funding)

3. Responses to COVID – Biobanks manager receives OBE (https://biobankinguk.org/biobank-manager-receives-obe-for-services-to-the-nhs-during-covid-19/)

International Agency for Research on Cancer

International Agency for Research on Cancer
World Health Organization

IARC

1
Number of biobanks
and stand-alone collections

5,901,628
Number of samples/
size of collections

59,330
Number of samples/
data used for research

28
Number of projects
supported

ABOUT THE NODE

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 2020

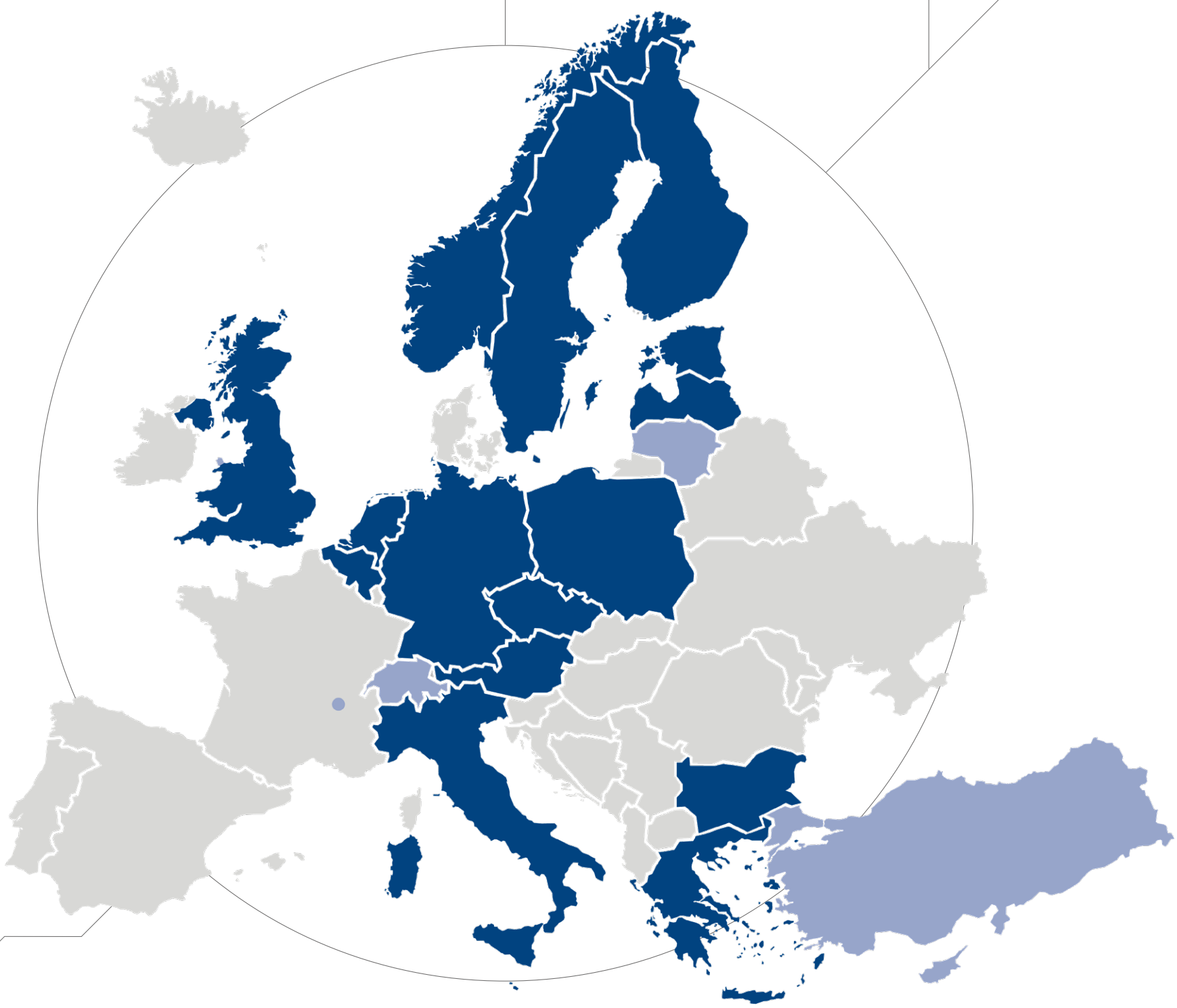
1. Partner in the key EU-funded project "Human Exposome Platform" (HEAP; https://heap-exposome.eu/)

2. Partner in the EU-funded project "Twinning for the Armenian Research Infrastructure on Cancer Research" (ARICE; https://www.arice.am/).

3. Partner in the major structural project "Impact of COVID-19 on Cancer" (IMCOCA), funded by the Cancéropôle Lyon Auvergne Rhône-Alpes.

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. 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 organized webinars to train BCNet members in Egypt, Kenya, Philippines and Nigeria using its online Biobanking learning platform, and relevant information on COVID-19 has been provided by BCNet partner institutions to all BCNet members.



ANNUAL REPORT
2020

BBMRI-ERIC, Graz

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

non-binding electronic copy

Building a better working world

BBMRI-ERIC,Graz

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

Duplicate

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BBMRI-ERIC, Graz December 31, 2020

TRANSLATION

TABLE OF CONTENT

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Note:

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

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.

We also:

- identify and assess the risks of material misstatement of the financial statements, whethe 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
Wirtschaftsprüfer / Certified Public Accountan

ppa Mag. Gerald Steckbauer mp
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 Germa 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.

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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 European Union and entered into force three days after publication on 3 December 2013. As from this date, the Biobanking and Biomolecular resources Research Infrastructure (BBMRI) was officially awarded the Community legal framework for a European Research Infrastructure Consortium (ERIC) and is henceforth to be called BBMRI-ERIC.

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

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

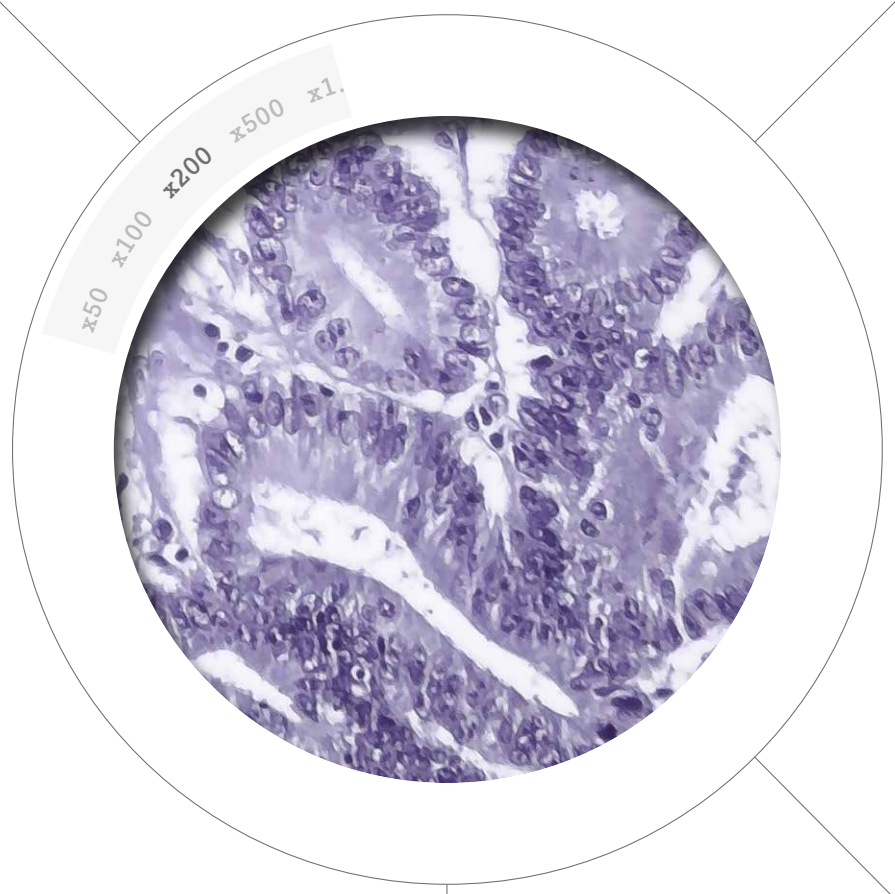
Liability
Members of BBMRI-ERIC

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 Republic, Republic of Latvia, Republic of Malta, Kingdom of the Netherlands, Kingdom of Norway, Republic of Austria, Republic of Poland, Republic of Finland, Kingdom of Sweden, United Kingdom of Great Britain and Northern Ireland

Observers
Republic of Cyprus, Republic of Lithuania, Swiss Confederation, Republic of Turkey, Internatinal 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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