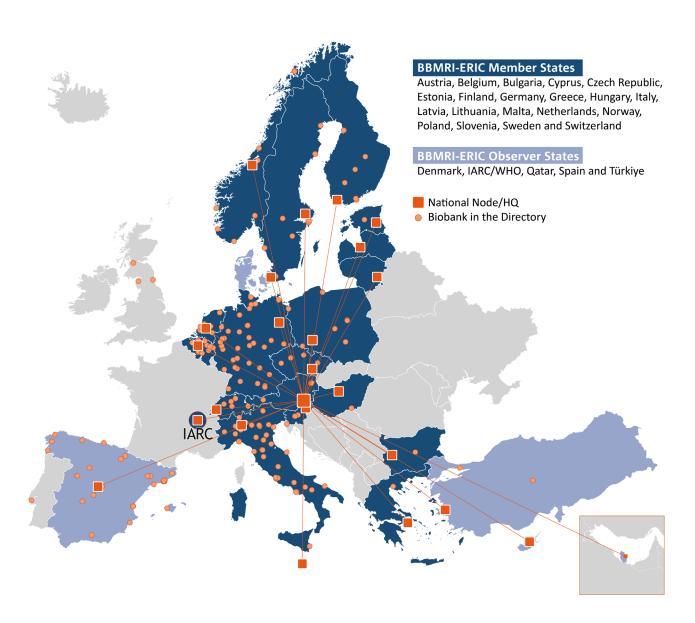


ANNUAL REPORT 2024

Participants of EBW24 at the Hofburg, Vienna, Austria



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BBMRI-ERIC
Members & Observers

About BBMRI-ERIC

BBMRI-ERIC is the European research infrastructure (RI) for biobanking and biomolecular resources, one of the largest RIs in the health and life sciences. Set up in 2013, its membership included over **400 biobanks** and **25 National Nodes** from 24 Member countries plus the **global organisation IARC/WHO** by the end of 2024.

A distributed research infrastructure, BBMRI-ERIC successfully develops multidisciplinary expertise and implements cutting edge services for the biobanking community that includes clinicians, researchers, biobankers, industry, patients and citizens.

The core services for, and provided by, the biobanking community are IT infrastructure, biobanking development support, quality management excellence and ethical, legal and societal implications expertise. These services facilitate access to high-quality samples, linked data and medical information through expertise in research, ethics, quality, datafication, imaging, Al and biobanking development. The aim is to achieve the core mission of facilitating access to samples, data, and biomolecular resources for public benefit.

BBMRI-ERIC's vision is that "by unlocking the potential of biobanking and biomolecular resources, BBMRI-ERIC inspires the best research to benefit patients, the public and the planet." This is simplified as: "Biobanking for a Healthier World".

BBMRI-ERIC takes a leading or key role in **EU Horizon projects** that cover genomics, AI, cancer, rare diseases, paediatrics, COVID-19 and other infectious diseases, federated platforms, personalised medicine, prevention, sensitive health data, European Health Data Space (EHDS), European Open Science Cloud (EOSC) and One Health.

BBMRI-ERIC in 2024

Members States:

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Slovenia, Sweden & Switzerland.

Observers:

Denmark, IARC/WHO, Qatar, Spain & Türkiye.

Governance

BBMRI-ERIC is governed by the **Assembly of Members (AoM)** which comprises delegates from our Member States who take collective decisions on matters relating to BBMRI-ERIC. This is supported by the **Finance Committee**, made up of Member States, to provide fiscal oversight to BBMRI-ERIC's operations.

The Assembly also receives assistance from the **Steering Committee** who are responsible for guiding and monitoring the activities of BBMRI-ERIC between the sessions of the Assembly of Members. This committee, reporting to the Assembly of Members, oversees implementing their decisions, including the Roadmap, the Work Programme and the budget.

The Management Committee (MC) comprises National Node (NN) Directors and coordinators who support Work Programme and budget development and implementation. The **Stakeholder Forum**, with Pillars Patient and Citizens, Industry, and Scientific Societies, exists with the aim to build a sustainable, egalitarian relationship between the biobank community and its stakeholders.

Finally, the **Scientific and Ethical Advisory Board** (**SEAB**), made up from distinguished scientists and experts, provides guidance to the Assembly of Members with regard to overall implementation and future developments of BBMRI-ERIC.

Executive Summary

For 2024, BBMRI-ERIC continued its focus on the three overarching topics of sustainability, community and collaboration as part of the third year of our Work Programme. Marking the research infrastructure's first decade of operation provided a vital opportunity to highlight how the community of biobanks and National Nodes scientifically contribute to and advance the health and life sciences landscape. We did this in several ways:

Increasing sustainability

Activities in 2024 contributed to rising awareness of **BBMRI-ERIC's** wide portfolio of scientific affairs in IT, Biobanking Development, Ethical, Legal and Societal Implications (ELSI) and Quality Management.

This was underpinned by integral services provided by the functions of Finance and Project Management, Public Affairs, Outreach, Education and Communications and Central Office, to provide support for the multitude of stakeholders.

Major outreach activities focused on BBMRI-ERIC's strategic stakeholders such as February's **10-year anniversary workshop** at the Austrian Embassy in Brussels. Here, we discussed with representatives from Member State ministries, the European Commission, and fellow research infrastructures how ERICs constitute a strong value proposition today and in the future.

2024 also marked looking into the future through the finalised BBMRI-ERIC 10-Year Roadmap (2025-2035). This was constructed through an unparalleled community and stakeholder co-creation process that led to a revised vision, mission and eight strategic objectives building on the developments and services of the research infrastructure's first of existence. The decade Roadmap adopts the "One Health" approach to prioritise the interconnection between human, animal and environmental health.

BBMRI-ERIC's 10-Year Roadmap for 2025–2035 was launched October 2024 in Brussels together with our Member State delegates, National Node Directors and representatives from the European Commission and partner organisations including scientific societies, research infrastructures and ERICs.

Strengthening community

The 10-Year Roadmap informed a new Work Programme 2025-2027 and its development began in 2024 in partnership with the National Nodes, biobanks and Stakeholder Forum Patient Pillar. Work Programme address all eight strategic objectives with a focus on prioritised operational goals. New special emphasis was given to National Nodes biobank engagement for the implementation by incorporating their expertise as responsible leads of individual operational goals. This enables them to act as "champions" for the wider BBMRI-ERIC community and create more synergies by benefiting from each other's cross-border activities. It is a responsible investment of resources yet also allows for acceleration of innovation.

Meanwhile, BBMRI-ERIC continuously fostered education, training and capacity building through BBMRI-ERIC's Academy, including CME accredited online courses and webinars. The flagship event, in partnership with ESBB, was the relaunched Europe Biobank Week congress (EBW) as an in-person event at the Hofburg, Vienna, in May 2024. This congress was attended by 653 participants from 38 countries representing citizens and patient organisations, clinicians, scientists and biobankers, policy makers and industry.

Leading collaboration

BBMRI-ERIC successfully continued its collaborations with scientific societies such as ESBB, EORTC, the Life Science Research Infrastructures and ERICs. Our continued coordination of the ERIC Forum 2 project was marked by onboarding three new ERICs, preparing and hosting a face-to-face consortium meeting in Brussels in February 2024, and substantially supporting the revision of the ERIC implementation statutes group led by the European Commission.

2024 saw the launch of major projects coordinated bv **BBMRI-ERIC** and its community including IntegrateLMedC with our National Node Director of Norway acting as the scientific coordinator. Key to strengthening the community and sustainability was the launch of EvolveBBMRI with specific emphasis on exploring new partnership models and datafication. BBMRI-ERIC continued to coordinate canSERV with 336 applications as of Dec 2024 from 41 countries worldwide and so far 56 service provisions.

During 2024, BBMRI-ERIC and its wider community invested substantial resources in EU project proposal applications in support of the Cancer Mission and synerdevelopments gistic among ERICs. As such, BBMRI-ERIC will be a significant partner in EU-CIP (building the European Cancer Patient Portal), CANDLE (conceptualising the National Cancer Data nodes connectivity to UNCAN) and UNCAN-CONNECT (building the European Understanding Cancer Platform being piloted through various use cases) and will coordinate PERI-FORMANCE – a project aiming to identify, optimise and promote innovative stakeholder engagement in cancer research by addressing the ethical, legal and societal implications (ELSI). These projects will kick off in May and September 2025.

In addition, BBMRI-ERIC will closely interact with the RI INFRAFRONTIER, which obtained ERIC status in 2024, in the funded project PRIM-TECH3R which will

allow both ERICs to explore closer interactions for service provision, e.g. by visualising state-of-the-art in vitro models from mouse disease models, complementing existing in vivo models, via BBMRI-ERIC's federated access platform.

BBMRI-ERIC successfully piloted the European Health Data Space and substantially supported the building of the EOSC Federation by chairing the EOSC Health Data Task Force and applying as EOSC Node. In fact, BBMRI-ERIC was selected as one of the first 13 EOSC Nodes in February 2025 with its unique value proposition in the sensitive Health Data domain. This is based BBMRI-ERIC's long-standing federated access and analysis platform connecting around 500 biobanks and 25 National Nodes across 32 countries with representation of over 7M citizens characterised by OMOP variables including clinical phenotype data. This comprises biochemical data, genomes and other OMICs related data, radiology and pathology imaging data as well as links to patient reported outcomes and survival registries along with various clinical sample types. This data conforms to FAIR principles and in a fully GDPR compliant manner to the highest technical readiness level (TRL9).

It is thus with some pride that we present our key achievements of 2024.



Prof. Dr. Jens Habermann, Director General, BBMRI-ERIC 6

PART 1

Service Achievements

Common Service IT

In 2024, BBMRI-ERIC significantly expanded its IT services, addressing broader needs of biobanks and biomolecular resources. A key advancement was the extended support for services and capabilities beyond previously available access to retrospective samples and data. Building on insights from projects like canSERV, EvolveBBMRI and EOSC4Cancer, BBMRI-ERIC implemented comprehensive updates to the MIABIS vocabulary and data model, facilitating better service description and integration within the Directory, Negotiator, and LifeScience Login authorisation model. This step allows clearer, standardised communication between biobanks and researchers, which enhances interoperability and security across BBMRI-ERIC services. Systematic User Experience analyses were performed across all services, leading to continuous improvements aimed at improving user satisfaction.

Directory

A notable infrastructure improvement in 2024 was migrating the BBMRI-ERIC <u>Directory</u> to the Molgenis EMX2 platform. This migration not only simplified deployment and operation but also prepared the Directory to host larger medical cohorts by integrating variable descriptors developed in the IntegrateLMedC project. Enhanced ontology and semantic data support aligned with FAIR principles now enable machine-actionable data encoding, significantly improving search and analysis capabilities.

Extensive updates to the quality analysis tools and sophisticated scripting ensured the smooth transition and added powerful new functionalities. The Directory also integrated Data Use Conditions (DUC) support, following recently published community standards. Collaboration between BBMRI-ERIC and ECRIN resulted in linking clinical trials with biobanks through the Directory and ECRIN's clinical trials repository thanks to the EOSC-Future project.



Negotiator

The **launch of** <u>Negotiator Version 3</u> represented another major upgrade, introducing flexible request forms and state management, coupled with a modernised user interface and robust software quality assurance practices through continuous integration and deployment (CI/CD).

Negotiator's integration within prominent EU initiatives such as the canSERV, ISIDORe and EUCAIM projects underscores its central role in facilitating secure, streamlined access to European biobanks. The team added robust monitoring tools in the Negotiator to assist National Nodes with efficient tracking of access request processes.

LifeScience Login/AAI

All of the BBMRI-ERIC services were **successfully transitioned to the LifeScience Login**; a collaborative effort with <u>ELIXIR</u> and <u>INSTRUCT</u>, which marked a key milestone for unified and secure authentication across research infrastructures.

MIABIS and Interoperability

BBMRI-ERIC's ongoing **development of MIABIS** in 2024 culminated in the publication of the MIABIS Core 3.0 paper, marking major progress in standardising biobank metadata. In alignment with the upcoming HealthDCAT-AP standard from the European Health Data Space, BBMRI-ERIC further developed the dataset component of MIABIS, ensuring compliance and interoperability with emerging European data standards. Furthermore, in collaboration with the EUCAIM project, a first proposal for incorporating digital pathology into MIABIS was initiated, representing a sizeable step toward standardising imaging data in biobanking.

Operational updates included the restructuring of the Helpdesk for improved responsiveness and reorganisation of MIABIS hosting on Github, now a definitive resource for MIABIS adopters. Maintenance updates were issued for MIABIS Sample and Donor components (version 1.1).

Federated Platform

The **Federated Platform Task Force** continued its vital work, onboarding new biobanks into Locator and Finder services, fostering active collaboration with solution providers to enhance service delivery and operational excellence.

Hosting centralised cohorts & data sets

In partnership with the EOSC4Cancer project, BBMRI-ERIC **integrated the widely-used** <u>cBioPortal</u> **with the xOpat viewer**. This integration facilitates simultaneous access to clinical, omics and digital pathology data, initially piloted on the BBMRI-ERIC colorectal cancer cohort and anonymised Whole Slide Images, offering researchers comprehensive, user-friendly analysis capabilities.

Federated Platform

The launch of the BBMRI-ERIC Federated Platform was a major milestone, integrating data from over 400,000 donors with more than 200,000 genomes. This platform represents a momentous enhancement in our capacity for federated analyses and querying, showcasing our commitment to improving biomedical research capabilities across Europe.

Continuous support to Nodes

Throughout 2024, BBMRI-ERIC continued to provide dedicated support to National Nodes, assisting with updates to data models and cohort documentation and reactivating the Negotiator monitoring group to maintain high standards in access request handling and guide future service development.

ELSI Services & Research

Multidisciplinary Expertise

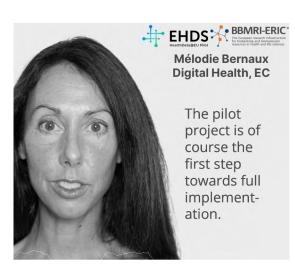
The Ethical, legal and societal issues (ELSI) Services & Research Department operates in partnership with a multidisciplinary network of experts from across the Headquarters, National Nodes and project partners, reaching different corners of science, technology and society. Our expertise comprises knowhow on privacy aspects, the ethics of AI, integration of sex and gender and risk typologies. We deliver reliable, practical and sustainable services based on state-of-the-art research for the immediate benefit of the life sciences community by setting standards, promoting best practices and enabling a sustainable platform for internal and public knowledge exchange.

Key activities

- Workshop at EBW24: <u>Ethics of Al: Hypes,</u> <u>Hopes and Risks of Al in Biobanking</u>
- Presentation at EBW24: Unlocking the Potential of Big Data and AI in Medicine: Insights from Biobanking
- Keynote at the 4th Paula Rantakallio symposium in Oulu, Finland
- Invited Speakers at ECR 2024: Societal Implications of AI in Radiology
- Workshop: Trustworthy AI and Guidance on Ethical and Societal Implications (<u>Bigpicture</u> <u>Annual Meeting</u>, 2024).
- Invited speaker at the BY-COVID Fest Training in data sharing and reuse under <u>GDPR IDTk</u> <u>contentathon</u> (23-25 January 2024, Athens)

Knowledge generation and transfer

Ethical, legal and societal expertise was provided for 23 research consortia, among which the ELSI team has been in the leading role for nine work packages such as the European projects INTERVENE, EHDS2-Pilot, EuCanImage, Bigpicture and Healthy Cloud. In 2024, we published five peer-reviewed articles, numerous public and confidential deliverable reports. In addition, Headquarter ELSI staff served as ethics reviewers (assessing Horizon Europe and MSCA proposals), ethics advisors providing practical guidance for granted EU projects, members of Scientific and Ethical Advisory Boards and evaluators. Moreover, we participated as keynote speakers and panel discussants at conferences and organised workshops.



Short interview with Mélodie Bernaux, Digital Health, EC, recorded at the EHDS Patient Data Workshop co-organised by BBMRI-ERIC's ELSI team.

BBMRI-ERIC Academy ELSI Symposium

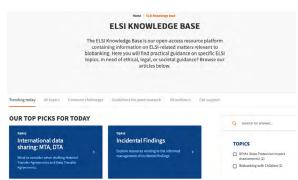
The BBMRI-ERIC, <u>UNIMIB</u> and <u>IARC</u> organised <u>Symposium</u> "Ethical, Legal and Societal Insights <u>& Outlook for Biobanks and Medical Research</u>" was held at the headquarters of the International Agency for Research on Cancer (IARC) in Lyon, France (June 4th - 6th 2024). Over two and a half days, the symposium featured seven keynotes and 30 unique presentations, offering cutting-edge perspectives on ethical, legal and societal implications (ELSI) relevant for biobanks

and biomedical research. The event celebrated the diverse range of ELSI expertise across different countries and disciplines, encompassing interdisciplinary services and research areas such as GDPR compliance, genetic counselling, science and technology studies, ethics and social sciences. A travel grant for young researchers was awarded as part of the symposium. Experience the event in this <u>Interactive multimedia story</u>.

Practical expert guidance

The ELSI Knowledge Base is an open access platform that translates research findings on ELSI related matters relevant to biobanking into hands-on guidance. It promotes practical knowhow for a diverse group of users ranging from researchers, biobankers, research participants to industry. Instead of lengthy lists of regulations, it strives to focus on "archetypical" situations (both topics and scenarios), so that users can quickly identify relevant best practices and frameworks. They can also find FAQs, model templates, and how-to guides — all vetted for long-term sustainability by an expert team. This approach ensures the Knowledge Base remains both user friendly and accurate over time, thereby closing the gap between researchers' practical needs and high-level compliance man-

dates. First conceptualised in 2018, the Knowledge Base is now solidified as an accurate, self-serving platform, which also promotes our <u>ELSI Dialogues</u> recordings that have reached an audience of 8,959 views since 2017 (an increase of 2000+ views over 2024).



Web portal fo the BBMRI-ERIC ELSI Knowledge Base

ELSI Helpdesk: A network of experts

The <u>ELSI Helpdesk</u> is continuously helping researchers navigate compliance with regulations (also informing about new/upcoming regulations such as the Artificial Intelligence (AI) Act or the European Health Data Space (EHDS) Regulation), ensures ethical best practices and addresses societal concerns related to emerging technologies and biomedical research. At the same time, it allows the ELSI team at HQ to identify emerging topics relevant for the community, which can be turned into future proposals, webinars or training. Focus areas and topics are often identified via ELSI Helpdesk requests. They come from across all stakeholders of the life sciences. The ELSI Helpdesk queries are counted

since 2017 (a total of 558 requests, comprising Ethics Checks, ELSI Helpdesk requests and consultations). In 2024, the Helpdesk responded to 109 requests, equalling 304 expert hours. Repeated topics included data privacy and genomics, ethics advisory boards or gender bias. The hours reported correspond to the time of the ELSI experts at the Headquarters alone. Whereas some requests can be solved in a few minutes, substantial requests required consultation among the ELSI Helpdesk Network, which comprises a distinct group of experts across BBMRI-ERIC Member countries and Observers. The Network meets quarterly, promoting knowledge transfer across Nodes.

Quality Management

Activities on standard developments standards developments

In 2024, the Quality Management (QM) department continued **supporting the biobanking community in standardisation**. BBMRI-ERIC is an active liaison partner in <u>ISO</u>, the <u>International Organization for Standardization</u>, and <u>CEN</u>, the <u>European Committee for Standardization</u>. QM representatives participate in ISO/TC 276 Biotechnology, ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems, ISO/TC 215 Health Informatics and in CEN/TC 140 In vitro diagnostic medical devices and provide updates, advice and training to the biobanking community on relevant standards.

In ISO/TC 276 Working Group (WG) 2, the QM department actively participates in the Systemic Review of the ISO 20387:2018 standard "General requirements for biobanking", contributing feed-

back and expertise from across its community to help improve and future-proof this standard. The revision is ongoing and anticipated for publication in 2026.

Furthermore, the ISO/TC 276 WG 5 decided to already revise Part 1: "Design concepts and general requirements of the planned seven-part ISO 23494 series on a provenance information model for biological material and data". The revision was led by the BBMRI-ERIC IT experts and it included restructuring the standard and addressing requirements which cannot be classified by different provenance information process stages. Additionally, the third part about the Provenance of Biological Material (ISO 23494-3) was approved as New Work Item Proposal.

Auditing for excellence

Once again, biobanks that committed themselves to excellence have been awarded the BBMRI-ERIC Quality Label by the QM department. Hannover Unified Biobank received it through the newly established fast-track pathway, following its successful ISO 20387 accreditation by DAkkS, Germany's national accreditation body. This procedure simplifies the process of obtaining a BBMRI-ERIC Quality Label and is being used more frequently by the community, which shows that the added value of having a BBMRI-ERIC Quality Label is being recognised.

At Europe Biobank Week 2024 in Vienna, the commitment to quality was celebrated as three biobanks received their BBMRI-ERIC Quality La-

bel certificates and trophies in an official ceremony. This recognition underlined the growing community of biobanks that fulfil the requirements of European and international standards.



BBMRI-ERIC Quality Label Award Ceremony at EBW24 (14-17 May, 2024) at the Hofburg Conference Centre in Vienna.

EU projects benefiting from QM expertise

The QM department was actively involved in the IMI projects ConcePTION and EPND, the H2020 project CY-Biobank and the Horizon Europe projects canSERV, EvolveBBMRI, INTEGRATE-LMedC, ISIDORe and QUANTUM. In particular, the contribution to quality-related tasks in two projects should be highlighted:

During the final year of the ConcePTION project important quality-related output was compiled in a publicly available deliverable called "Standard Documents for pre-examination processes for breast milk handling and Guideline for Biobanking". This and other key results of the project aiming at enhancing knowledge on the effects and safety of medication used during pregnancy and breastfeeding were celebrated at the closing event of the project in November in Brussels with all key partners attending.

The QUANTUM project started in 2024 with a kick-off meeting taking place in February in Brussels. The QM department co-leads Work Package 4 on "Capacity building, community engagement and scale up", where a milestone was achieved after conducting a survey on stakeholder learning needs in data quality leading to submitting the publicly available deliverable "Stakeholder learning needs assessment mapped to learning objectives".

Our active contribution in writing proposals led to the involvement in one approved Horizon Europe project called PRIM-TECH3R whose results are expected to fit well into BBMRI-ERIC's One Health vision and which will start in 2025.

BBMRI.QM contributions to training

The QM department contributes to the improvement of skills and knowledge in QM through a variety of activities. In 2024, lectures were given by QM department members to biobanking dedicated meetings such as the "BBMRI.it National Day" in Bologna (Italy) and the "ISCIII Platform meeting" in Lleida (Spain) as well as part of educational courses such as the biobank training at Medical University of Graz (Austria), a Training School in Izmir (Türkiye) and the Swiss Biobanking Platform biobanking courses. Topics focused on the importance of QM in biobanking and included introductions to the ISO 20387 standard and the BBMRI-ERIC audit programme. Furthermore, video modules on "Quality Management in biobanks" were created and offered to industry professionals and start-ups by EIT Health as part of a comprehensive biobanking course to which several BBMRI-ERIC departments contributed. A pre-conference workshop was organised at EBW24 titled "Making your way to ISO 20387

accreditation". A balanced mix of theoretical input and exchange among the participants was achieved through an introduction to the standard and hands-on training in four groups with insights from experts of already accredited biobanks. Additionally, three sessions with a focus on Data Quality were organised as part of the BBMRI-ERIC Academy. These activities combined with work of the EU project EvolveBBMRI WP1: "Acceleration of datafication of biobanks and biomolecular resources to enable reproducible advanced medical research". Training was conceptualised in the task "Support for BBMRI Nodes to develop IT expertise and operate Task Forces" and delivered as informational sessions on data standards in the context of the BBMRI.QM Newsroom, or as data quality themed training sessions. The QM department provided support for organising and hosting the sessions and recordings are available on the BBMRI-ERIC Academy website.

Engaging with the BBMRI-ERIC community on quality topics

As in previous years, the focus was on **building a network** of people interested in quality issues and promoting the exchange of knowledge and experience in various formats. In particular, the addition of data quality to our thematic focus led to a significant expansion of our network to over 290 experts. Internally, the QM department was strengthened by the recruitment of Stella Antoniou.

In 2024, the Working Group Quality Management System (WG QMS) held five meetings, engaging 281 participants from BBMRI-ERIC Member Countries and Observers. Discussions in 2024 covered crucial topics such as innovative quality control approaches, the importance of certified sample containers, accreditation efforts at national level, Swiss Biobanking Platform (SBP) Quality Labels approach and the potential of veterinary samples in advancing "One Health" research. Additionally, 59 participants engaged in two meetings dedicated to understanding the ISO 20387 standard and preparing for the BBMRI-ERIC Quality Label certification.

As complementary to the WG QMS, a new **Working Group Data Quality** was established to address topics specifically related to data quality

and quality of data management. It is a bridge between quality and IT in biobanking, targeted to a wider community. The aim is to support biobanks to verify and monitor the quality of data they host and to facilitate data interoperability within biobanks. The topics of the WG Data Quality are planned to be varied, ranging from organisational guidelines and standards to data standards and data models. At the end of 2024, two meetings were arranged with a total of 144 participants. During one meeting the WG and its aim were introduced, whereas the other one focused on Data quality, utility and maturity in the QUANTUM project.

The well-established virtual format BBMRI.QM Newsroom attracted 373 participants in four sessions, not only from Member Countries and Observers but also from Egypt, UK, France, South Africa and Moldova. In line with the expansion of our data quality capabilities, the focus this year has been on informing our community about activities such as MIABIS, OMOP and FHIR to standardise data in biobanks and improve their data interoperability and quality.



Group picture during Training School in Izmir (Türkiye)

Biobanking Development

The Biobanking Development (BBD) department experienced a dynamic year 2024, marked by the launch of numerous new initiatives and expansion of the team to address emerging needs. BBD maintained its core activities and services to support our community, as detailed below:

Community engagement through Green Biobanking

BBD led strategic activities towards Green Biobanking within BBMRI-ERIC through its leadership of the Teaming with Industry towards Green Biobanking within the EvolveBBMRI project. Here, we teamed up with BBMRI.at to engage with our biobanking community to map gaps and challenges in implementing and maintaining green biobanking practices. The work package aims to collaboratively establish a Green Biobanking Strategy with key industrial partners to co-create sustainable solutions aimed at reducing the environmental impact of daily biobanking practices while enhancing the long-term sustainability of biobanks.

Within this scope, BBD launched the Green Biobanking survey that was well received by our community as it focused on core environmental practices such as Energy Sources and Technology, water conservation, waste management and the three Rs (Reduce, Reuse and Recycle). In addition, BBD led two Green Biobanking workshops: "Greening of Biobanking" during EBW24 and "How to make Biobanking Greener" at the Nordic Conference on Future Health, September 2024, with active participation from our BBMRI-ERIC Biobanking community as well as key industry partners where best practices and challenges were presented and discussed with the community.

This work laid the foundation for the development of the Foster green biobanking and Research Infrastructure operations strategic objective within BBMRI-ERIC's newely developed 10-year Roadmap that was launched on the 15th of October 2024.

The INTEGRATE-LMedC project also launched in January 2024 with the objective to develop a comprehensive framework for managing and optimising the integration of large medical cohorts within research infrastructures. This involves establishing effective governance structures, defining clear policies and procedures and facilitating data sharing agreements. The project will enhance collaboration among researchers and healthcare providers, ensuring that patient benefits are prioritised. The goal is to accelerate scientific and medical advancements by im-



The Greening of Biobankingworkshop at EBW4.

proving the utilisation and harmonisation of medical cohort data across Europe and beyond. BBD is leading a work package on the Governance Framework and co-leading two other work packages, all of which will commence activities in 2025 and 2026. This project relies on strong leadership from our National Node in Norway.

BBD supports BBMRI-ERIC Access-pipeline Tools

BBD continued to support enquiries of researchers, biobankers and industries that are using our access pipelines (Directory, Negotiator and Federated Platform) to identify and gain access to samples/data essential for their research projects. BBD continuously monitored these submitted requests to ensure smooth communication and timely response by the biobanks within our network. Moreover, BBD continued to coordinate the Negotiator Monitoring Group which engages with representatives from the commu-

nity to examine issues pertaining to requests and the use of the Negotiator tool, development of new features etc., in collaboration with colleagues from the BBMRI-ERIC IT department. BBD played a leading role in the coordination of the BBMRI-ERIC Virtual Cohorts with strong participation from our National Nodes with cohorts that meet the pre-determined criteria to engage with academic and industry partners in future projects.

Enhanced visibility of our community through EU projects

Over 2024, BBD continued to lead scientific activities in on-going EU projects that rely on strong participation from the BBMRI-ERIC Biobanking community, such as:

ISIDOR BBD continued to facilitate samples/ data exchange of retrospective and on-demand collections of high-quality human biological samples (and associated clinical phenotype data) and high-quality data for the purpose of research projects on COVID-19 and different SARS-CoV-2 variants and epidemic-prone pathogens. Transnational Access (TNA) service within the ISIDORe project came to an end by January 2025. The project relied on the engagement of 40 biobanks from our 11 member states of our wider BBMRI-ERIC community.

canserv packages to provide access to samples and data to cancer researchers worldwide, relying on the active participation of 32 biobanks from 11 member states. In 2024, access to our biobanks for samples and data provision was requested in 22 submitted proposals.

BBD continued its activities in the CY-Biobank through collaboration on developing a state-of-the-art biobanking facility.

Outreach, Education, Communications

Developing outreach

2024 marked the final year over delivering the Work Programme 2022-2024, with its emphasis on community outreach and engagement. OEC welcomed new team members with specialist skills to support and enrich in-house processes that better serve and amplify National Nodes, biobanks and our wider community. Improvements included refining BBMRI-ERIC's image and event presentation, further developing the BBMRI-ERIC brand as part of the 10-Year redemarketing and highlighting and BBMRI-ERIC's achievements. Our 36 news articles in 2024 aimed at a variety of stakeholders and covered major strategic perspectives such

as FP10 and the value of QM, IT, BBD and ELSI training to the community. Our multimedia coverage approach also included engaging story-telling and social media content, building on our strong podcast platform with 14 rich community stories and training episodes related to the core BBMRI-ERIC scientific services. By continuing to bring in-house print and production services we are able to achieve deeper engagement that enhances value, visibility and recognisability of BBMRI-ERIC and its core services.



BBMRI-ERIC logo with: "Biobanking for a healthier world.

Highlighting BBMRI-ERIC's contribution

Over 2024, OEC provided key stakeholder dissemination and outreach support to 25 EU funded projects including ERIC Forum 2.

canSERV OEC played a key role in the flagship project canSERV. During 2024, this entailed outreach support on Open Calls, organising outreach webinars and materials and coordination of the annual meeting held in Brussels during October. OEC increased ambition for outreach for this project through a series of User Stories - real use cases of scientists explaining their canSERV facilitated cancer research projects. From interviews, graphic stories geared to different stakeholder audiences and audio were created for social media, presentations and the canSERV website. These were particularly well received by the European Commission. In addition, key stakeholder video interviews were recorded and released that focus on the value that canSERV provides across the translational cancer research communities.

Outreach goals of the EHDS2Pilot project were met by OEC producing podcast and accompanying content from the patient focused EHDS workshop. This profiled input from the European Commission, patient organisations, data and legal specialists as well as healthcare professionals.



canSERV User Story for wider public audiences

EVOLVE BBMRI, an infrastructure development project, launched in January with OEC partnering with BBMRI.DE to lead and develop communications and outreach. As part of the training and outreach work package, the team worked with National Nodes to produce strategic materials. This main element of the project, core to supporting the BBMRI-ERIC community is detailed below. In addition, articles, newsletters and social media coverage emphasised key messages and out-

OEC leads the communications work for INTEGRATE-LMedC that also launched in 2024 and centres on building a concept for large medical cohorts. Outreach activities included designing the visual branding, developing the plan for communications and outreach, producing articles and newsletters for internal and external stakeholders and building presence on social media.

puts of the project thus far.

Strengthening community

Task Force Communications and Outreach took on a stronger shaping role in 2024 as the main collaborative environment for communications tasks in the EvolveBBMRI project. It played a pivotal role in developing the Plan for Communications and Dissemination, pitching and developing value demonstrating success stories aimed at key stakeholders (patient advocates, scientists, clinicians, and institutions (universities, university hospitals, scientific societies)) and contributing to brand resources. This agile method of working supported not only the EvolveBBMRI project but facilitated this task force meeting its aims and delivering the work programme. The outcomes of this work benefit the entire community and support their sustainability.

The **10**th **anniversary workshop**, held in Brussels on 29 February, provided a key opportunity to showcase a decade of the research infrastructure to high-level stakeholders. OEC supported this by shaping communications, 10-year branding and, in particular, success stories that were collaboratively told by National Node represent-

ative and service heads. These were captured in case study and podcast form and augmented by National Node and Assembly of Members video portraits.

The first part of 2024 saw intense preparation of the first post-pandemic in-person Europe Biobank Week Congress. Overseen by BBMRI-ERIC and the European, Middle Eastern and African Society for Biopreservation and Biobanking (ESBB), the Congress was held at The Hofburg, Vienna from 14-17 May. It was supported by over 650 delegates, sponsors and speakers. The four days played host to high-quality workshop education, keynotes, parallel sessions and industry input. OEC provided comprehensive support through strategic marketing, uniform branding, social media campaigns and producing #EBWLive (an ambitious series of articles, full photography coverage, podcasts and video). This last element adds distinct identity and lasting value to the congress whilst also forms soft marketing for future years. Getting the congress back onto a yearly cycle is a major outreach and education achievement.

Developed over a series of workshops and key stakeholder consultations, the BBMRI-ERIC 10-year Roadmap launched at a high-profile Brussels event on 15 October. For the Roadmap, OEC pushed forward BBMRI-ERIC branding with a fresher look that incorporates the new vision 'biobanking for a healthier world'. This soft rebrand informs our look and feel for 2025 and beyond. The Roadmap itself contains a strong thread of developing value and impact focused communications and outreach that is led by the BBMRI-ERIC community with strong OEC support.



Official group shot with participants at EBW24.

Public Affairs

Driving Impactful Engagement in the European Research Area for the Research Infrastructure Community

Towards BBMRI-ERIC 10-Year Roadmap jointly with Member States

After a decade of operation, BBMRI-ERIC's 10th anniversary event took place in Brussels in February 2024. The high-level workshop brought together around 100 representatives of Member States, National Nodes, as well as key European partners and high-level officials of the European Commission. It highlighted examples of BBMRI-ERIC's achievements and impact in a session featuring headquarters staff, Member State National Node Directors and key biobanking community experts. The European Commission also outlined the successes of BBMRI-ERIC in a welcome speech, which was delivered by Ms Signe Ratso, DG RTD Deputy Director General. The keynote was delivered by Prof. Walter Ricciardi, EU Cancer Mission Board Chair and Chair of the BBMRI-ERIC Scientific and Ethical Advisory Board.

During 2024, BBMRI-ERIC further deepened its engagement with already existing Member States and Observers. In this context, BBMRI-ERIC participated in a variety of stakeholder events with Member States, including a presentation by DG Jens Habermann at the Nordic Conference on Future Health: Biobanks, Research, Innovation, Precision Medicine in Trondheim, Norway. Also, the Director General visited several Member States and met with the national biobanking communities and government including representatives, Prof. Mrówczyńska, Undersecretary of State for Science and Education, Laetitia Philippe, Vice Director, Head of the National Research and Innovation Division at the Swiss State Secretariat for Education, Research and Innovation and Cypriot

government and community representatives. By the end of 2024, the research infrastructure had 25 Members and Observers

Throughout the year, BBMRI-ERIC also continued to reach out to countries which are interested to join or cooperate with the community. Visits were made to non-member countries, such as Ireland in September, where a presentation was delivered at the 3rd BioBANC Symposium – a key event hosted by the University of Galway. In December, BBMRI-ERIC was also represented at the congress "102 Years Institute of Pathology (Back to the Future)" at the University of Zagreb School of Medicine in Croatia, as well as at the ICRI 2024 Global Conference on Research Infrastructures in Brisbane, Australia.

Through these visits and the surrounding activities, **meaningful relationships** were established with national stakeholders and the local biobanking community.



BBMRI-ERIC team with Ireland team

Towards BBMRI-ERIC 10-Year Roadmap and 3-Year Work Programme – jointly with Member States

Over the past decade, BBMRI-ERIC has successfully implemented cutting-edge services to support the European biobanking community in fulfilling its core mission: facilitating access to samples, data and biomolecular resources for public benefit. Building on this foundation, BBMRI-ERIC launched the development of a strategic roadmap for 2025-2035 through a co-creation process in autumn 2023.

This 10-Year Roadmap was adopted at the Assembly of Members in June 2024 and officially launched at a policy event in Brussels in October 2024. The event attracted over 60 participants from different directorates of the European Commission, ESFRI representatives, and representatives of other Research Infrastructures and communities related to the "One Heath" paradigm.

The Roadmap aims to enable ground-breaking science that benefits European patients, citizens and economies, while also recognising the critical interdependence between environmental and health outcomes. In this context, it embraces the "One Health" approach, prioritising the interconnectedness of human, animal and

environmental health. The Roadmap provides a strategic alignment framework for BBMRI-ERIC, grounded in the values of scientific excellence, equity, diversity, inclusion and fairness.

Following its adoption, the process began to develop the Work Programme 2025-2027, which operationalises the first three years of the co-created 10-Year Roadmap. Adopted at the AoM in November 2024, the Work Programme outlines strategic objectives and operational goals for biobanks, National Nodes and BBMRI-ERIC Headquarters. Its implementation will be jointly led by the National Nodes and Headquarters, guiding BBMRI-ERIC's operations in the coming years.



Launch of the BBMRI-ERIC 10-Year Roadmap (2025-2035) in Brussels on 15 October 2024.

Stakeholder Forum - Patients and Citizens' Pillar

Relations with patient organisations and patient representatives were further strengthened. In 2024, BBMRI-ERIC organised two meetings of its Patients and Citizens' Pillar, where further organisations joined in. By the end of 2024, the Pillar had 23 members from 14 countries and eight organisations at the European level. New members joined from Bulgaria, Italy, the Netherlands, and EU level. The patient

organisations, under the leadership of the Chair, prepared for their participation at the Europe Biobank Week in 2024 and have been involved in public activities related to the legislative process of the European Health Data Space, as well as in the activities of several EU projects, where BBMRI-ERIC oversees stakeholder and patient engagement.

ERIC Forum

FORUM its role as coordinator of the ERIC Forum — a clear sign of the trust placed in the research infrastructure by the broader ERIC community. The second phase of the ERIC Forum project (ERIC Forum 2) aims to further structure cooperation among ERICs, support the implementation of the ERIC Regulation and related services and strengthen their integration within the European Research Area (ERA). It emphasises deeper contributions to research policy, the systematic collection of aggregated and coherent data across ERICs and addresses key topics such as VAT implementation and engagement with third countries.

As **project coordinator**, BBMRI-ERIC remains committed to ensuring the timely and high-quality delivery of project activities and outputs. It also continues to serve as the secretariat for the ERIC Forum Executive Board and drives a variety of activities. In this context, the ERIC Forum Annual Meeting was organised in Brussels in February 2024 and the ERIC Forum Position Paper was published in April regarding "The Role of ERICs in the 10th Framework Programme (FP10)". Additionally, BBMRI-ERIC's Head of Public Affairs contributed as an expert to the European Commission's revision of the <u>practical guidelines on implementing the ERIC Regulation</u>.

EvolveBBMRI

The EvolveBBMRI project, coordinated by the Public Affairs department in close partnership with ten National Nodes, kicked off in Vienna on 30 January 2024. The three-year project aims to further develop the research infrastructure for the advantage of its scientific communities and users, to increase its capacity to serve EU policy priorities and fur-

ther deepen its collaboration with industry. With its focus on datafication, greening, collaborations, training and outreach, EvolveBBMRI activities and outputs will increase the long-term sustainability of BBMRI-ERIC and contribute to a better structured and strengthened European research infrastructure landscape.



Launch of the EvolveBBMRI project - joint MC/AoM

Key partnerships



Chairing the European Life Science Research Infrastructures cluster: Until Oc-

tober 2024, BBMRI-ERIC DG Jens Habermann was chairing the Life Science Research Infrastructure Strategy Board. In this role, BBMRI-ERIC organised the second in-person meeting of the cluster and acted as the contact for the Belgium EU Presidency and the EC, enabling the cluster to present at the EU Presidency event in 2024. Under BBMRI-ERIC's lead, the European Life Science Research Infrastructures launched a joint LS-RI Position Paper, outlining key messages for the next Framework Programme for Research (FP10): "Driving Innovation and Collaboration: A Strategic Vision for European Life Science Research Infrastructures in Framework Programme 10".



In 2024, BBMRI-ERIC chaired the European Alliance of Medical Research Infrastructures (EU-AMRI).

<u>EU-AMRI</u> is the collaboration between the European research infrastructures BBMRI-ERIC, EAT-RIS-ERIC, and ECRIN-ERIC. The three research infrastructures work in parallel to provide complementary services to researchers in the field of biomedical sciences and support the development of personalised medicine and new treatments. BBMRI-ERIC organised regular meetings to exchange and drive joint activities.

BBMRI-ERIC represented the ERIC Forum as mandated organisation in the EOSC Association until May 2024. As such, BBRMRI-ERIC chaired the ERIC Forum Working Group ERICs in EOSC and is representing ERIC Forum in the ESFRI-EOSC Task Force. BBMRI-ERIC coordinated the provision of collective input on materials

produced by EOSC Association from the ERICs,

advocating on behalf of the whole ERIC community for a clear and transparent process on key topics, such as establishment of EOSC Nodes. As a member of EOSC Association, BBMRI-ERIC engaged in various EOSC Association task forces.

Other partnerships and public affairs activities. In 2024, we strengthened our biobank community by connecting partners:

BBMRI-ERIC coordinated the **AoM Working Group on Strategic Partnerships** with drafting support for the concept for Strategic Partnership. This is a new concept for BBMRI-ERIC which will be tested with a pilot use case in 2025.

In 2024, the Public Affairs department was responsible for organising two meetings of the **Scientific and Ethical Advisory Board (SEAB)** of BBMRI-ERIC. One online meeting concerned the periodic implementation review that took place in April, plus several bilateral exchanges. The second online meeting addressed the ELSI review and took place in November.

In May 2024, the <u>BBMRI-ERIC Position Paper</u> was published on the next Framework Programme 10, outlining six key topics (focus on One Health, prioritise research in cancer, rare diseases and paediatrics, shape EHDS, strengthen international partnerships, enable access to different funding initiatives and avoid diversification). The paper was timed with the current evaluation of Horizon Europe and mapping out the research, technology and innovation policies that should be shaped beyond 2027.

Finance and Project Management

In order to leverage the organisation's growth over the last three years, the digitalisation of processes and automation of financial data management were, and remain, key to keeping the demand on resources as flat as possible.

In 2024, the **incoming invoices' approval process** as well as the time sheet approval process were digitalised. These two processes were quite time-consuming and inefficient, not only for the finance team but also for the employees and their respective supervisors.

The database-structured approach to handle financial data has allowed to prepare external (e.g., reports for EC funded projects, year-end closing, etc.) as well as internal standard and ad-hoc reports with less effort and higher reliability.

In project management, competencies and know-how were enlarged in the course of the execution of the projects which BBMRI-ERIC coordinates. In particular, this included the canSERV project with a consortium of 18 partners, a catalogue of more than 400 services offered by more than 150 service providers and a project budget of appr. 15 Mio. €, created a very valuable knowledge base, not only for BBMRI-ERIC but also for other potential future EC funded **SERV-projects**. This knowledge can be built on and become established structures of BBMRI-ERIC. An exchange with the respective department of the European Commission to build upon this experience and know how already took place.

Central Office

In 2024, the Central Office of BBMRI-ERIC continued to play a vital role as the administrative backbone of the organisation, supporting internal operations and facilitating effective coordination across scientific departments. It remained central to delivering efficient, high-quality services and enabling smooth communication and collaboration across the wider BBMRI-ERIC community.

In its support role, the Central Office contributed to the planning and execution of conferences, workshops and stakeholder meetings, further strengthening BBMRI-ERIC's event management capabilities and engagement with external partners. It oversaw all related travel logistics, including bookings, invoice control and reimbursement processes. In addition, the Central Office prepared regular reports, analyses and presentations for management and governance bodies.

Supplementary to operational tasks, the Central Office supported the development and refinement of internal policies, as well as the continuous improvement of organisational standards and procedures.

Working closely with the ELSI and IT teams, the Central Office also **supported key functions** such as the Data Protection Officer (DPO), the Gender and Diversity Expert (GED), and Systems Administration.

2024 KPIs

Key Performance Indicators

10,444	Users of BBMRI-ERIC Directory (during 2024)
183	Active Users of the BBMRI-ERIC Negotiator (during 2024) 46 requesters, 44 biobanker and biomolecular resource representatives*
88	Requests filed into the BBMRI-ERIC Negotiator (during 2024)
6	Requests successfully handled via BBMRI-ERIC Negotiator in that calendar year (2024)
9,134	Requests successfully handled outside of the BBMRI-ERIC Negotiator (during 2024).
304	Hours of BBMRI-ERIC ELSI Services provided (during 2024)
209	Attendees in BBMRI-ERIC ELSI Dialogues (during 2024)

Denmark did not collect KPIs for 2024. They will be available from 2025.



^{*} Note: 2024 is based on the new methodology approved by AoM, asking for separate number of requesters and biobank representatives.

2024 KPIs

Key Performance Indicators

- 1 New BBMRI-ERIC Quality (Q)-Label on BBMRI-ERIC Biobank, Laboratory/Institute or Expert Centre level in BBMRI-ERIC Directory (during 2024)
- New BBMRI-ERIC Quality (Q)-Label on Collection / Subcollection level in BBMRI Directory (during 2024)
- New Certified/Accredited BBMRI-ERIC Biobanks, Laboratories/ Institutes & Expert Centres (during 2024)
- 3,204 New publications involving BBMRI-ERIC (in 2024)
- 42,992 Participants reached by BBMRI-ERIC outreach events (in 2024)
 - **116** Participants in Stakeholder Forum (during 2024)
 - New successful grants (during 2024)



PARI 2

Financial Information

Financial Information

Core budget expenditures and allocated competitive research grants

The inflationary development in Europe over the last three years has necessitated a gradual shift in BBMRI-ERIC capacities from core to project activities. The impact on the financial stability was partially compensated by an increase in membership fees from existing member states as well as the stepping up of some Observer States to Member status.

2024 was a particularly successful year in the acquisition of new EC grants. In total 5,1 Mio. € in research grant funding were secured for

BBMRI-ERIC in seven new projects with a project duration between three and seven years. At the beginning of 2025, an additional project (PERIFORMANCE) was granted, which BBMRI-ERIC will coordinate (starting date: September 2025, grant amount: 0,86 Mio. € for BBMRI-ERIC). Together with PERIFORMANCE, BBMRI-ERIC will then coordinate five projects in total.

Profit & Loss Statement

Profit & Loss Statement					
In EUR	2020	2021	2022	2023	2024
Turnover	3.305.108	3.292.908	3.920.923	4.334.553	5.556.156
Other operating income	8.907	7.441	7.537	72.327	106.123
Material/Service Expenses	-	-	(1.920)	(291.054)	(329.875)
Staff expenses	(2.143.081)	(2.477.511)	(3.053.131)	(3.389.773)	(4.058.794)
Amortisation	(30.000)	(54.819)	(52.595)	(48.282)	(53.101)
Other operating expenses	(847.735)	(758.648)	(791.673)	(786.231)	(1.388.099)
Operating result	293.198	9.371	29.142	(108.460)	(167.590)
Other interest and similar income	-	-	1.355	3.548	200.617
Interest and similar expenses	(54)	(204)	(21)	-	(0)
Financial result	(54)	(204)	1.333	3.548	200.617
Loss from operating activities, Earnings before taxes	293.144	9.167	30.475	(104.911)	33.027
Taxes on income and revenue			(339)	339	(5.494)
Profit of the year	293.144	9.167	30.136	(104.573)	27.532
Reversal of profit reserves	-	-	_	-	-
Allocation to profit reserves	(293.144)	(9.167)	(30.136)	104.573	(27.532)
Profit carried forward from the previous years	367.775	367.775	367.775	367.775	367.775
Balance sheet profit	367.775	367.775	367.775	367.775	367.775

Balance Sheet

In EUR	2020	2021	2022	2023	2024
Intangible Assets	2.820	91.920	68.940	45.960	22.980
Tangible Assets	54.414	41.891	37.777	32.984	40.950
Fixed Assets	57.233	133.811	106.717	78.944	63.930
Receivables and other Assets	299.341	439.425	409.394	880.771	801.309
Receivables arising from deliveries services	93.001	254.117	51.397	167.914	173.581
Other receivables and assets	206.340	185.308	357.997	712.857	627.728
Cash on hand and Bank deposits	2.491.713	2.667.526	9.633.534	7.963.174	8.375.429
Current Assets	2.791.055	3.106.951	10.042.927	8.843.945	9.176.738
Prepaid expenses, deferred charges	2.811	3.923	1.453	1.643	51.734
Assets	2.851.099	3.244.685	10.151.097	8.924.532	9.292.401
Reserves pursuant to the articles of association	884.166	893.333	923.470	818.897	846.429
Balance sheet profit	367.775	367.775	367.775	367.775	367.775
Investment grants	-	13.189	9.791	6.448	3.217
Capital and Reserves	1.251.941	1.274.297	1.301.036	1.193.120	1.217.421
Other accruals	68.792	127.273	119.580	158.468	159.401
Accruals	68.792	127.273	119.580	158.468	159.401
Liabilities arising from deliveries and services	30.026	246.162	220.003	92.274	181.155
Other liabilities	396.798	221.866	312.529	221.685	263.182
Liabilities	426.824	468.027	532.532	313.959	444.337
Deferred income	1.103.541	1.375.087	8.197.949	7.258.986	7.471.241
Liabilities and Owner's Equity	2.851.099	3.244.685	10.151.097	8.924.532	9.292.401

Cash Flow

In EUR	2020	2021	2022	2023	2024
Profit of the year	293.144	9.167	30.136	(104.573)	27.532
Amortisation	30.000	54.819	52.595	48.282	53.101
Cash Flow from the Result	323.144	63.986	82.731	(56.291)	80.633
Δ Receivables arising from deliveries services	(6.258)	(161.116)	202.721	(116.518)	(5.667)
Δ Other receivables and assets	50.142	21.032	(172.689)	(354.860)	85.129
$\boldsymbol{\Delta}$ Liabilities arising from deliveries and servic-	(196.610)	216.136	(26.158)	(127.729)	88.881
es					
Δ Other liabilities	11.441	(174.932)	90.664	(90.844)	41.497
Δ Prepaid expenses, deferred charges	2.221	(1.113)	2.471	(190)	(50.091)
Δ Accruals	(593.752)	330.027	6.815.168	(900.075)	213.189
Δ Investment grants	-	13.189	(3.397)	(3.344)	(3.231)
Δ Working Capital	(732.817)	243.223	6.908.778	(1.593.560)	369.708
Cash Flow from Operations	(409.672)	307.209	6.991.509	(1.649.851)	450.341
Investing / Deinvesting	(15.256)	(131.397)	(25.501)	(20.508)	(38.086)
Cash Flow from Investing Activities	(15.256)	(131.397)	(25.501)	(20.508)	(38.086)
Δ Capital and Reserves					
Cash Flow from Financing Activities	-	-	-	-	-
Total Cash Flow	(424.928)	175.813	6.966.008	(1.670.360)	412.255
Cash Beginning	2.916.641	2.491.713	2.667.526	9.633.534	7.963.174
Δ	(424.928)	175.813	6.966.008	(1.670.360)	412.255
Cash End	2.491.713	2.667.526	9.633.534	7.963.174	8.375.429
·					

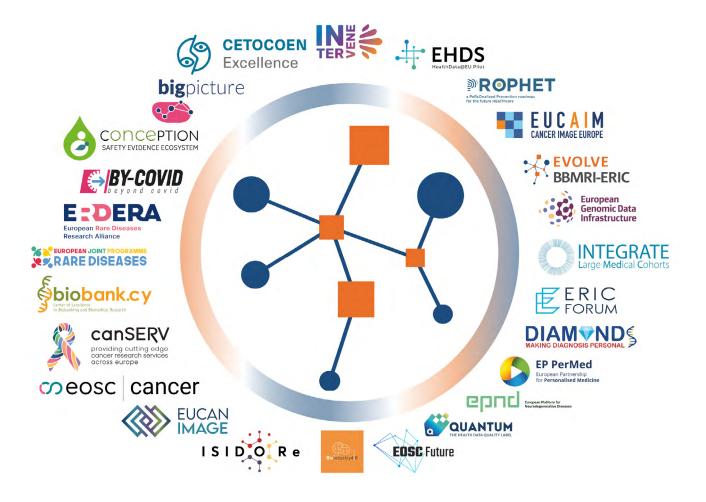
The cash flow in 2023 of +0,4 Mio. € shows that cash-out as well as cash-in from membership fees and project payments (relating to finalised and approved reporting periods from 2023 and 2024) are well balanced.

Over the next 1.5 years approx. 5 Mio. € from the current cash position will be used to finance canSERV TNA (TransNational Access) services for the research community in the field of cancer research as well as respective management, communication and dissemination activities.

PART 3 Projects

Active Projects

BBMRI-ERIC was active in the following projects during 2024:



Projects launched in 2024:

Coordinated by **BBMRI-ERIC**

INTEGRATE-LMedC

BBMRI-ERIC Budget: €862,286.25

Start date: 01.01.2024



The INTEGRATE-LMedC consortium will develop a new concept to guide

and support decision-making for the next-generation research infrastructure (RI) to facilitate efficient utilisation and harmonisation of large medical cohorts (LMedC) and to accelerate scientific and medical breakthroughs in Europe and beyond. Achievement of the ambitious objectives will only be possible through the integration of 11 highly interdisciplinary partners including established ERIC / ESFRI infrastructures such as BBMRI-ERIC, ECRIN, EIRENE and EBRAINS with unique expertise in conceptualising and implementing European RIs.

EvolveBBMRI

BBMRI-ERIC Budget: €2,683,178.75

Start date: 01.01.2024



The EvolveBBMRI project aims to further develop BBMRI-ERIC for the benefit of

Coordinated by

BBMRI-ERIC

its scientific communities and users, increase its capacity to serve EU policy priorities and further deepen its collaboration with industry. The project is structured in four thematic pillars: 1) Acceleration of datafication of biobanks and biomolecular resources to enable reproducible advanced medical research in support of EU health priorities; 2) teaming up with industry to facilitate greener biobanking; 3) setting longterm sustainability measures for BBMRI-ERIC that also address RI landscape gaps; and 4) strengthened approaches related to career paths, training and outreach activities to maximise impact.

Quantum

BBMRI-ERIC Budget: €170,000.00

Start date: 01.01.2024



Data users (i.e., research-QUANTUM ers, innovators, regulation agencies and poli-

cv-makers) need high-quality data. HealthData@EU, data holders are expected to make their datasets available for secondary use, providing a notion of their quality and utility and the maturity of their data quality procedures. In article 56 of the HealthData@EU proposed regulation, this notion would take the form of a label. With a consortium of 35 partners, QUANTUM is an EU-funded project that aims to create a common label system for Europe that guarantees the quality and utility of datasets for scientific and health innovation purposes. These labels will enable researchers, policymakers and healthcare professionals to identify high-quality data for research and decision making.

ERDERA

BBMRI-ERIC Budget: €111,878.75

Start date: 01.09.2024



The European Rare Diseases Research Alliance (ERDERA) aims to improve the health

and well-being of the 30 million people living with a rare disease in Europe, by making Europe a world leader in Rare Disease (RD) research and innovation to support concrete health benefits to rare disease patients, through better prevention, better diagnosis, better treatment. This Partnership will deliver a RD ecosystem that builds on the successes of previous programmes by supporting robust patient need-led research, developing new diagnostic methods and pathways, spearheading the digital transformational change connecting the dots between care, patient data and research, while ensuring strong alignment of strategies in RD research across countries and regions.



Central repository of digital pathology slides to support the development of artificial

intelligence (AI) tools.

BIGPICTURE

BIOINDUSTRY 4.0 R&D for the next generation of scientific instrumentation, tools and methods.

BY-COVID



BeYond-COVID (BY-COVID) aims to provide comprehensive open data on SARS-CoV-2 and other infectious diseases across scientific, medical, public health and policy domains.

canSERV

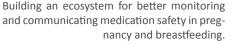


European wide research infrastructures, oncology experts and patient associations team to provide transnational access to cutting-edge, interdisciplinary oncology services across the entire cancer continuum.

CETOCOEN EXCELLENCE

To create the European Centre of Excellence in Environmental Health Sciences.

CONCEPTION



CY-BIOBANK



DIAMONDS

Demonstration pilots for implementation of personalised medicine in healthcare.

EHDS2 PILOT

Developing a pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, policy-making and regulatory purposes.

Expanding research infrastructure visibility to strengthen strategic partnerships.

EOSC4CANCER:



COPPED CANCEL FAIR and open data sharing in support of cancer research.

EOSCFuture

Integration and consolidation of the existing pan-European access mechanism to public research infrastructures and commercial services through the EOSC Portal.









Coordinated by

BBMRI-ERIC

















EPND

European Platform for Neurodegenerative Diseases for accelerating biomarker discovery and validation to support therapeutics development for neurodegenerative diseases.



EP PerMed

The European Partnership for personalised medicine.



ERDERA

European Rare Diseases Research Alliance. Improve the health and well-being of the 30 million people living with a rare disease in Europe.



ERIC FORUM 2

Coordination and monitoring of the European Research Infrastructure Consortia (ERICs).





EUCAIM

Federated European infrastructure for cancer images data.

EuCanImage

A European Cancer Image platform linked to biological and health data for next-generation artificial intelligence and precision medicine in oncology.



EUCAIM

CANCER IMAGE EUROPE

EvolveBBMRI

Further develop BBMRI-ERIC for the benefit of its scientific communities and users.





GDI

European Genomic Data Infrastructure. Federated European infrastructure for genomics data.



INTEGRATE-LMedC:

A new concept to guide and support decision-making for the next-generation research infrastructure (RI) to facilitate efficient utilisation and harmonisation of large medical cohorts (LMedC).





INTERVENE

International consortium for integrative genomics prediction.

ISIDORe

Integrated Services for Infectious Disease Outbreak Research. Research infrastructure services for rapid research responses to COVID-19 and other infectious disease epidemics.



PROPHET

A Personalised prevention roadmap for the future healthcare.



QUANTUM

To create a common label system for Europe that guarantees the quality and utility of datasets for scientific and health innovation purposes.



Coordinated by



PART 4

National Nodes

BBMRI-at biobanking for a healthier world



BBMRI.at comprises the Medical Universities of Graz, Vienna, Innsbruck, Salzburg, the JKU Linz and the University of Veterinary Medicine with their biobanks. The University of Vienna brings in legal expertise. BBMRI.at develops the Austrian biobanking research infrastructure and links it to the European community. The focus is to increase close cooperation and harmonisation between biobanks and fos-

ter research collaborations using samples/data and expertise. BBMRI.at partners hold 22+ million human and animal samples with associated data to support academic and industrial research. 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

Quality & data management: Developing/implementing ISO/CEN (pre-analytics) standards; QM cross-audits; Training/webinars; BSL-3 high-risk-pathogen-containing material biobanking; Data quality; High-capacity tissue slide digitalisation (whole-slide-imaging) & AI; Trusted data environment/access model; Catalogue/Biobank-Editor; Input to BBMRI-ERIC-Directory/Negotiator development.

Non-human & green biobanking: Veterinary/animal biobanking for comparative medicine/One-Health; Non-human biobanks (QM, ELSI); Green biobanking.

Stakeholder & user engagement: Stakeholder interviews (biobanking, data-citizenship); education/training (e.g., QM, standards & IVDR; courses and MSc Biobanking); public engagement (e.g., Long-Night-of-Research, biobank tours, children's courses); Industry-Forum; conferences; Online-Donor-Portal.

Top 3

Achievements

Harmonisation & standardisation: Leading "ISO-18701 human specimens for microbiome DNA"; ISO-24051-2 "Digital pathology & Al-based-image analysis" development: remote QM-cross-audits; Preparation for ISO-21899 implementation; driving the Austrian-Cohort-Initiative as platform for research groups with cohorts; Implementation of BBMRI.at Legal Helpdesk & Knowledge-Base supporting ELSI harmonisation.

Data management: Austrian biobank data landscape analysis; "trusted environment for patient/research data" in EvolveBBMRI; complementing biobank samples with digital whole-slide-images (WSI).

Stakeholder and user information and engagement: Multiple grants and industry collaborations with BBMRI.at partner contributions; Awareness raising on veterinary biobank collections' potential for comparative medicine/One-Heath and on environmental biobank sustainability; Joint BBMRI.at/BBMRI.de/GBN/BBMRI.ch/SBP animated video 'biobanks for researchers'; Numerous scientific publications with biobank/BBMRI.at contribution, presence in/on public media, newsletters, websites, social media; Biobanking education (e.g. courses, MSc programme).

BBMRI.at team at 56 MC Meeting, 13 May 2024 at UNIVIE. ©BBMRI.at







Belgium's scientific participation in BBMRI-ERIC was initiated in 2013 by merging the three existing Belgian network biobank initiatives. The activities of BBMRI.be are coordinated from the coordination office located at the Belgian Cancer Registry. All relevant biobank topics are addressed by more

than 60 biobank experts in the six working groups of BBMRI.be (IT, ELSI, Quality, Sustainability, Stakeholder Involvement, Networking & Valorisation). The BBMRI.be network currently connects 21 Belgian biobanks linked to public institutions such as hospitals, universities and research centres.

Top 3

Areas of Expertise

Clinical biobanks

Healthcare

integrated biobanking

Quality management of samples and data

Top 3

Achievements

Release of first annual BBMRI.be report with KPI's of BBMRI.be and BBMRI-ERIC. These KPIs will support the visualisation of BBMRI.be's added value, both nationally and internationally, while driving continuous improvement and alignment with strategic goals.

Development of a template to map all biobank related costs: Within the BBMRI.be sustainability working group, a tool has been developed to visualise the costs associated with biobanks. This will enable them to share these financial insights with researchers as well as the institutions management and help the biobanks with transparent reimbursement of their biobank costs.

Development of support documents SOP's and templates to support biobanks in the quality improvement process towards ISO-20387 accreditation (B3-ISO project). Templates have been harmonised and integrated in the domains of IT, ELSI and sustainability. These project deliverables received positive feedback from participating biobanks and are being validated by both biobanks and stakeholders.

Group picture taken at the BBMRI.be annual meeting on Nov 7th 2024 in Liège. ©BBMRI.be







The Bulgarian National Node of BBMRI-ERIC is based at Molecular Medicine Center, Medical University of Sofia, hosting the biggest national biobank with various clinical research collections. At present the biobanking network involves biobanks and collections in two of the biggest Medical Universities in Sofia and Plovdiv. Since 2019, the Ministry of Education and Science has supported the establishment of the National Node and biobanking network in Bulgaria in the frame of the National Roadmap of Research Infrastructures. Currently, biobanking is done in re-

search and diagnostic setting and various types of samples are collected, processed and stored such as tissue, serum, plasma, DNA and RNA, cell lines and associated clinical and demographical data. The goal of the National Node is to establish a 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

Research biobanking in oncology

Clinical biobanks for research in rare diseases

National expertise in QC and ELSI issues

Top 3

Achievements

More than 1,000 participants from Sofia and Plovdiv were recruited for the pilot 1,000 Bulgarian Genomes Project, data collected, DNA isolated and genome sequencing in progress.

Participation in several large infrastructure projects such as EvolveBBMRI, GDI and Genome of Europe aiming at datafication of biobanks and biomolecular resources for advanced medical research and support for the 1+MG initiative.

Stakeholders and users' information and engagement. Participation in multiple scientific events; presence in public media; working closely with patients' organisations, pharmaceutical industry, clinical researchers and public authorities to increase the knowledge and awareness of the role of biobanking and genomics for personalised medicine.









BBMRI.cy is the Cypriot National Node led by the Ministry of Health (MoH). Dr. Carolina Stylianou, Chief Inspector in the MoH, spearheads this initiative in collaboration with Prof. Constantinos Deltas, Coordinator of the biobank.cy Centre of Excellence in Biobanking and Biomedical Research, University of Cyprus Medical School, which is hosting the Biobank of Cyprus. Also engaged in the BBMRI.cy is a representative from the Cyprus Institute of Neurology and Genetics.

BBMRI.cy encompasses the nation's two biobanks and coordinates local collections. The Node offers secure, GDPR-compliant access to high-quality samples and data, provides ELSI expertise and links Cypriot researchers, clinicians, industry and international partners to Europe's federated biobanking platform.

Top 3

Areas of Expertise

We have been at the forefront of **pioneering research in inherited kidney disorders** for over 30 years, making a significant impact both locally and internationally.

Currently, the CoE is **expanding its scope** to encompass a broader range of inherited disorders, as well as complex genetic traits found within the Cypriot population. This expansion is driven by a systematic integration of biobanking and research.

- General population
- Kidney disorders
- Heart conditions
- Eye problems
- Others

Top 3

Achievements

Participation at the <u>Genome of Europe project</u> (GoE).

Completion of the <u>CYPROME_v3 project</u> (Cyprus Human Genome Project).

Renewal of ISO 9001-2015.

Biobank.cy CoE team portrait 2023. © UCY







BBMRI.cz is a distributed large research infrastructure supported by the Ministry of Education, Youth and Sports through the project called: "Network of Czech Biobanks". Since 2023, this infrastructure has 8 members, including specialised medical institutions (3) and universities cooperating with faculty hospitals (5). Our biobanks store material from

donors with cancer diagnoses, rheumatological diseases, diseases associated with hematopoietic disorders, or material collected in population or environmental studies. In addition to biological material and data, BBMRI.cz offers a unique set of technologies, services and knowledge needed especially for translational research.

Top 3

Areas of Expertise

FAIRification and **datafication** of biobanks

Digital and molecular pathology with focus on liquid biopsies

Analysis of exosomes and circulating DNA

Top 3

Achievements

Datafication: Seven of our eight member biobanks are already connected to the BBMRI-ERIC Federated Platform via the Locator tool.

Scientific awareness: A Memorandum of understanding was signed between BBMRI.cz and the Czech Health Research Council to raise awareness of biobanks, as a source of quality biological material, processed and archived in a standardised manner. Representatives of BBMRI.cz participated in multiple scientific and student events to increase the visibility of BBMRI.cz among scientists.

Visibility of BBMRI.cz at public authorities and patients: BBMRI.cz increased its visibility through participation in a patient-focused conference, the release of a podcast about biobanks and the publication of a Czech-language article aimed at popularising the concept and importance of biobanking. Additionally, on the occasion of the 10th anniversary of BBMRI-ERIC, the Czech national node was selected to present "success stories" illustrating the societal benefits of large research infrastructures (02/2024).

The team at Masaryk Memorial Cancer Institute. © Petr Uhlíř







The Danish Biobank Network is a national network that brings together Danish population-based, research and clinical biobanks to support scientific progress. By facilitating Denmark's participation as an Observer in BBMRI-ERIC, the network enhances international collaboration, linking Danish biobanks with European partners to promote knowledge exchange and joint research efforts. Additionally, the

network ensures strong cooperation among Danish biobanks, fostering synergy and coordination across institutions. The network consists of members from the Danish regions, the Ministry of the Interior and Health, universities with health faculties and the Danish National Biobank, creating a strong foundation for cooperation in biomedical research.

Top 3

Areas of Expertise

Strong Data Foundation

- Large population cohorts and high-quality disease specific biobanks available for research
- Extensive research data
- Seamless linkage to national health registries

Strong National Network

 National collaboration in a robust and open network

Extensive experience in providing and utilising biobank data

- High trust and support from the citizens
- Extensive use of biobank samples
- High utilisation of biobank samples in active research

Top 3

Achievements

Biobank Network Established and Strengthened

- Successfully consolidated a national biobank network
- Cross-national strategic goals defined
- · Joint application for funding

Returning Findings to Donors

- First phase: Returning incidental findings on familial hypercholesterolemia (400 individuals)
- Next steps: Expansion to cancer-related findings (BRCA and Lynch syndrome)
- Ethically responsible process with strict adherence to Danish guidelines on clinical validity and treatment pathways

Transparency & Citizen Involvement

- Notified 1.3 million individuals, increasing transparency and public engagement
- Ensured correct ethical handling and communication of findings

Representatives of the Danish Biobank Network (BBMRI.dk) at the network's steering committee meeting on 3 Sept 2024. © Eva Albertsen







The Estonian Biobank (EstBB) is a volunteer-based prospective and longitudinal biobank, maintaining and managing the biological samples and healthcare, lifestyle and omics data of 212,000 biobank participants. Available samples include DNA, plasma and buffy coat cells for all participants and more sample types for smaller subsets. Available data includes periodically updated health records from national

healthcare and other relevant registries, genotyping data from Illumina GSA microarrays and metabolomics data from Nightingale Health for all participants. Smaller subsets of participants have WGS (short-read and long-read), gut metagenome sequencing data, clinical biochemistry measurements, RNAseq and other data. More info here.

Top 3

Areas of Expertise

Sample and data collection from biobank participants, including initial recruitment as well as follow-up visits for specific research purposes. Recall studies can be conducted based on specific genetic findings.

Integration of electronic health records from structured data sources and transformation of more detailed free-form medical records to a research-ready format.

DNA analysis, including long-read whole genome sequencing, genotyping arrays and metagenomic sequencing.

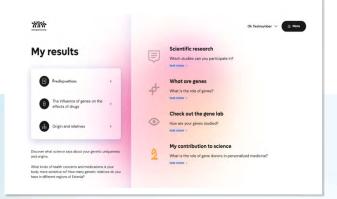
Top 3

Achievements

The public launch of the Estonian Biobank participant portal "MyGenome", providing all biobank participants with personalised information on their genetic predisposition to type II diabetes and coronary artery disease, pharmacogenetic reports, genetic ancestry information and fun facts.

Acquiring 3 PacBio Revio long-read sequencers for the Institute of Genomics of the University of Tartu as part of a project for long-read whole genome sequencing of at least 10,000 DNA samples from Estonian Biobank participants.

Estonian Genome Centre microbiome research group headed by Professor Elin Org recognised with Estonian national research award for the work series "Gut microbiome and health relations – new perspectives in health research", utilising the Estonian Microbiome Cohort (EstMB) at the Estonian Biobank.



The Estonian Biobank's "MyGenome" participant portal landing page illustrating the educational content (right) and personalised reports (left) available in the portal.
© bbmri.ee





BBMRI.fi (<u>www.bbmri.fi</u>) is a research infrastructure comprising ten biobanks in Finland. Finnish Biobank Cooperative (<u>FINBB</u>) has coordinated BBMRI.fi since

2020, appointed by the Finnish Ministry of Education and Culture.

Top 3

Areas of Expertise

National one-stop shop biobank services for researchers through Fingenious® services which includes Availability, Request and Recruit Services. More information: www.fingenious.fi.

High quality sample collections with associated clinical data derived from Electronic Health records (EHRs), as well as study / population cohorts and expert data analysis capabilities.

Capability and processes to contact biobank sample donors for participation in clinical and other studies and to inform them of research results and incidental findings.

Top 3

Achievements

Fingenious® services continue to enhance international collaboration. Already over 2,000 researchers from 40 countries have registered at www.fingenious.fi. Over 400 projects have been conducted and 2,000 scientific papers published in peer-reviewed journals.

BBMRI.fi grant application got excellent expert reviews and led to a grant of over 3 Mio. € by the Research Council of Finland (for 2025-2027).

FINBB organised 2024 Fingenious® Symposium

"From Target Discovery to Precision Medicine – the Unique Potential of Finnish Biobanks in Biomedical Research", which was a great success and received praise from the participants (e.g. "Real life cases, practical approach, and excellent speakers. Whole Fingenious ecosystem was presented.")

The 2024 Fingenious® Symposium "From Target Discovery to Precision Medicine – the Unique Potential of Finnish Biobanks in Biomedical Research". ® bbmri.fi



The BBMRI.fi team. © bbmri.fi

2024 Fingenious® Symposium

Registered: 423
Onsite: 171
Online: 252

Symposium recording:
https://www.youtube.com/live/KLTcXoEYeWg

2024 Symposium website





The <u>German Biobank Node (GBN)</u> serves as the umbrella organisation for academic biobanks in Germany that manage human biospecimens and associated data. As a founding member of BBMRI-ERIC, GBN has been driving progress in biobanking for over a decade. Under its coordination, 36 academic biobank sites and an IT development centre have joined forces in the <u>German Biobank Alliance (GBA)</u>.

Committed to improving biomedical research and ensuring reproducibility, GBA biobanks provide high-quality biospecimens and data for research throughout Europe. GBN is funded by the German Federal Ministry of Education and Research (BMBF, as of 2025: Federal Ministry of Research, Technology and Space, BMFTR). Learn more at bbmri.de.

Top 3

Areas of Expertise

Diverse expertise: GBA biobanks provide bioresources for almost all anatomical sites and diseases. A matrix is being developed showing where specific services are offered.

Quality management: Most GBA biobanks have trained auditors conducting 'friendly audits'. Hannover Unified Biobank was first in Germany to <u>achieve a BBMRI-ERIC 'Quality Label'</u> and is ISO 20387 accredited.

Networking: GBA biobanks are increasingly integrated into research initiatives, with 50% collaborating with industry.

Top 3

Achievements

Community-based strategy process: Based on a survey of GBA biobanks, a strategy meeting was held, from which the idea of 'biobanking on demand' emerged to efficiently support multicentre studies. Details of the concept are being developed.

Activities at European level: The EvolveBBMRI collaborative project has given an even greater focus to work at EU level. GBN also carried out a proficiency test with 21 biobanks from six European countries and produced a promotional video for researchers together with BBMRI.at and BBMRI.ch.

Patient participation: Together with representatives of several national patient organisations, GBN published a position paper on strengthening academic biobanks, which now serves as a basis for collaborative lobbying.









BBMRI.gr has received national funding for its preparatory phase (2019 – 2023). The final report of the PSF Country – Greece assessment (2022) of the EU, found that the RI had an excellent alignment with national RIS3 strategy and its goals to develop novel diagnostic techniques and personalised approaches and treatment for precision medicine. The report noted the strong perspectives for European collaboration and indicated that further effort was needed to develop governance, user access policy and orientation to innovation outcomes.

BBMRI.gr is ready to officially launch its operation based on an established national biobanking network with structured activities, linked to each other, so that data and material can be made mutually comparable, with phenotype descriptions and data registration, and be used under standard operational

procedures (SOPs). A common ICT (Information and Communication Technology) infrastructure in collaboration with BBMRI-ERIC, is established - a network using the hub and spoke topology to connect the National Nodes around Greece.

Regarding ELSI:

- (a) Coordinated ethical review process.
- (b) Data protection policy.
- (c) Access to the original tools in use in EU countries for transparent sharing of bioresources are provided to the members of the network.

Expert Centres established as public-private partnerships in the pre-competitive domain for the analysis of human biological samples with throughput technologies make the data available to industry, supporting innovation.

Top 3

Areas of Expertise

The RI offers expertise in critical areas:

- Molecular biology and genomics (BRFAA, Pasteur, EKETA), precision medicine, molecular pathology and oncology (participating medical schools, EKETA).
- Biomedical informatics (FORTH ICS/CBML, Harokopio).
- Biomedical engineering and big data (FORTH BRI/MEDLAB), public health and nutritional sciences (CPHRE and Harokopio), as well as social sciences and gender aspects (EKKE).

Top 3

Achievements

Successful Phase A application for funding at national level.

Integration of new biobanks in BBMRI.gr.

Strategic collaboration with <u>One Million Genome project.</u>







The BBMRI-ERIC Hungarian Biobank Node (HBN) serves as the national umbrella for Hungary's largest biobanks and represents the Hungarian biomedical research community within BBMRI-ERIC. Established in 2021 and supported by the Hungarian Research and Innovation Office, HBN connects six key biobanks from major academic, clinical and industry

institutions. Its mission is to ensure ethical, standardised and FAIR-compliant access to high-quality biospecimens and clinical data and supporting precision medicine and research innovation. HBN also fosters collaboration, training, and infrastructure development to enhance the national and international visibility and impact of Hungarian biobanks.

Top 3

Areas of Expertise

Disease-focused biobanking with rich, longitudinal clinical and molecular data.

Supporting clinical trials, especially in oncology, rare diseases and cardiovascular disorders.

High-throughput, quality-controlled biospecimen processing for academic and industry partners. Several sites contribute to real-world evidence generation and are active participants in the EMA's <u>DARWIN project</u>.

From left to right: Dr. Gergely Kriván, Dr. Hajnalka Andrikovics, Dr. Marta Szell, Dr. Maria Judit Molnar, Dr. Gyorgy Nemeth, Dr. István Balogh, Dr. Attila Gyenesei. Lab photo: Institute of Genomic Medicine and Rare Disorders. © bbmri.hu

Top 3 Achievements

Semmelweis Federated Data Warehouse was launched to enable secure, FAIR-aligned data sharing among biobank partners.

University of Szeged upgraded its biobanking system with a Liconics robotic platform and a new BSL-2 lab, enhancing capacity and biosafety.

HBN reached over 48,000 citizens through a <u>YouTube campaign</u> co-created with a local influencer to raise awareness of biobanking and the BBMRI-ERIC mission. Together, these efforts strengthen infrastructure, visibility and public engagement.







The International Agency for Research on Cancer (IARC) is the specialised cancer agency of the World Health Organization (WHO). The objective of IARC/WHO is to promote international collaboration in cancer research. The Agency is interdisciplinary, bringing together skills in epidemiology, laboratory sciences, biobanking and biostatistics to identify the causes of cancer so that preventive measures may be adopted and the burden of disease and associated

suffering reduced. A significant feature of IARC/WHO is its expertise in coordinating research across countries and organisations; its independent role as an international organisation facilitates this activity. IARC/WHO has a particular interest in conducting research in low- and middle-income countries through partnerships and collaborations with researchers in these regions.

Top 3

Areas of Expertise

Laboratory Support, Biobanking and Services (LSB) is a cross-cutting function of IARC/WHO, providing core laboratory and biobank services in order to support ongoing research across the continuum of activities at the Agency, serving as a reference point for many studies across the WHO. Three areas of expertise are:

- The IARC/WHO biobank conducts its own research activities (e.g., in particular in infrastructure research and ethics).
- It provides laboratory safety advice and training across IARC/WHO and serves as the interface with regulatory authorities and external collaborating bodies on these issues.
- The IARC/WHO biobank provides expert support and leadership to biobanks internationally through the <u>Biobank and Cohort Building Network (BCNet)</u> focusing on low- and middle-income countries (LMICs).

Top 3

Achievements

The hosting of the inaugural "BBMRI-ERIC Academy": Symposium – Ethical, legal and societal insights & outlook for biobanks and medical research". A showcase of 10 years of insights and perspectives on ethical, legal and social implications (ELSI) that are relevant for biobanks and biomedical research (June 04-06 2024).

The presentation of the ASEAN Healthcare study on biobanking, informing the 'ASEAN Leaders' Declaration on Strengthening Regional Biosafety and Biosecurity' (October 09 2024).

The hosting of a side-event at the World Health Assembly dedicated to "Childhood Cancer and Nutrition" (May 28 2024).









The <u>Italian Node of BBMRI-ERIC (BBMRI.it)</u>, established in 2013, is a distributed infrastructure including biobanks and biological resource centres 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, 45 hospitals,

15 patient associations and 98 biobanks, organised in thematic networks. 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 and 290 research groups. Annually, the BBMRI.it Help Desk processes a median of 250 requests related to ethical and legal issues and 300 request related to quality matters.

Top 3

Areas of Expertise

Quality Management (QM): QM training and support to biobanks. Support to implementation of the ISO 20387 standard.

Healthcare integrated biobanking and ELSI with a specific focus on co-production of knowledge as well as on stakeholder and user engagement.

Data management: secure IT solution for managing big data and sensitive data. Adoption of BBMRI-ERIC standards and development of tools to improve interoperability of research databases.

Top 3

Achievements

Development of an audit process for BBMRI-ERIC biobanks aimed at ensuring quality, regulatory compliance and the adoption of best practices in the management of biobanks.

Launch of the Knowledge Base digital platform and the Community of Practice Platform, collaborative virtual spaces to consolidate the extended BBMRI-ERIC community as an ELSI/RRI community of practice.

To improve the interoperability of biobanks and enable their connection to the BBMRI-ERIC Federated Platform, a <u>small-fire</u> has been developed. It is a framework designed to convert <u>MIABIS</u>-based minimum information datasets into HL7-FHIR transaction packets. Two additional biobanks joined the BBMRI-ERIC Federated Platform in 2024.

The large BBMRI.it community attending the BBMRI.it National Day.
© Lorenzo Merignati







The aim of <u>BBMRI.LV</u> is to provide resources for biomedicine research in Latvia and collaborate with institutions abroad, ensuring knowledge circulation,

development and setting of new goals, that will encompass international standards, best practices and promote scientific excellence.

Top 3

Areas of Expertise

Biological samples of population-based and disease-specific collections, survey data and information retrieval from health care system.

Large-scale sequencing (genome, transcriptome, exome, metagenome) and digitalisation of biological samples in national scale "omics" projects.

Activities in ELSI and quality management on national and international level.

Top 3

Achievements

Whole Genome sequencing and establishment of genomic data storage and processing infrastructure in Latvia for Latvian Genome Reference project under the "European Million Genomes Initiative" (1+MG). This will serve as foundation of future personalised medicine development in Latvia.

Organisation of national-level activities for biobanks and researchers about ELSI, QM and data protection and local level consultations. Promotion of Biobank law for coming in into force in Latvia participation in the working group for development of national regulation for secondary data use for research.

Participation in the development of more than 20 national-level and more than 10 international-level research projects; proposals include areas of diabetes, tumour research, rare disease, microbiome, omics data, ELSI and other.



Kristine at work in The Genome Database of the Latvian Population (LGDB). © bbmri.ly





The National Cancer Institute of Lithuania (NCI) coordinates the BBMRI.It infrastructure in partnership with Vilnius University, Vilnius University Hospital Santaros Klinikos (VUHSK), Innovative Medicine Centre, Lithuanian University of Health Sciences, and The Hospital of Lithuanian University of Health Sciences Kauno Klinikos. The National Biobank Network maintains a comprehensive collection of oncology, haematology, rheumatology and infectious disease

samples. These include unfixed, snap-frozen and formalin-fixed paraffin-embedded tissue samples and digital images, as well as blood, serum, plasma samples, viable cells, DNA/RNA and associated clinical/demographic data. The collection will be enriched through the expanded inclusion of biological material from various segments, including population-based collections. More at <a href="https://nxiv.ncbi.nlm.nih.gov/nxiv.nlm.nih.g

Top 3

Areas of Expertise

Advanced biorepositories for oncological and other diseases are being developed, integrating cutting-edge freezing and storage technologies tailored for preserving high-quality samples, including living tissue and cells. 3D cell cultures for advanced in vitro models.

NGS methodologies alongside data science to explore various diseases and population-based health concerns.

High-capacity pathology data digitalisation of whole slide images and AI solutions.

Top 3

Achievements

As presented at the "Biobank Infrastructure for Future Biomedicine" closing conference, the Human Biological Resources Center (HBRC) project has established a national biobank infrastructure with a standardised system for collecting and storing biological samples and managing related health data to advance biomedical science and health innovation.

HBRC is part of the Lithuanian RI Roadmap 2024 as an established research infrastructure and a member of BBMRI-ERIC.

HBRC plays a critical role in biomedical research, as evidenced by the results of the <u>Kidney Cancer Mutographs</u> published in Nature (NCI co-author) and the first dissociated tissue cell lines, along with the <u>ONCOINTEGRA project</u> focused on kidney, prostate and colorectal cancer research (VUHSK).

Conference "Biobank Infrastructure for Future Biomedical" organised by the National Cancer Institute and the Government of the Republic of Lithuania.







The <u>Malta National Node</u> is the smallest within the BBMRI-ERIC. It was established at the University of Malta, Faculty of Medicine and Surgery in conjunction with the signing of the ERIC, after many years of biobanking. The national biobank in Malta is <u>DwarnaBio</u>, a national initiative led by the University of Malta with the primary goal of establishing a central population-based biobank representative of the general Maltese population.

The University of Malta launched DwarnaBio, the country's national population biobank in June 2023. To date, approximately 300 have participated in this initiative, which collects and stores biological samples, such as blood or saliva, from volunteer participants across the Maltese Islands. These samples, along with health and lifestyle data, will serve as a resource for researchers investigating genetic links to various diseases.

DwarnaBio's primary objective is to establish a comprehensive representative collection of biological samples and associated clinical and genomic data, with consent to access health records and for longitudinal follow-up.

One of the standout features of DwarnaBio is its dynamic consent system, accessible via the web portal dwarna.mt. Unlike traditional models, DwarnaBio will allow participants to actively manage how their samples and data are used in research. Participants can amend or withdraw consent via the webportal, ensuring transparency and ongoing engagement. The portal will be further developed into a platform for disseminating research findings to the public.

Top 3

Areas of Expertise

Population biobanking

Dynamic consent models

Rare disease genetics

Through collaboration with the Ministry for Health and Active Ageing, DwarnaBio is in the process of performing whole genome sequencing on its collection, aiming to build a reference genomic database. This resource will provide access to both clinicians and researchers to aggregate anonymised genomic data from the biobank. This data help scientists understand genetic factors influencing both common and rare health conditions, while serving as an invaluable resource for the interpretation of genetic test results. Access and sharing of personalised data from DwarnaBio is regulated by an independent access committee. This initiative also forms part of Malta's contribution to the pan-European 1 Million Genomes of Europe initiative.

DwarnaBio is hosted at the Centre for Molecular Medicine and Biobanking within the University of Malta, which is part of the European network for biobanking, BBMRI-ERIC. This affiliation ensures that the biobank adheres to international standards for biobanking practices.

The project is open to volunteers from the general population, and those interested can register via the dwarna.mt portal.

Top 3 Achievements

Participation in large infrastructure events – Genome of Europe.

Ongoing recruitment for the Genomes of Malta project – to date over 300 participants recruited, with access to health records, DNA and genome sequencing in progress.

Incorporation of existing collections in DwarnaBio – the establishment of a rare neurological disorders collection, the rare skin disorders collection and the use of these collections in several projects and publications.

BBMRI.mt team with the local university of Malta administration. © bbmri.mt







Health-RI aims to enable data-driven health and life sciences research and to provide the national infrastructure to make health and life science data reusable at scale for research, policy and innovation. Health-RI collaborates with university medical centres, universities, private research organisations, patient organisations, national ministries and funders.

Health-RI hosts the distributed National Nodes of BBMRI-ERIC, EATRIS and ELIXIR and works towards a shared, ESFRI-overarching, international-grade service portfolio. <u>BBMRI.nl</u> facilitates harmonised collection, management, and distribution of health records, images, and biomaterials originating from a wide range of registries, cohorts, data and biobanks.

Top 3

Areas of Expertise

Promoting harmonisation by (further) developing and implementing procedures, guidelines and standards for biomaterial, image and associated data collections based on evidence and (inter)national alignment.

Providing support by (co-) developing, implementing, advertising and supporting Health-RI services that enable the finding and sharing of biomaterials, images and associated data.

Distributing knowledge with added value for the biobanks and collections via websites, contribution to current discussions and gatherings of the community.

Top 3

Achievements

Annual Health-RI conference with theme 'Trusting Forward', held on October 10th attracted more than 600 professionals from health care, policy, research and innovation. Together we strive for national agreements on and the implementation of the health data infrastructure.

Three national projects running to harmonise the pre-analytic process ("Dutch biobanking standard") and the consent procedures ("Mutual recognition") for biobanks and to provide guidance for the evaluation of biobank collections and ensuring long-term sustainability.

Regional biobank representatives of the seven academic hospitals and the two dedicated cancer hospitals meet at a monthly basis to work on the agenda of Health-RI, including the onboarding of collections towards a national catalogue and the activities of BBMRI-ERIC.



On 19 November 2024, the second edition of the Knooppuntendag took place in the Experience Center of the Radboudumc in Nijmegen. Under the theme "Advancing Together – accelerate & strengthen in a common course", the nodes came together to work on the future of the health data infrastructure. © bbmri.nl





<u>Biobank Norway (bbmri.no)</u> is a large-scale national research infrastructure for clinical and population-based biobanks, established in 2011. Over the last years, Biobank Norway has increased the number of users exponentially, offering a wide range of well-described, richly annotated biospecimens and

corresponding health related data, as well as genome wide genetic analyses (array-based) on 450,000 samples from population studies. These efforts have contributed to several hundred research projects subsequently published in a vast number of high-profiled publications.

Top 3

Areas of Expertise

Initiating and running population-based and clinical biobanks.

Digitised biobank data – secure solution for handling of sensitive big data.

Integrating data from multiple sources, such as national and local registries, electronic health records and population studies, mostly accessed through one national entry point

Top 3

Achievements

Nordic Conference on Future Health arranged in Trondheim with 450 participants/21 countries.

Scientific coordination of the EU-project INTEGRATE-LMedC 2024-2027.

Internal audit on ISO 20387 performed.

Panel discussion during the Nordic Conference on Future Health arranged by bbmri.no Sept. 2024. © Geir Otto Johansen







The <u>Polish National Node</u> coordinates the activities of the Polish biobanking community and its integration with the European infrastructure. The core BBMRI.pl consortium currently consists of eight biobanking institutions, with many others collaborating under the <u>Polish Biobanking Network</u>. Our node is responsible for internal and external communications, maintaining contacts and coordination with BBMRI-ERIC, representing the Polish biobanking community to na-

tional and international stakeholders and promoting Polish biobanking experts in the European initiatives and working groups. Our shared vision is to continue developing and expanding an integrated, sustainable and state-of-the-art biobanking network in Poland. To realise this vision, the biobanking community is committed to enhancing coordination, efficiency and quality in the management of biobank samples.

Top 3

Areas of Expertise

Collaborative biobanking with an expanded research dimension: an ability to bridge biobanking and disease research with the special focus on the new cellular models and digital pathology data acquisition and analysis, specifically tailored for the individual research projects.

Advisory role for the medical staff on the best practices for collecting and preparing the biological samples for state-of-art biobanking.

Extensive expertise in quality management in biobanking, aligning its practices with international standards such as ISO 20387. The consortium supports the implementation of robust quality systems across Polish biobanks, offering training, audits and guidance to ensure high-quality, reliable biological samples and data.

Top 3

Achievements

Collaborative Initiative towards a Harmonised European Quality Handbook for Biobanks - Quality Leaders from: BBMRI.pl (Agnieszka-Matera-Witkiewicz), BBMRI.be (Annemieke De Wilde), BBMRI.de (Nguyen Nhutuyen), BBMRI.ch (Josephine Uldry).

Development of Telemedicine IT Tools for Digital Histopathology - implementation of a virtual microscope to support remote diagnostics and analysis.

Regional Digital Medicine Centers (RDMC) Network formation - financed by Medical Research Agency (in 10 RDMCs Polish Biobanking Network Members are Leaders).

The Team of the Laboratory for Cell Research and Application, Medical University of Warsaw, BBMRI.pl © Medical University of Warsaw







Through ISO-certified and CAP-accredited opera-

tions, QBB supports local and international biomed-

ical research, enables clinical translation of scientific

discoveries and informs national health strategies.

By engaging actively with the BBMRI-ERIC commu-

nity, QBB-QPHI contributes to shaping a global bio-

banking ecosystem grounded in innovation, inclusiv-

Qatar Biobank (QBB), operating under the <u>Qatar Precision Health Institute (QPHI)</u> and Qatar Foundation, serves as the national biobanking infrastructure advancing precision health in the State of Qatar. As Qatar's designated National Node within the BBMRI-ERIC network, QBB-QPHI plays a central role in the ethically governed collection, processing and long-term storage of high-quality biospecimens and associated health data from both population and disease-based cohorts.

Top 3 | Top

Areas of Expertise

Large-scale longitudinal cohort studies (both population and disease-specific) with deep phenotypic and multi-omic profiling.

Integration with the national healthcare system to enable early intervention and delivery of personalised preventive care based on genetic and pharmacogenomic risk.

Biospecimen quality governance under ISO 20387, with rigorous standards for traceability, reproducibility and harmonisation.

Top 3

Achievements

ity and operational excellence.

Launched two landmark initiatives: the first Multiple Sclerosis (MS) Disease Cohort in Qatar and a Twin Study, both designed to investigate genetic, environmental and lifestyle determinants of disease, contributing new insights to global precision health research.

Established and operationalised a national referral pathway connecting biobank participants to the healthcare system, enabling clinical decision-making based on individual pharmacogenomic and genetic risk profiles.

Strengthened global visibility by leading the high-impact session "Ensuring Excellence: Elevating Data Quality in Biobanking" at Europe Biobank Week 2024 and organising the workshop "Achieving Biological Material Quality Harmonisation Outcomes" at the ISBER Annual Conference 2024. These activities, alongside leadership roles in BBMRI-ERIC, ISBER and ESBB, underscored QBB's commitment to shaping international biobanking best practices.









BBMRI.si consists of all three Slovenian public universities, the Slovenian National Institute of Biology, the University Medical Centre Maribor and the University Clinic Golnik. It is very interdisciplinary in its nature covering medical, biological, biochemical, IKT, legal, ethical and societal aspects. We tightly collaborate with the Slovenian Ministry of Health to prepare a new law on biobanking. Moreover, a tight collaboration with the Slovenian Society of Patient Organisations was established to further enhance our outreach. We successfully published important research findings in leading scientific journals including Nature Genetics, Nature Chemical Biology and

Proceedings of the National Academy of Sciences (U.S.A.). We tightly collaborate with Slovenian pharmaceutical companies Krka and Lek. The Director of the Slovenian National Node Prof. Dr. Urban Bren significantly contributed to the establishment of the new Sandoz high-tech centre for the production of biosimilars worth over 400 Mio. € in Lendava and was awarded with the corresponding Lek Prize. This investment will also create more than 300 new jobs with high added value. In 2014, he was also elected a full member of the European Academy of Sciences and Arts (EASA). He represents the class IV: Natural Sciences.

Top 3

Areas of Expertise

Autoimmune disorders

Cancer

Rare diseases

Top 3

Achievements

Obtaining stable government funding.

Inclusion of several Slovenian biobanks and their sample collections into Directory.

Shooting a 60-minute documentary about biobanking for the Slovenian public television to capture the interest of a general audience.

Urban Bren, National Node Director of Slovenia. © bbmri.si







The ISCIII Biomodels and Biobanks Platform (P_IS-CIII_BB) is a national infrastructure under the Institute of Health Carlos III (ISCIII) and serves as Spain's BBMRI-ERIC National Node. It currently consists of 42 core units and 23 affiliated units, structured into four scientific-technological HUBs: Biobanks (56 units), Organoids (25 units), Animal Models (28 units) and

3D Printing (21 units). Operating across 14 Autonomous Communities, P_ISCIII_BB enhances biomedical research by facilitating the collection, handling and supply of biological samples, along with associated clinical data, to support scientific and technological advancements on a national and international level.

Top 3

Areas of Expertise

ELSI experts within the P_ISCIII_BB provide top-tier guidance, training and consultations for researchers both nationally and internationally, responding to 4 ELSI-related consultations via the P_ISCIII_BB website helpdesk in 2024.

The P_ISCIII_BB Quality Management team, composed of 60+ members, oversees quality management, SOPs and the implementation of ISO 20387 in biobanking.

The P_ISCIII_BB enhanced visibility through an intense activity in Communication and Dissemination, contributing to 580 courses, 1,477 national projects, and over 1,100 dissemination activities in 2024.

Top 3

Achievements

Extensive Support for Research: The Biobank HUB catalogue expanded to 47 COVID-19 collections (69,552 samples) and 452 Rare Disease collections (106,166 samples), while the Animal Model HUB grew to 827 identifiers/services. Over 353,000 samples were provided for research, supporting biomedical studies and innovation.

Strong Patient and Research Collaborations:

With 307 partnerships with patient associations and national platforms, along with 152 international collaborations, the network continues to foster meaningful connections between researchers and the broader community.

Strengthening Global Research Collaboration:

With participation in 213 international research projects, the network has reinforced its role in high-impact studies. In line with this commitment, it co-organised the II JORNADAS DE LAS PLATAFORMAS ISCIII in October 2024, fostering national and international collaboration in biomedical and health sciences research.

Representatives of the Spanish National Node (BBMRI.es) at the BBMRI-ERIC – MC & AOM F2F Meeting (February 2025). © bbmri.es







<u>Biobank Sweden</u> is not a biobank but a national infrastructure for biobanking where healthcare, academia, industry and patient organisations collaborate to attain good healthcare and research. We do this by national coordination of regulatory and operative management including documentation, communication, education, quality management and

ELSI matters. Biobank Sweden also builds a national biobank registry with several functionalities including consent management for health care samples, finding samples for research and healthcare, management of biobank applications and management of applications for clinical trials that need access to biobank samples.

Top 3

Areas of Expertise

Regulatory management

Operative services for collecting, storing and accessing samples

Access to pathology samples

Top 3

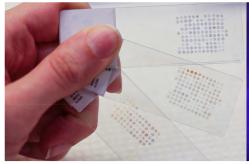
Achievements

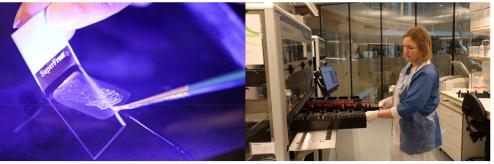
New long-term plan for 2025-2029 produced and decided as well as secured funding as an infrastructure of national relevance from the Swedish research council 2025-2028.

Continued implementation of the biobank legislation including harmonised, nationwide interpretation.

12 new national coordinated studies started as well as a national network for pathology study coordinators

Staff at Uppsala Biobank working with DNA extraction from whole blood. © Åsa Forsberg









In Switzerland, many biobanks operate with heterogeneous processes that make the usability and comparability of samples difficult. Moreover, biobanking practices have greatly evolved over the last ten years, from individual collections of biological material to professional infrastructures. In 2013, the SNSF launched a competitive call for constituting a national biobanking platform. The Swiss Biobanking Platform (SBP) concept was selected by an international panel of experts in biobanking activities.

Today, SBP is the national coordination platform for human and non-human biobanks which supports biomedical and biological research to address questions around quality, access, interoperability and the interconnectedness of biobanks and their related data.

Top 3

Areas of Expertise

Quality and Practice Harmonisation – SBP supports biobanks through documentation and its SBP Labels strategy, ensuring compliance with legal, ethical and professional standards (e.g., ISO 20387).

Interoperability and Visibility – SBP BIMS integrates SBP Datasets to streamline biobank data management and enhance biobank and sample <u>visibility via</u> <u>NExT (Network Exploration Tool)</u>.

Education – SBP offers a <u>CAS in Biobanking</u> in three modules to increase knowledge and competencies in biobanking.



Top 3

Achievements

SBP BIMS: Developed with DiData to support sample management, this professional Biobank Information Management System (BIMS) features two modules to configure intuitive workflows and facilitate operations and documentation by integrating datasets for various environments (e.g., Human Liquid, Bacteria).

A Certificate of Advanced Studies (CAS) in Biobanking: Launched in collaboration with Geneva University and Pasteur Institute, this online training covers foundational insights, implementation and professional management, engaging Swiss and international experts to address the demand for skilled biobankers.

Enhanced collaborations with national and European initiatives: Support of national projects (Genome of Switzerland, map of services, Biology Roadmap) and strengthen collaborations with national initiatives (SCTO, SPHN) and at the European level with BBMRI-ERIC (Film for researchers, Quality Manual, Quality Labels, 10 Year Roadmap).

The Swiss National Node team. © Louise Roy.





<u>BBMRI.tr</u>, the Turkish National Node of the Biobanking and BioMolecular Resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC), is dedicated to advancing biobanking excellence in Türkiye and beyond. Its mission is to build a robust, collaborative ecosystem that connects biobankers, biomedical researchers, clinicians, policymakers and patient organisations to strengthen the national capacity in the collection, management

and sharing of high-quality biological samples and associated data. With a particular focus on rare diseases and cancer, BBMRI.tr works to harmonise biobanking practices across the country by promoting the implementation of international standards (CEN and ISO), fostering interoperability and enabling secure, ethical access to biospecimens for research and innovation.

Top 3

Areas of Expertise

Biobanking of Rare Disease Samples and Associated Data

Activities in ELSI and quality management on national and international level

R&D and QC Studies in the Biobanking of Tissue Specimens

Educators from the BBMRI.tr team at the COST-TRANSLACORE Biobank Training School in June 2024, Izmir.

Top 3

Achievements

An application for accreditation by TÜRKAK under the ISO 20387 Biobanking standard has been officially initiated.

National and international educational activities continued with two events. <u>COST-TRANSLACORE Biobank Training School</u> was held with the participation of trainees from different countries across Europe. The workshop titled "The Use of Biobanks in Rare Diseases, the Dissemination of Standards in Biobanks and Analytical Processes" was conducted with the involvement of National Nodes and participants.

Four new collaborative projects have been initiated in partnership with the Departments of Pediatric Oncology, Medical Genetics and Gastroenterology.



PAR Additional Information

National Node Directors

BBMRI-ERIC's National Nodes are represented by National Node Directors. Our 2024 National Node Directors are:



Assoc. Prof. Georg Göbel Austria, BBMRI.AT



Anne-Marie Vangsted, MSc, Denmark, BBMRI.DK



Prof. Nine Knoers BBMRI.NL



Dr. Annelies Debucquoy Belgium, BBMRI.BE



Marco Hautalahti, MSc MBA Finland, BBMRI.FI



Prof. Kristian Hveem Norway, BBMRI.NO



Prof. Radka Kaneva Bulgaria, BBMRI.BG



Dr. Dimitris Thanos, Greece, BBMRI.GR



Dr. Michał Malewicz Poland, BBMRI.PL



Dr. Sara Nußbeck Germany, BBMRI.DE



Prof. Mária Judit Molnár Hungary, BBMRI.HU



Dr. Anna Beskow Sweden, BBMRI.SE



Prof. Lili Milani Estonia, BBMRI.EE



Prof.ssa Marialuisa Lavitrano Italy, BBMRI.IT



Prof. Urban Bren Slovenia, BBMRI.SI



Dr. Christine Joye Switzerland, BBMRI.CH



Dr. Daiva Dabkevičienė Lithuania, BBMRI.LT



Dr. Fatima Qafoud Qatar, BBMRI.QA



Dr. Carolina Stylianou Cyprus, BBMRI.CY



Dr. Vita Rovīte Latvia, BBMRI.LV



Prof. Bayram Yilmaz Türkiye, BBMRI.TR



Dra. Teresa Escámez Spain, BBMRI.ES



Dr. Nikolai Pace Malta, BBMRI.MT



Dr. Zisis Kozlakidis IARC/WHO



Assoc. Prof. Roman Hrstka, Czech Republic, BBMRI.CZ



Prof. Gerrit Meijer Netherlands, BBMRI.NL

The BBMRI-ERIC Headquarters Team

The 2024 headquarters team is based across Europe.



Saba Abdulghani Head of BBD



ELSI / Scientist



Stella Antoniou Quality Manager



Judit Balogh Senior Project Manager



Viridiana Beltrán Venegas Senior Administrative Assistant



Marthe Bierens
Public Affairs
Specialist



Verena Borecky-Kutej Research Assistant / ELSI



Saša Božić-Kraljik
Administrative
Assistant E



Mónica Cano Abadía Senior Scientist & Gender, Equality, and Diversity Specialist



Olivera Ciraki Research Assistant / IT



Ilaria Colussi
Data Protection Specialist
Data Protection Officer



Niina Eklund Data Quality Manager



Erdina Ene Legal Expert



Alexander Fürbaß Systems Administrator



Eva Garcia Álvarez IT Scientist & Project Manager



Melanie Goisauf Senior Scientist / ELSI Lead Ethics of AI Lab



Jasjote Grewal ELSI Services Officer



Jens K. Habermann Director General



Barbora Halmová Head of CO



Petr Holub
Head of IT / CIO



Jirka Horák Developer for WSI



Johanna Kostenzer Senior Public Affairs Specialist



Łukasz Kozera Senior Programme Manager



Konrad Lang Lead Developer & Service Operator



Kurt Majcen IT Scientist & Project Manager



Grazia MalovanBiobanking Specialist



Mariangela Masiello Media Relations Specialist



Michaela Th. Mayrhofer Head of ELSI



Aurel Molina
Project Management
Officer



Lana Mulabdic Finance Officer



Heimo Müller IT Senior Scientist



Nadja Palko QM Representative



Manuela Pausan Scientific Stakeholder Specialist



Jana Pavlič-Zupanc Head of PA



Michael Prattes Media Relations Specialist



Sára Pungor Administrative Assistant



Ulrike Rohrer Human Resources Specialist



Bridget SheehanMedia Relations Specialist



Eleanor Shember Head of OEC



Thomas Steger
Head of Finance/PM



Maike Tauchert
Quality Manager



Milos Terzic
UI Developer



Radovan Tomášik Developer & Service Operator



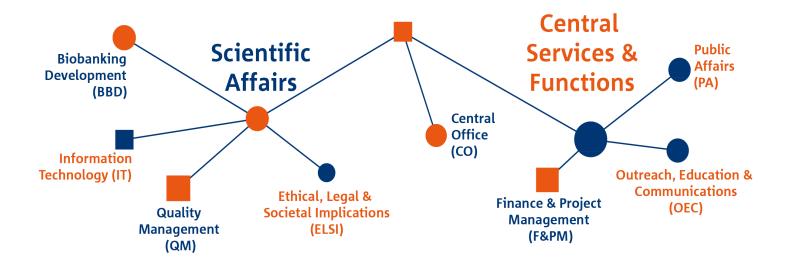
Rudolf Wittner
IT Scientist



Andrea Wutte Head of QM

BBMRI-ERIC's core domains

The BBMRI-ERIC headquarters, based in Graz, Austria, comprises the following scientific affairs and central services and functions:



Acknowledgements

We thank

Our Headquarters staff
National Node Directors and Biobanks
Ministries in Member and Observer States
for their continued
dedication and persistence
in supporting groundbreaking
medical research.

This Annual Report was co-authored by the Headquarters team and National Node Directors.

Layout and design: BBMRI-ERIC Department for Outreach, Education and Communcications.

Abbreviations

AI Artificial Intelligence
AoM Assembly of Members
BBD BioBanking Development

BBMRI Biobanking and BioMolecular Resources Research Infrastructure

BIMS Biobank Information Management System

BSL BioSafety Level

CI/CD Continuous Integration and Deployment

DUC Data Use Conditions

EBW Europe Biobank Week

EHDS European Health Data Space

EC European Commission

Ethical, Legal and Societal Implications

European Medicines Agency

EURTC European Organisation for Research and Treatment of Cancer

EUROPean Open Science Cloud

European Research Infrastructure Consortium

ESBB European, Middle Eastern & African Society for Biopreservation and Biobanking

ESFRI European Strategy Forum on Research Infrastructures

EU European **U**nion

FAIR Findable, Accessible, Interoperable, Reusable
FHIR Fast Healthcare Interoperability Resources
GDPR General Data Protection Regulations
HealthDCAT-AP Health Data Catalog – Application Profile

HQ HeadQuarters

IARC International Agency for Research on Cancer
ICT Information and Communications Technology

IMI Innovative Medicines Initiative

ISO International Organisation for Standardisation
IVDR In Vitro Diagnostic Medical Device Regulation

MC Management Committee

MIABIS Minimum Information About Biobank data Sharing

MS Member State

MSCA Marie Skłodowska-Curie Actions

NN National Node

OEC Outreach, Education and Communications
OMOP Observational Medical Outcomes Partnership

QM Quality Management
RI Research Infrastructure

RRI Responsible Research and Innovation
SEAB Scientific and Ethical Advisory Board

TNA Trans National Access
TRL Technology Readiness Level

United Nations

UNCANWHOWGSUNderstanding CANcerWorld Health OrganisationWhole Genome Sequencing

WSI Whole Slide Imaging

XOpat Explainable Open Pathology Analysis Tool

Legal Notice

Legal Address

BBMRI-ERIC

Neue Stiftingtalstrasse 2/B/6

8010 Graz, Austria

Phone: +43 316 34 99 17-0
Fax: +43 316 34 99 17-99
Email: contact@bbmri-eric.eu

This legal notice applies to the following internet addresses:

bbmri-eric.eu

twitter.com/BBMRIERIC

linkedin.com/company/bbmri-eric

youtube.com/channel/UCL2n13WcvK4jLg6AkFner4Q

bsky.app/profile/bbmrieric.bsky.social

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

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

Republic of Austria, Kingdom of Belgium, Republic of Bulgaria, Republic of Cyprus, Czech Republic, Republic of Estonia, Republic of Finland, Federal Republic of Germany, Hellenic Republic, Hungary, Italian Republic, Republic of Latvia, Republic of Lithuania, Republic of Malta, Kingdom of the Netherlands, Kingdom of Norway, Republic of Poland, Republic of Slovenia, Kingdom of Sweden, Swiss Confederation

Observers

Denmark, International Agency for Research on Cancer (IARC/WHO), Qatar, Kingdom of Spain, Republic of Turkiye

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.

Images titles and credits

Austria ©BBMRI.at (BBMRI.at team at 56 MC Meeting, 13 May 2024 at UNIVIE)

Belgium Group picture BBMRI.be taken at the BBMRI.be annual meeting on Nov 7th 2024 in Liège

Bulgaria The National Node Director presented BBMRI activities and the Genome of Bulgaria as part of

the Genome of Europe Project in 2024. Photo by Krasimira Pastirova

Cyprus Biobank.cy CoE team portrait 2023. Photographer: UCY

Czech Republic The team at Masaryk Memorial Cancer Institute. Photo by Petr Uhlíř.

DenmarkRepresentatives of the Danish Biobank Network (BBMRI.dk) at the network's steering

committee meeting on the 3rd of September 2024. Photo by Eva Albertsen

Estonia The Estonian Biobank's "MyGenome" participant portal landing page illustrating the educational

content (right) and personalised reports (left) available in the portal.

Finland The BBMRI.fi team

Germany Meeting of the German Biobank Alliance (GBA) in Göttingen. © GBN / Verena Huth

Hungary From left to right: Dr. Gergely Kriván, Dr. Hajnalka Andrikovics, Dr. Marta Szell, Dr. Maria Judit

Molnar, Dr. Gyorgy Nemeth, Dr. István Balogh, Dr. Attila Gyenesei. The lab photo is from the

Institute of Genomic Medicine and Rare Disorders, shot by David Kresalek.

IARC/WHO biobank team. Photo by Xuexun Zhou.

Italy The large BBMRI.it community attending the BBMRI.it National Day.

Photo by Lorenzo Merignati.

Latvia Kristine at work in The Genome Database of the Latvian Population (LGDB)

Lithuania Lithuanian Biobank Conference—Round Table Discussion. Photo by National Cancer Institute

of Lithuania, Cancer Information and Communication Department

Malta BBMRI.mt team with the local university of Malta administration

The Netherlands On Tuesday 19 November 2024, the second edition of the Knooppuntendag took place in the

Experience Center of the Radboudumc in Nijmegen. Under the theme "Advancing Together – accelerate & strengthen in a common course", the nodes came together to work on the future

of the health data infrastructure.

Norway Panel discussion during Nordic Conference on Future Health arranged by bbmri.no Sept. 2024

Photo credit: Geir Otto Johansen, Norwegian University of Science and Technology.

Poland The Team of the Laboratory for Cell Research and Application, Medical University of Warsaw,

BBMRI.pl; Credit: Medical University of Warsaw

Qatar Copyright 2025: Qatar Precision Health Institute

Slovenia Portrait of Urban Bren, National Node Director of Slovenia

Spain Representatives of the Spanish National Node (BBMRI.es) at the BBMRI-ERIC – MC & AOM

F2F Meeting (February 25-27, 2025).

Sweden Staff at Uppsala Biobank working with DNA extraction from whole blood. Photographer: Asa

Forsberg

Switzerland The Swiss National Node team. Photographed by Louise Roy.

Türkiye Left: This photo was taken in Izmir during the COST-TRANSLACORE Biobank Training School

in June 2024. Featuring the educators from the BBMRI.tr team. /unknown photographer. Right: This photo was taken in Bologna during EBW2025 in May. Featuring the representatives from

the BBMRI.tr team. / unknown photographer



To the Director General of BBMRI-ERIC, Graz

We have completed the audit of the financial statements as of December 31, 2024 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, 2024, including the accounting system pursuant to sections 269 et seqq. UGB (Austrian Company Code).

The Company is a small corporation pursuant to section 221 UGB (Austrian Company Code).

The audit is a voluntary audit.

The **audit included**, taking into account the accounting records, an assessment whether the statutory requirements were adhered to concerning the preparation of the financial statements.

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

We performed the audit, with interruptions, from March to April 2025 mainly at the premises of our office. The audit was substantially completed at the date of this report.

The **audit partner** responsible for the proper performance of the engagement is Mr. Clemens Corti alle Catene, 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 Auditors and Tax Advisors (refer to Appendix II) 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 UGB (Austrian Company Code) 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 of the financial statements. Therefore, we refer to the respective disclosures made by the Director General in the notes of the financial statements.

3. Summary of audit findings

3.1. Compliance of the accounting system and the financial statements

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

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

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

3.2. Information provided

The Director General and the Company's employees provided all evidence and explanations requested by us. We obtained a representation letter signed by the legal representative 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. 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 par. 1 subsec. URG (Austrian Corporate Restructuring Act).

4. Auditor's Report

Report on the Financial Statements

Audit Opinion

We have audited the financial statements of

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

These financial statements comprise the balance sheet as of December 31, 2024, 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, 2024, 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 (ISAs). 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.

Responsibilities of the Director General for the Financial Statement

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 consolidated 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 International Standards on Auditing will 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 ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit.

We also:

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

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

Limitation of Liability

The engagement to audit the financial statements was undertaken without a legal obligation ("voluntary audit"). We shall only be liable to the client and third parties in case of willful intent and gross negligence; liability for gross negligence is limited in accordance with the liability provisions of Section 275 (2) UGB (Austrian Company code) for the statutory audit of a small or medium-sized company to EUR 2 million.

PKF Corting Partner GmbH Wirtschaftsprüfer und Steuerberater

Mag Clemens Corty and Catene
Wirtschaftsprüfer CE Tiffed Public Accountant

Graz, April 09, 2025

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 and the management report are identical with the German audited version. This audit opinion is only applicable to the German and complete financial statements with the management report. Section 281 par. 2 UGB (Austrian Company Code) applies to alternated versions.



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