

BBMRI-ERIC[®]

The European research infrastructure
for biobanking and biomolecular
resources in health and life sciences

Annual report
2023

A background network diagram with orange lines connecting various nodes. Two prominent blue circular nodes are visible, one near the top center and one near the bottom center. The overall aesthetic is clean and modern, with a light orange and blue color palette.

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PART 1

Executive Summary

Executive Summary

For 2023, **BBMRI-ERIC** continued to focus on three themes: enriching sustainability, community and collaboration.

Set within the second year of our three-year Work Programme, this enabled BBMRI-ERIC — alongside the wider community of biobanks and National Nodes — to scientifically further advance, and substantially contribute to, the health and life sciences landscape. We did this in several ways:

Leading collaboration

As its coordinator, **BBMRI-ERIC** launched the ERIC Forum 2 project in September 2023 which brings together all ERICs.

BBMRI-ERIC also continuously runs the secretariat for the Executive Board of the ERIC Forum; hereby supporting further structuring of the European Research Area (ERA).

BBMRI-ERIC continued its coordinating role of canSERV. This project significantly contributes to the acceleration of transnational research in line with the EU Cancer Mission Board recommendations. By providing one access portal to over 400 cutting-edge services across 12 different Life Science Infrastructures, it defragments ERA. Through its first calls, canSERV has received over 150 applications from across 32 countries.

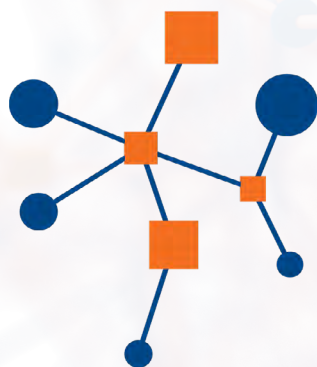
BBMRI-ERIC was successfully granted the projects EvolveBBMRI and Integrate Large Medical Cohorts (INTEGRATE-LMedC).

EvolveBBMRI targets future developments of our wider infrastructure and INTEGRATE-LMedC conceptualises how to leverage accessibility and use of large medical cohorts by closing gaps between clinical routine and

translational research. Both projects will be kicked-off at the beginning of 2024. We are particularly delighted that the BBMRI Norwegian National Node has taken the scientific coordinating lead of the INTEGRATE-LMedC project.

BBMRI-ERIC further supported the European Health Data Space 2 Pilot project (EHDS2) by leading the Work Packages on IT and ELSI expertise; hereby representing the only RI with an operating Federated Data Platform across its EU Member States.

BBMRI-ERIC also acted as Mandated Organisation on behalf of the ERIC Forum in the EOOSC Association and, as such, actively participated in the ESFRI-EOOSC Task Force. BBMRI-ERIC also became chair of the Life Science Research Infrastructure Strategy Board in 2023. Both activities demon-



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strate how BBMRI-ERIC not only fosters cross RI collaboration, and therefore alignment across the EU research priorities, but actively supports defragmentation of ERA within different flagship projects of the EC.

Increasing sustainability

Marking **BBMRI-ERIC's** 10th anniversary end of 2023, engagement and communications with Member States at Ministry and National Node levels have intensified through interactive workshops to develop a roadmap for the infrastructure's next ten years. This will ensure continuous alignment with National Nodes and their community activities while allowing an increased level of community engagement and co-creation with BBMRI's various stakeholder groups. BBMRI-ERIC's Evolve-BBMRI project, which has been granted by the European Commission and launched at the beginning of 2024, is closely aligned to this strategy development.

Strengthening community

Our strong education activities continued throughout 2023 with further EACCME[®] accredited BBMRI QM Academy training, ELSI Dialogues offered throughout the year and one successful Europe Biobank Week Roadshow in Innsbruck on Data Integration in Biobanking. The Roadshows are a new concept of community-engaging meetings that are conducted at different locations within our Member States with specific focus topics. In 2023, we also prepared to re-start our annual Europe Biobank Week Con-

gress taking place during May 2024 in Vienna – the first time as face-to-face meeting after the COVID-19 pandemic.

Strategic collaborations with the EU-AMRI Alliance, ELIXIR, EORTC and ESBB (European, Middle Eastern & African Society for Biopreservation and Biobanking) have been continuously strengthened. New partnerships have been initiated focusing within the Life Science Research Infrastructures and European Scientific Societies operating in the health domain.

BBMRI core services continued to seamlessly operate for the wider community and we are happy to report an increase of users of the services. For example, BBMRI-ERIC Directory counted an increase of users from 6300 in 2022 to more than 8900 in 2023.

BBMRI further grew in its membership by welcoming the biobanking communities from Denmark and Qatar as Observers. Cyprus, Lithuania and Switzerland stepped up from Observer to full Member status.

BBMRI-ERIC thus currently comprises 24 Member States and Observers and one international organisation – the IARC/WHO.

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



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

PART 2





Service Achievements

Common Service

Directory & MIABIS Enhancements

This year marked the successful finalisation and implementation of the MIABIS star-schema¹ and its integration into the BBMRI-ERIC Directory. The star-schema facilitates medium-depth information processing, allowing for a deeper characterisation of variables and their combinations per collection. This implementation was crucial for optimising search functionality without necessitating real-time federated querying, though it requires columns to be pre-selected based on anticipated search criteria. Directory has been continuously developed to optimise the user experience, in collaboration with a dedicated User Experience team within Common Service IT.

Negotiator Tool Developments

We continued to enhance our negotiation tools, maintaining *Negotiator V2* and preparing for the launch of *Negotiator V3* in early 2024. V3 features a completely redeveloped user interface, utilising new technologies for greater flexibility in managing access requests and negotiation workflows, thus enhancing the tool's functionality in projects like EUCAIM and EJP RD.

1 <https://www.liebertpub.com/doi/10.1089/bio.2023.0074>

2 <https://www.iso.org/standard/80715.html>

3 <https://github.com/BBMRI-ERIC/miabis?tab=read-me-ov-file#miabis-core>

4 <https://athena.ohdsi.org/search-terms/terms?query=miabis>

5 <https://www.nature.com/articles/s41467-023-37991-y>

Data use conditions: disease specific research
health or medical or biomedical research
return to database or resource

Cohort (CRC-Cohort) Network network

Collaboration

Commercial:

Not for profit:

Split by: Material type Sex Age range Disease codes

Material type	Sex	Age range	Disease codes	#Donors	#Samples
All	All	All	All		
Tissue (frozen)	Female	Aged (>80 years)	Malignant neoplasm of colon - Malignant neoplasm: Caecum	22	89
Tissue (paraffin preserved)	Female	Aged (65-79 years)	Malignant neoplasm of rectosigmoid junction	64	64
Tissue (paraffin preserved)	Female	Aged (>80 years)	Malignant neoplasm of rectosigmoid junction	21	21
Tissue (paraffin preserved)	Female	Adult (25-44 years)	Malignant neoplasm of rectum	61	61
Tissue (frozen)	Female	Middle-aged (45-64 years)	Malignant neoplasm of rectum	42	135
Tissue (paraffin preserved)	Female	Middle-aged (45-64 years)	Malignant neoplasm of rectum	437	446
Tissue (paraffin preserved)	Female	Aged (>80 years)	Malignant neoplasm of colon - Malignant neoplasm: Caecum	133	141
Other	Female	Middle-aged (45-64 years)	Malignant neoplasm of rectum	25	105
Tissue (frozen)	Female	Aged (65-79 years)	Malignant neoplasm of rectum	55	203

Standardisation Initiatives

Significant strides were made in standardising biobanking processes, with the release of ISO 23494 Part 1 as a final ISO Technical Specification². Moreover, the data model describing sample types in the Core component of *Minimum Information About Biobank Data Sharing* (MIABIS Core)³ has been accepted into the *Observational Health Data Sciences and Informatics* (OHDSI) *Observational Medical Outcomes Partnership* (OMOP) OMOP model⁴, a major step towards globally harmonising biobanking data standards.

LifeScience Authentication & Authorisation Infrastructure (AAI)

All BBMRI-ERIC services were successfully migrated to the LifeScience Login, enhancing our security framework within the broader *LifeScience Authentication and Authorisation Infrastructure* (AAI). This transition included implementing a new authorisation model for biobanks, collections, and networks, aimed at enhancing security and interoperability across our services.

Infrastructure Developments

We continued to enhance our IT infrastructure with tools such as status.bbmri-eric.eu, providing real-time visibility of system statuses, and Zabbix for network monitoring. Our newly developed *continuous integration* (CI) infrastructure has become crucial in maintaining the quality and reliability of software developments, ensuring seamless updates and deployments.

Involvement in Flagship Projects

Our IT department played a pivotal role in supporting flagship projects like EUCAIM, canSERV, EJP RD, and EHDS2Pilot. These collaborations underscore our leadership in advancing the infrastructure that supports Europe's biomedical research landscape. On finalisation of the EOSC-Life project, the BBMRI community published guidelines for assessment of privacy risks of sharing digital pathology imaging and guidelines on how to develop anonymised whole slide image archives⁵.

BBMRI-ERIC 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 significant enhancement in our capacity for federated analyses and querying, showcasing our commitment to improving biomedical research capabilities across Europe.

Outreach

Our advancements and milestones were prominently featured in various publications, and we actively engaged with the community through events like the EBW IT Roadshow. Additionally, we created video tutorials to further educate and inform stakeholders about our core services and initiatives.



ELSI Services & Research

Multidisciplinary Expertise

The 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 know-how on privacy aspects, ethics of AI, integration of sex and gender, or 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.

Train the Trainer
Integration of the sex and gender dimension in life sciences research

Venue Barcelona Supercomputing Center (BSC)
Barcelona, Spain

Dates Wednesday, June 28th, 2023 | 14h - 18h
Thursday, June 29th, 2023 | 09h - 13h

Organized by

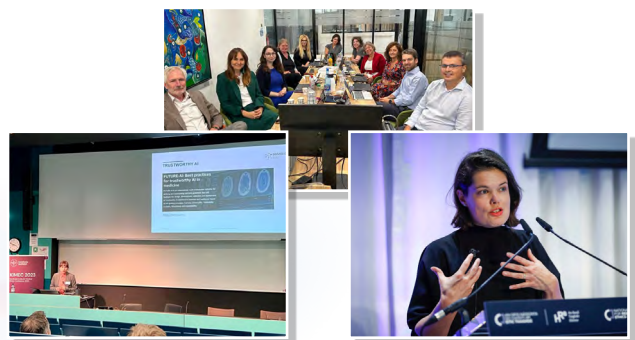
This training is funded by EOSC-Life, which has received funding from the European Union's Horizon 2020 programme under grant agreement number 8240877.

F2F Train-the-Trainer course organised by BSC (Bioinfo4Women programme), BBMRI-ERIC, INB/ELIXIR-ES, EATRIS, and EOSC-Life.

Knowledge

Generation & 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, EHDS2Pilot, CINECA and Healthy Cloud. In 2023, we published nine peer-reviewed articles, numerous public and confidential deliverable reports and undertook three public consultations. In addition, Headquarter ELSI staff served as ethics reviewers (assessing H2020 proposals), ethics advisors (providing practical guidance for granted H2020 projects), members of *Scientific and Ethical Advisory Boards* (SEAB), and evaluators. Moreover, they participated as keynote speakers and panel discussants in conferences and organised workshops.



Top: Code of Conduct Expert Group meeting (Paris)

Left: Trustworthiness in Medical AI (Karolinska Medical Ethics Conference 2023)

Right: Invited talk at the National Conference on Research Ethics (Dublin)

Practical Expert Guidance

The ELSI Knowledge Base is an open access platform that translates research findings into hands-on guidance. It promotes practical know-how for a diverse group of users ranging from researchers, biobankers, research participants to industry. It provides users with an initial sense of orientation on the subject matter, as well as allowing them to independently explore more detailed information.

First conceptualised in 2018, the Knowledge Base is now solidified as an accurate, self-service platform, which also promotes our ELSI Dialogues recordings that have reached an audience of 6 267 viewers since 2017.

LATEST CONTENT

Helpdesk Network

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. In 2023, the ELSI Helpdesk responded to 159 requests, equalling 319 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 Member and Observer countries. The Network meets quarterly, promoting knowledge transfer across Nodes.

- 2013: ELSI HELPDESK launched
- 2014: Response to Public Consultation Comments to WMA facilitated; Response to Public Consultation Comments to Council of Europe facilitated; Day of Action at the European Parliament; FAQs GDPR published
- 2015: ELSI HELPDESK expanded; 1st topical ELSI task forces/expert groups formed; ELSI KNOWLEDGE BASE conceptualised
- 2016: Code of Conduct: 1st stakeholder input received; Response to Public Consultation on Transformation Health and Care in the Digital Single Market submitted
- 2017: ELSI KNOWLEDGE BASE launched; Data in Question survey results published; 1st ELSI DIALOGUES Webinar
- 2018: Code of Conduct: joint meeting with 'sister initiatives'
- 2019: Digital International Conference "Biosamples & Biodata in Medical Research - ELSI Challenges" co-organised; Response to the European Health Data Space Questionnaire coordinated
- 2020: Statements on opt-out mechanisms for the EHDS published; European Biobank Week Roadshow "Paediatric Biobanking and Minor Engagement held"; Statements on opt-out mechanisms for the EHDS published
- 2021: Response to Public Consultation Comments to WMA facilitated
- 2022: ELSI HELPDESK expanded
- 2023: ELSI KNOWLEDGE BASE expanded

Quality Management

Activities on standards developments

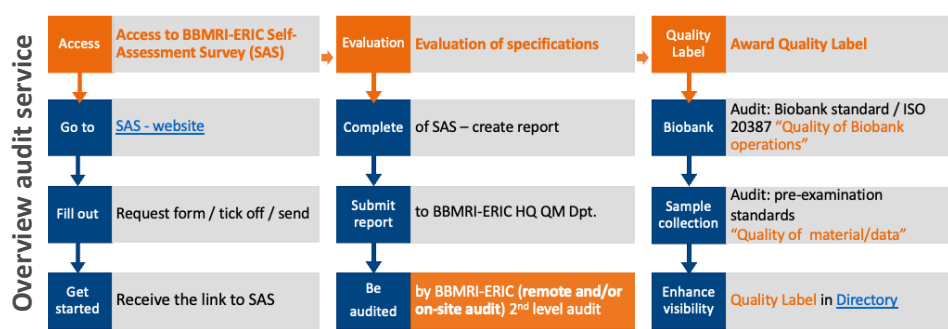
The QM service continues to support the biobanking community by actively engaging with both standardisation organisations (ISO on the international level and CEN on the European level) and by providing updates, advice, and training on biobanking related standards. Two new relevant standards were launched in 2023 and have been disseminated to the community. Biotechnology — Provenance information model for biological material and data — Part 1: Design concepts and general requirements (ISO/TS 23494-1:2023), on which BBMRI-ERIC IT experts provided training for the QM community. The new provenance standard also holds significance to biobanking in the context of ISO 20387 — General requirements for biobanking. It offers a more detailed insight on how compiling a tracked history, or provenance, of samples and data not only facilitates in their governance as required by ISO 20387, but also allows for improved predictions of samples and data usability for future research purposes.

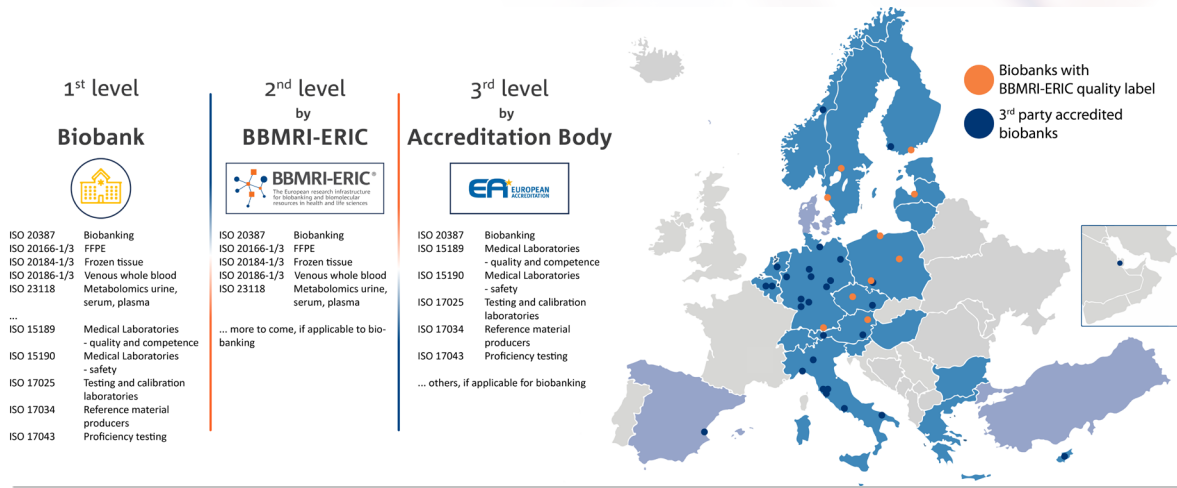
Additionally, the ISO/TC 276 WG 2 initiated a *Systemic Review (SR)* of the ISO 20387:2018 standard. This matter was discussed in the BBMRI-ERIC WG QMS, where member feedback was requested. The responses were forwarded to the ISO/TC 276 WG2 for review by the committee's experts. Based on all the comments received from Member States and Liaison partners, a decision to revise the standard was made

during the annual meeting of ISO/TC 276 Biotechnology. The revision of the standard is expected to be completed in three years. BBMRI.QM will keep the Quality Managers of biobanks up to date with the latest developments. Moreover, in 2023, the ISO/TC 212 Medical Laboratories WG1 put a spotlight on Artificial Intelligence (AI) with their *new working item proposal (NWIP)* on Digital Pathology and AI. This proposed standard provides insight into the requirements and recommendations for the workflow of AI-based image analysis primarily targeting FFPE tissues, although it can also be applied to other types of samples. The NWIP also emphasises the connection to the pre-analytical standard ISO 20166-4 on pre-examination processes for FFPE tissue samples and is expected to influence how samples are processed in biobanks. BBMRI.QM will continue to provide information on further developments and the impact on biobanks in the coming year.

Auditing for Excellence

Based on the audit service set up in 2017, biobanks in our community can demonstrate that they work in accordance with European and international standards. In 2023, QM continued to support biobanks in their commitment to excellence through offered audit processes. As a result, Biobank Łukasiewicz – PORT in Wrocław, Poland achieved the BBMRI-ERIC Quality Label, aligned with ISO 20387, after successfully completing an audit conducted by BBMRI.





EU projects benefiting from QM expertise

In 2023, QM made significant contributions to quality-relevant tasks in:

IMI projects: ConcePTION, EPND

H2020 projects: CY-Biobank, IC2PerMed, DIAMONDS

Horizon Europe projects: ISIDORE, canSERV

Particularly in the EPND project, an audit procedure was established, and an audit programme successfully executed that provided input to participating cohorts for improving biobanking processes and adherence to relevant ISO biobanking standards.

A dedicated “BBMRI-ERIC QM Services and Research” community page has been set up in Zenodo, the EU open repository for EU-funded research outputs. BBMRI.QM provides this platform for the open access of

quality-relevant results of projects but also for the sharing of biobank-relevant guidelines, SOPs, process descriptions and publicly accessible publications.

In 2023 QM also actively contributed to project proposal writing, which led to three approved projects, EvolveBBMRI, INTEGRATE-LMedC (Large Medical Cohorts), and QUANTUM, to be kicked off in 2024. The QM team further extended its capacities towards data quality in biobank data management. It facilitates the QM services to expand and cover quality issues in biobank data and data governance related topics. Initial plans on extending the existing service pillars QM Knowledge Hub, Training & Support, and Auditing have already been set, and the data quality activities will be initiated in 2024.

Collaborating with the BBMRI-ERIC Quality community

Throughout 2023, QM stayed focused on building a dynamic and connected quality management community. Dedicated Quality Leads from all National Nodes have formed a network of over 230 experts within BBMRI’s tenth year of existence. Through various initiatives, we brought this community together along with experts from outside BBMRI:

Six Working Group *Quality Management System (QMS)* meetings were held with a total of 329 participants. Topics included user satisfaction, biobanking challenges, and community inquiries. Additionally, four meetings focused on ISO 20387 to prepare the biobanking community for obtaining the BBMRI-ERIC Quality Label, engaging 110 participants.

In four virtual meetings, the QM Newsroom engaged 276 participants from Member and Observer countries, as well as Ireland, Serbia,

the United Kingdom, the United Arab Emirates, Albania, and Brazil. This year, the focus was on quality-related efforts in EU projects such as EPND, canSERV, ISIDORE and ConcePTION, with the participation of renowned internal and external quality experts.

The QM Academy hosted a well-received webinar titled “Validation and Verification of Processing Methods and Biobanking,” drawing 228 participants from 39 countries. QM supported participants’ continuous professional development by offering *Continuing Medical Education (CME)* credits, resulting in the issuance of 81 European CME certificates on behalf of the European Accreditation Council for Continuing Medical Education (EACCME®). In addition, 130 people took advantage of the growing range of QM-related webinars during the year to access online learning content.

Biobanking Development

In 2023, the Biobanking Development (BBD) department was involved in the following tasks that cover its main core services to the BMMRI-ERIC community:

BBD involvement in the Stakeholder Forum

As part of the Stakeholder Forum - Industry Pillar, BBD continued to lead and strengthen collaborations with biotech companies where there is benefit to our biobanking community. BBD led the preparation of an educational course in collaboration with EIT Health Europe focusing on educating industry on how to explore and interact with the biobanking landscape in Europe to increase collaboration. The course also relied on participation from other departments in BMMRI: QM and ELSI.

BBD participation in EU projects:

Additionally, Biobanking Development was also co-leading a work package on *Accelerated Transition into Personalised Oncology Clinical Practice* working on establishing and operating a *European Molecular Tumour Board Network* (EMTBN) collaborating with Clinical and *Comprehensive Cancer Centres* (CCCs) across Europe.



canSERV: The Biobanking Development Department is leading the Work Package that provides access to human samples and data, where we support access to 1,200 samples and datasets on different cancers in collaboration with 32 biobanks from our community. In 2023, two calls for applications were launched where 24 applications were received requesting access to samples and data, one project was approved for funding and a further two are under review.



BBD continues to provide support to the **CY-Biobank project** through collaboration on developing a state-of-the-art biobanking facility. BBD co-authored a manuscript on the *“Implementation of a biobanking cost recovery model, at biobank.cy Centre of Excellence”*. The manuscript summarises all activities related to estimating the costs of running a biobank and preparing biological samples and is currently under submission.



ISIDORE: Biobanking Development is leading a work package on providing 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 in general through active engagement of 40 biobanks from our community. Successful provision of sample & data within the ISIDORE project continued throughout 2023, where two projects were approved for funding and service provision was provided.

BBD supporting National Nodes

BBMRI-ERIC Task Forces: The BBD department supports Task Force 1 “Quality Assurance Markers development”. The aim of TF1 is to define and provide biomarkers (intrinsic/extrinsic) that allow standardised assessment of sample quality through engagement in biospecimen research. Applying such biomarkers will allow pooling of samples of comparably high-quality EU-wide and beyond while fostering large-scale cohort studies. A first draft of the publication on pre-analytical phase biomarkers which can be used for the assessment of sample quality has been updated and discussed in Oct 2023. BBD has supported the BBMRI internal surveys on National Nodes objectives and Operations as an integral part of TF7 “NN Operations & NNs’/Biobanks’ Sustainability”. Conclusions drawn from these surveys are of paramount importance to defining the BBMRI-ERIC vision for the next 10 years.

Community engagement with BBD’s first education series

Webinar “Cost recovery model in biobanking”:

This webinar outlined a model for biobanks to calculate costs associated with sample/data provision to stay sustainable. The model is currently being implemented in two EU projects: ISIDORE and canSERV. Within public biobanks, there is no universally acknowledged model for charge/fee calculation for sample and/or data provision. Cost of access varies among countries due to labour expenses and is heavily influenced by the nature and complexity of the collection (i.e., population-based vs. specialised collection of unique samples). Thus, a general model has been developed to calculate costs depending on the complexity of the request. This model is based on the guidelines and calculation grid for biobanks published by Clément *et al.*, 2014.

BBMRI-ERIC Podcast “Episode 09 – The International Freezer Challenge and driving biobanking carbon reduction”.

As BBMRI-ERIC turns its attention to the climate crisis and how the community can reduce energy use, we spoke with Jörg Hamann, head of the Amsterdam UMC Biobank and MC member for The Netherlands’ National Node about their win of the Freezer Challenge and why sustainability matters. We also talked to Phil Korb, Co-Founder and Director of Advocacy at the Carbon Literacy Project, who will be working with BBMRI to develop a certified Carbon Literacy Toolkit. This initiative will be part of the Green Label enabling Biobanks to demonstrate recognised sustainability credentials.

New members & observers

In May 2023, BBD organised the onboarding workshop for Cyprus (Member), Qatar (Observer), Slovenia (Member) and in September also organised the onboarding workshop for Denmark.

BBD supports BBMRI-ERIC Tools

BBD supports users from the biobanking, scientific and industry community in identifying the samples/data needed for their projects on the Directory of BBMRI and monitors the requests submitted by users on the Negotiator tool to ensure timely response and exchange with our biobanking community. Additionally, BBD is leading the Negotiator Monitoring group that meets with representatives from our community to discuss issues related to requests and the Negotiator tool in collaboration with colleagues from the IT department of BBMRI.

Webinar “Genomics & biobanking – a perfect match”:

This webinar covered how recent advances in genomic technology (e.g., sequencing and data analysis) allow European biobanks to use genomics/multiomics approaches to further increase their samples’ value. Genomics is a rapidly evolving field constantly pushing the boundaries of cost/time efficiency of analysis. Lately, researchers are looking beyond the genome – at transcriptional, epigenetic, and proteomic signatures to reveal new insights into disease aetiology. By taking advantage of these new technological developments, biobanks can maximise the value of their samples by identifying and validating multiomic biomarkers and thus creating new opportunities for collaborations with industry, academia, and other organisations.

New podcast episode
Biobanking Development: Amsterdam UMC’s Freezer challenge win and carbon literacy

“I learned that health care has a share of 6-8 % in our total energy consumption - equal to the aviation sector. As health care researchers, we need to face this reality and act.”

Jörg Hamann, Repr. BBMRI.nl

Outreach Education Communications

Developing Outreach

The Work Programme 2022-2024, with its emphasis on community outreach and engagement, formed the backbone of reshaping Outreach, Education and Communications (OEC) activities during 2023. The growing team continued to refine in-house processes to better serve and amplify National Nodes, biobanks and our wider community. Improvements included standardising BBMRI's image and event presentation, adding to and extending the value of QM and ELSI training through captioned videos and pod-

casts, increasing the pace and quality of social media content, focusing news articles on highlighting BBMRI's achievements to a variety of stakeholders, creating audio to tell rich community stories related to the core BBMRI-ERIC scientific services and standardising, by bringing in-house, print and production services. The result constitutes deeper engagement that enhances visibility and recognisability — areas that all research infrastructures find a communications challenge.

BBMRI-ERIC AND THE STAKEHOLDER FORUM PATIENT PILLAR RELEASE CO-WRITTEN STATEMENT IN SUPPORT OF EHDS OPT-OUT MEETING

This article is 1745 words and is an approximate ten minute read.

The following statement, co-written by BBMRI-ERIC and the Stakeholder Forum Patient Pillar, has been made in support of the EHDS opt-out meeting that happened on 6 September 2023. Details can be found [here](#).

The purpose of this statement is to highlight the risks and opportunities of EHDS for biobanking from the viewpoint of patient advocates and patient representatives.

By utilising health data, such as information collected during routine patient care or stored in biobanks, for scientific purposes researchers can uncover valuable insights into disease patterns, treatment effectiveness, and population health trends. This data-driven approach enables the development of personalised medicine, identification of genetic markers, and discovery of novel therapies with increased treatment efficacy and reduced adverse effects. Moreover, the secure sharing, and analysis of health data across borders, particularly at European Reference Network (ERN) level, can foster collaboration among scientists, accelerate medical breakthroughs, and enhance public health strategies.

Embracing the secondary use of health data empowers researchers to make evidence-based decisions, shape healthcare policies, and ultimately improve the well-being of individuals and communities. In the biobanking field, health and clinical data associated with the samples and data stored in biobanks are crucial for advancing biomedical research and medical knowledge. The use of samples for research is much less valuable without the associated health and clinical data. Therefore, the new framework for the secondary use of data will greatly impact the biobanking field.

For BBMRI-ERIC, its National Nodes and the Stakeholder Forum Patient and Citizen Pillar, the European Health Data Space (EHDS) framework and the use of health data to drive innovation and promote scientific discoveries means a paradigm shift. This poses challenges and opportunities which are addressed in this statement.



Supporting projects and highlighting **BBMRI-ERIC's contribution**

During 2023, OEC played a key role in several projects including the wrapping up of EOSC-Life for which the department led on communications including management of social media, multiple newsletters and the website. This involved multimedia production for a major researcher and research infrastructure matching event in Utrecht, event coordination and media coverage of the final general meeting in Brussels and editing and production of the key achievements brochure.

OEC also co-leads the Training, Outreach and Stakeholder Engagement work package for the flagship project canSERV. During 2023, this entailed outreach support on Open Calls, organising outreach webinars and materials and coordination of the annual meeting held in Brussels during September. Outreach goals of the EUCAN-Connect project were met by OEC producing a series of explanatory films

from the final in-person meeting. OEC also highlighted the significant contribution of BBMRI-ERIC core infrastructure in projects such as EUCAIM, development of the Common Provenance Model and coordinating Patient Pillar input into major EHDS impacted EU policy announcements. In addition, OEC continues to provide support to 20 EU funded projects where the key role is dissemination and outreach with and beyond each project's target stakeholders.



Strengthening **community**

Task Force Nine – Communications and Outreach (TF9) continued to be strengthened throughout 2023 with a series of National Node collaborative presentations and training sessions that focused on stakeholder focused good practice, digital skills and resource sharing. The learning from these sessions was consolidated to inform BBMRI-ERIC's successfully approved EvolveBBMRI project. This ensures that the ambitious aims of TF9 will be met and thus further strengthen outreach across the biobanking community. Both TF9 and EvolveBBMRI focus on stakeholders such as patient advocates, scientists, clinicians, and institutions (universities, university hospitals, scientific societies) to increase the perceived value of biobanking and therefore, the sustainability of the community.

The autumn Management Committee and Assembly of Members workshop in Milan provided a unique opportunity to capture personal well wishes and reflections on BBMRI's impact as we geared up to mark the 10th anniversary of operation. The video series, involving all National Nodes, was edited in preparation for release during 2024. Relations with ESBB continued to be strengthened through the organisation and communications activities support of the EBW IT Roadshow education event: "IT: data integration in biobanking" was coordinated by BBMRI.at and the wider IT community and held in Innsbruck, Austria during Sept 2023. The second half of 2023 saw intense preparation of the first post-pandemic in-person Europe Biobank Week Congress to be held in May 2024.



Public Affairs

BBMRI membership has further grown and BBMRI has driven impactful engagements in the overall European research arena on behalf of the wider research infrastructure community. End of 2023, BBMRI marked its 10-year anniversary of operation. Planning was undertaken for key anniversary events to take place in 2024 that bring together representatives of Member States, National Nodes, as well as key European partners and high-level officials of the European Commission. These events are to explore the impact of BBMRI over the past decade and point to key future perspectives of the organisation.

During 2023, BBMRI deepened its engagement with Cyprus, Switzerland and Lithuania as all three countries upgraded their Observer status to full Member of the organisation. In addition, Denmark and Qatar became Observer countries. By the end of 2023 BBMRI had 25 Members and Observers.

BBMRI continued to reach out to other countries which are interested to join the community, and potential applications for membership are expected in 2024.

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

Over the past decade, BBMRI-ERIC has successfully implemented cutting-edge services for the biobanking community in Europe to achieve its core mission of facilitating access to samples, data, and biomolecular resources for public benefit. Building on this success, in autumn 2023, BBMRI-ERIC started to develop the draft strategic roadmap for the next 10 years. The aim of this document is to foster ground-breaking science to benefit not only European patients, citizens and economies but to also ensure that the wider interdependence of the environment and health outcomes is fully recognised.

The plan for the 10-year Roadmap is to provide a path based on strategic objectives and operative goals so that the ambition is realisable by our research infrastructure (Headquarters, National Nodes, biobanks, Assembly of Members, and other stakeholders).

For this reason, a co-development process was launched in 2023, hand-in-hand with both the National Nodes and the Assembly of Members. Through two in-person workshops taking place in Brussels and Milan, the Assembly Delegates and National Node Directors started to co-design the roadmap, thereby making it truly European and relevant not only for the Headquarters, but also for the Members and their communities. Whenever requested, bilateral meetings with country representatives, for example with Finland, Germany, Sweden, Belgium, Switzerland, Spain and Austria also took place. Further alignment is anticipated for the first half of 2024.

Stakeholder Forum – Patients & Citizens' Pillar

Relations with patient organisations and patient representative were further strengthened. In 2023, a new Chair of the Patients and Citizens' Pillar, Eric Vermeulen from the Netherlands, was elected. BBMRI facilitated two meetings of its Patients and Citizens' Pillar, where further organisations joined in. By the end of 2023, the Pillar had 19 members from 13 countries and seven organisations on the European level organisation. The patient or-

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

ERIC Forum

The second iteration of the ERIC Forum project (ERIC Forum 2) was started in September 2023 and BBMRI was again commended the role of coordinator; a sign of trust the ERIC community holds towards BBMRI.

ERIC Forum 2 aims to further structure the cooperation between ERICs; support implementation of the ERIC Regulation and ERICs services; to consolidate the integration of the ERICs in the ERA by deepening the ERIC Forum's contribution to research policies and emphasise the development of a more systematic collection of aggregated and coherent data within ERICs. It also tackled topics

like VAT implementation and attraction of third countries. As the coordinator of the ERIC Forum project, BBMRI-ERIC remains committed to guaranteeing the timely and high-quality execution of project activities and deliverables. BBMRI continues to serve as the secretariat for the ERIC Forum Executive Board. In addition, the Head of Public Affairs was appointed an expert to the European Commission on the revision of the practical guidelines on the implementation of the ERIC Regulation.

Key partnerships

Chairing the **European Life Science Research Infrastructures cluster**: In September 2023, BBMRI-ERIC became the Chair of the Life Science Research Infrastructure Strategy Board. This enables BBMRI to internally and externally lead and represent on key topics, such as future European funding and policy recommendations related to research infrastructures within its community. BBMRI organised the first in-person meeting of the cluster and two digital meetings, bringing the community even closer. BBMRI acted as the contact for the Belgium EU Presidency and the EC, enabling the cluster to present at the upcoming EU Presidency event in 2024.

EOSC: BBMRI-ERIC represented the ERIC Forum as mandated organisation in the EOSC Association in 2023, taking over the rotating position from EuroBio-Imaging. As such, BBMRI-ERIC is also chairing the ERIC Forum Working Group ERICs in EOSC and is representing the ERIC Forum in the ESFRI-EOSC Task Force. BBMRI-ERIC coordinated the provision of collective input on materials produced by the EOSC Association from the ERICs and advocating for a clear and transparent process on key topics such as establishment of EOSC Nodes. As a member of the EOSC Association, BBMRI engaged in various EOSC Association task forces.

Other partnerships: In 2023, BBMRI and Elixir signed a Statement on Strategic Collaboration which outlines joint topics of interest such as knowledge sharing and strategic cooperation on national level, ELSI, or research data management. The relationship has further grown with EuroBioImaging, as all three infrastructures committed to further cooperation and sought European funding support. Activities within the EU-AMRI alliance was on-going and discussions with ECRAID towards cooperation continued in 2023.

LIFE
SCIENCE RI

eosc

ecraid elixir
EUROBIOIMAGING

2023 Key Performance Indicators (KPIs)

8,924 **Users** of BBMRI Directory (during 2023)

183 Active **Users** of the BBMRI Negotiator (during 2023)

83 **Requests** filed into the BBMRI Negotiator (during 2023)

8 **Requests** successfully handled via BBMRI Negotiator in that calendar year (2023)

319 **Hours** of BBMRI ELSI Services provided (during 2023)

196 **Attendees** in BBMRI ELSI Dialogues (during 2023)

1 **New BBMRI Quality (Q)-Label** on BBMRI Biobank, Laboratory/Institute or Expert Centre level in BBMRI Directory (during 2023)

5 **New Certified/Accredited** BBMRI Biobanks, Laboratories/Institutes & Expert Centres (during 2023)

11 New **publications** involving BBMRI-ERIC HQ in 2023

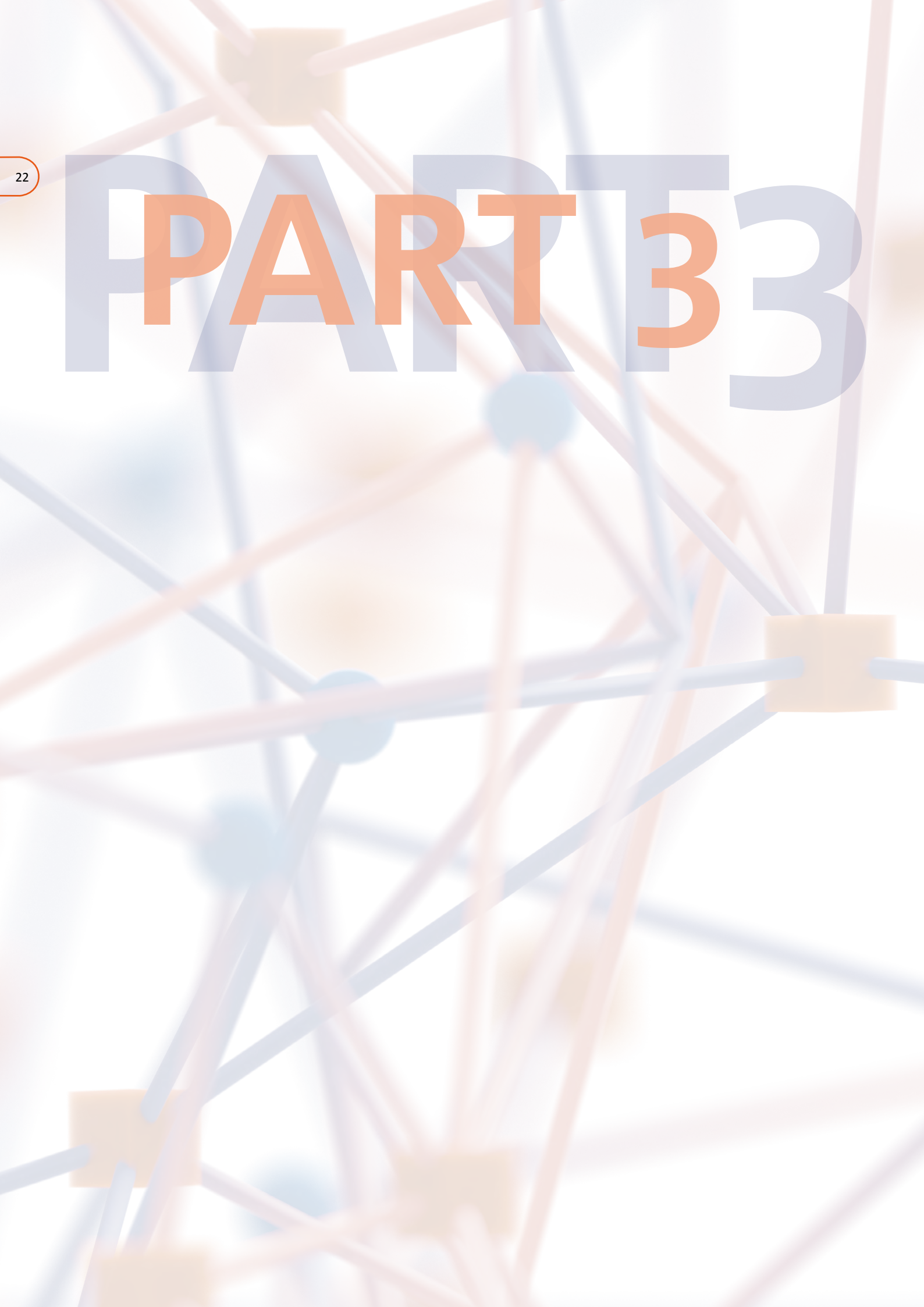
1,645 **Participants** reached by BBMRI HQ outreach events in 2023

75 **Participants** in Stakeholder Forum (during 2023)

4 **Successful grants** (during 2023)



PART 3





Financial Information



FINANCIAL Information

Core budget expenditures and allocated competitive research grants

An inflation rate of 8,6 % in 2022 and 7,8 % in 2023, as well as the exit of the United Kingdom as per 31st of December 2022, necessitated a gradual shift in BBMRI capacities from core to project activities. Fortunately, this negative impact was partially compensated by an increase in membership fees by the other members.

In 2023, Switzerland and Lithuania also advanced from Observer status to full membership and Denmark became an Observer, further mitigating the negative financial impact on BBMRI-ERIC.

In addition, four new proposals received funding and officially started in 2023 (EUCAIM, BioIndustry 4.0, ERIC Forum 2, EP PerMed), securing roughly 1,7 Mio € in competitive research grant funding for BBMRI and related research infrastructures and service providers with project durations between two and four years.

Three more projects, out of which two are coordinated by BBMRI (INTEGRATE-LMedC, EvolveBBMRI) were awarded to BBMRI and started at the beginning of 2024 (maximum grant amount for BBMRI: 3,2 Mio €).

Table 1: Profit & Loss Statement

In EUR	2019	2020	2021	2022	2023
Turnover	4.091.202	3.305.108	3.292.908	3.920.923	4.334.553
Other operating income	10.882	8.907	7.441	7.537	72.327
Material/Service Expenses	-	-	-	(1.920)	(291.054)
Staff expenses	(1.840.023)	(2.143.081)	(2.477.511)	3.053.131)	(3.389.773)
Amortisation	(31.683)	(30.000)	(54.819)	(52.595)	(48.282)
Other operating expenses	(1.676.029)	(847.735)	(758.648)	(791.673)	(786.231)
Operating result	554.348	293.198	9.371	29.142	(108.460)
Other interest and similar income	-	-	-	1.355	3.548
Interest and similar expenses	-	(54)	(204)	(21)	-
Financial result	-	(54)	(204)	1.333	3.548
Loss from operating activities, Earnings before taxes	554.348	293.144	9.167	30.475	(104.911)
Taxes on income and revenue	-	-	-	(339)	339
Profit of the year	554.348	293.144	9.167	30.136	(104.573)
Reversal of profit reserves	-	-	-	-	-
Allocation to profit reserves	(554.348)	(293.144)	(9.167)	(30.136)	104.573
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

Table 2: Balance Sheet

In EUR	2019	2020	2021	2022	2023
Intangible Assets	5.639	2.820	91.920	68.940	45.960
Tangible Assets	66.339	54.414	41.891	37.777	32.984
Fixed Assets	71.978	57.233	133.811	106.717	78.944
Receivables and other Assets	343.225	299.341	439.425	409.394	880.771
Receivables arising from deliveries services	86.743	93.001	254.117	51.397	167.914
Other receivables and assets	256.482	206.340	185.308	357.997	712.857
Cash on hand and Bank deposits	2.916.641	2.491.713	2.667.526	9.633.534	7.963.174
Current Assets	3.259.867	2.791.055	3.106.951	10.042.927	8.843.945
Prepaid expenses, deferred charges	5.031	2.811	3.923	1.453	1.643
Assets	3.336.876	2.851.099	3.244.685	10.151.097	8.924.532
Reserves pursuant to the articles of association	591.022	884.166	893.333	923.470	818.897
Balance sheet profit	367.775	367.775	367.775	367.775	367.775
Investment grants	-	-	13.189	9.791	6.448
Capital and Reserves	958.797	1.251.941	1.274.297	1.301.036	1.193.120
Other accruals	157.473	68.792	127.273	119.580	158.468
Accruals	157.473	68.792	127.273	119.580	158.468
Liabilities arising from deliveries and services	226.636	30.026	246.162	220.003	92.274
Other liabilities	385.357	396.798	221.866	312.529	221.685
Liabilities	611.993	426.824	468.027	532.532	313.959
Deferred income	1.608.612	1.103.541	1.375.087	8.197.949	7.258.986
Liabilities and Owner's Equity	3.336.876	2.851.099	3.244.685	10.151.097	8.924.532

Table 3: Cash Flow

In EUR	2019	2020	2021	2022	2023
Profit of the year	554.348	293.144	9.167	30.136	(104.573)
Amortisation	31.683	30.000	54.819	52.595	48.282
Cash Flow from the Result	586.031	323.144	63.986	82.731	(56.291)
Δ Receivables arising from deliveries services	47.559	(6.258)	(161.116)	202.721	(116.518)
Δ Other receivables and assets	773.407	50.142	21.032	(172.689)	(354.860)
Δ Liabilities arising from deliveries and services	61.913	(196.610)	216.136	(26.158)	(127.729)
Δ Other liabilities	254.335	11.441	(174.932)	90.664	(90.844)
Δ Prepaid expenses, deferred charges	8.301	2.221	(1.113)	2.471	(190)
Δ Accruals	(420.727)	(593.752)	330.027	6.815.168	(900.075)
Δ Investment grants		-	13.189	(3.397)	(3.344)
Δ Working Capital	724.789	(732.817)	243.223	6.908.778	(1.593.560)
Cash Flow from Operations	1.310.820	(409.672)	307.209	6.991.509	(1.649.851)
Investing / Deinvesting	(39.280)	(15.256)	(131.397)	(25.501)	(20.508)
Cash Flow from Investing Activities	(39.280)	(15.256)	(131.397)	(25.501)	(20.508)
Δ Capital and Reserves					
Cash Flow from Financing Activities	-	-	-	-	-
Total Cash Flow	1.271.540	(424.928)	175.813	6.966.008	(1.670.360)
Cash Beginning	1.645.101	2.916.641	2.491.713	2.667.526	9.633.534
Δ	1.271.540	(424.928)	175.813	6.966.008	(1.670.360)
Cash End	2.916.641	2.491.713	2.667.526	9.633.534	7.963.174

The cash flow in 2023 of -1,7 Mio EUR is mainly due to cash flow in the canSERV project, in which BBMRI-ERIC as coordinator passed on prefinancing funds received from the EC to the partner organisations in the project. Over the next 1,5 years approx. 5 mio. EUR from the cur-

rent cash position will be used to finance TNA services (Transnational Access services) for the research community in the field of cancer research as well as the respective management, communication and dissemination activities.

PART 44

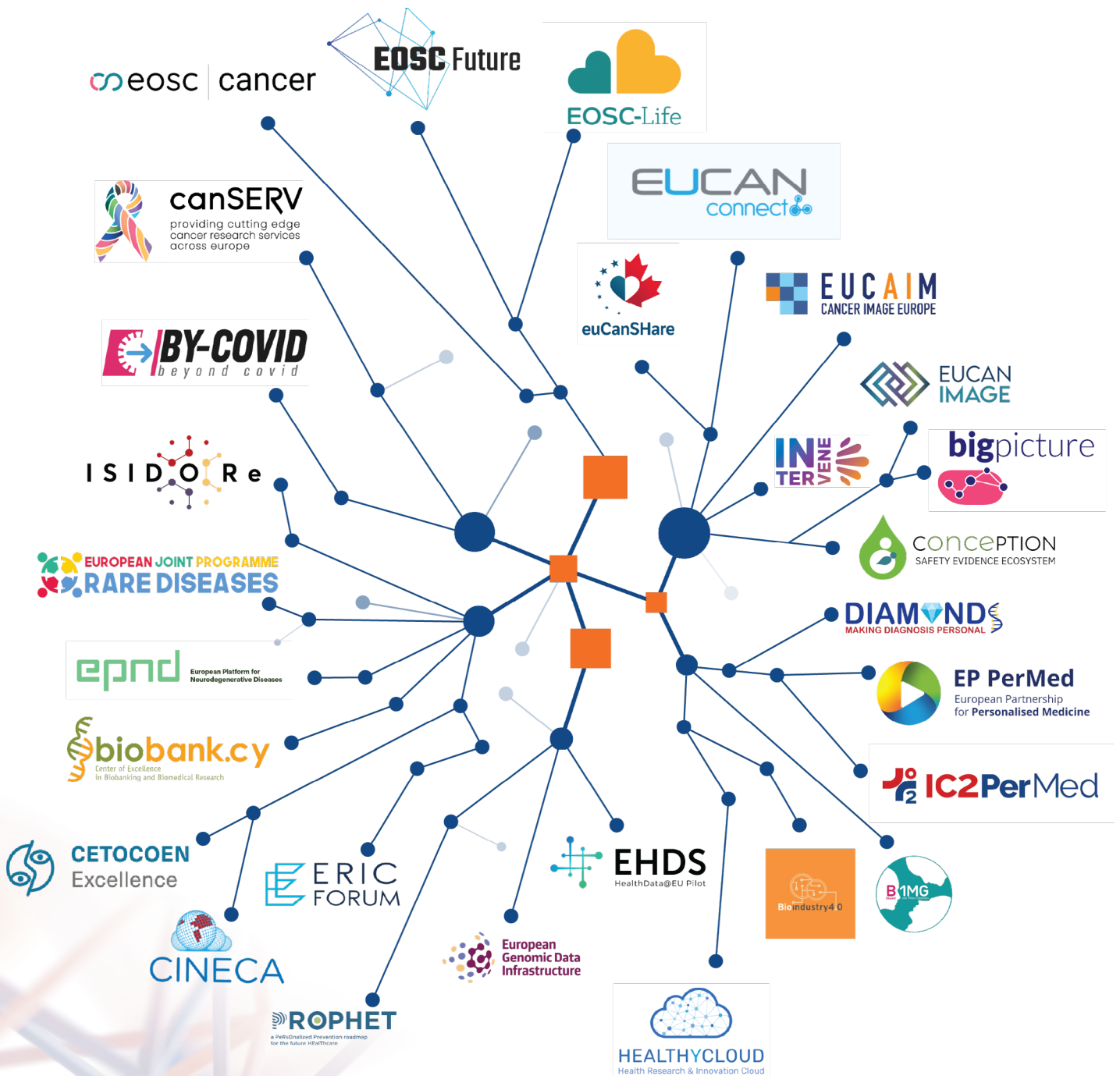


A network diagram with orange nodes and lines on a light blue background. The nodes are connected by lines, forming a complex web. The background is a light blue gradient with a subtle pattern of lines and nodes.

Projects

Projects

BBMRI-ERIC was active in the following projects **during 2023**:



Projects **launched** in 2023:

EUCAIM

BBMRI Budget: €505.361
(+956.000 for AEs *)
Start date: 01.01.2023

EUCAIM’s aim is to build a pan-European digital federated infrastructure of cancer-related images which will be used for the development of AI tools towards precision medicine. The hope is that this infrastructure will provide the means to develop AI tools that will be able to enhance the (cancer) diagnosis procedure, treatment and the identification of the need for predictive medicine benefiting patients across Europe.

* AEs: Affiliated Entities



Bioindustry 4.0

BBMRI Budget: €148.469
Start date: 01.01.2023

Bioindustry 4.0 is a cutting-edge initiative bringing together academia and industry in Europe to shape the future of industrial biotechnology. Its mission is to enhance the global competitiveness of the European biotech sector.

By refining technologies such as AI, digital twin and cloud technologies, the project aims to empower professionals from academia and industry to collaborate and push the boundaries of bioprocess design and control – making these technologies faster, cheaper, and more sustainable.



Coordinated by
BBMRI-ERIC



ERIC-FORUM 2

BBMRI Budget: €736.837
Start date: 01.09.2023

The ERICs (*European Research Infrastructure Consortia*), under the umbrella of the ERIC Forum, represent one of the leading science policy voices in Europe and play a key role in structuring the research infrastructure landscape. This project aims to structure the cooperation between ERICs, support the implementation of the ERIC Regulation and ERICs services, and consolidate the integration of the ERICs in the European Research Area by deepening the ERIC Forum’s contribution to research policies.



EP PerMed

BBMRI Budget: €399.500
Start date: 01.01.2023

EP PerMed is a new European Partnership dedicated to Personalised Medicine (PM). It supports PM-related R&I, but also facilitates and accelerates all steps so that PM achievements successfully pass through the full value continuum to be implemented in sustainable health systems for the benefit of people and societies. The partnership will foster demonstration projects and promote successes and lessons learned to highlight evidence of PM implementation. EP PerMed activities cover overarching aspects, like patient involvement, exchange with medical societies, infrastructures and international and regional collaboration.



2023 Active Projects



B1MG:
Coordination and Support to better secure data and cross-border digital infrastructures building on European capacities for genomics and personalised medicine



BIGPICTURE:
Central repository of digital pathology slides to support the development of artificial intelligence tools



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.

Coordinated by
BBMRI-ERIC



canSERV
providing cutting edge
cancer research services
across europe

canSERV:
European wide research infrastructures, oncology experts, and patient associations team up to battle cancer by providing transnational access to cutting-edge transnational research services



CETOCOEN
Excellence

CETOCOEN EXCELLENCE:
To create the European Centre of Excellence in Environmental Health Sciences



CINECA:
Common Infrastructure for National Cohorts in Europe, Canada, and Africa



CONCEPTION
SAFETY EVIDENCE ECOSYSTEM

CONCEPTION:
Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding



CY-BIOBANK:
Towards the Establishment of a Research and Innovation Center of Excellence for Biobanking and Biomedical Research at the University of Cyprus



DIAMONDS:
Demonstration pilots for implementation of personalised medicine in healthcare



EHDS
HealthData@EU Pilot

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



EJP RD:
Expanding research infrastructure visibility to strengthen strategic partnerships



EOSC4CANCER:
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

2023 Active Projects

EOSC-Life:

Providing an open collaborative space for digital biology in Europe



EPND:

A platform for accelerating biomarker discovery and validation to support therapeutics development for neurodegenerative diseases



EP PERMED

European partnership for personalised medicine



ERIC FORUM 2:

Coordination and Monitoring of the European Research Infrastructure Consortia (ERICs)



EUCAIM:

Federated European infrastructure for cancer images data



EUCAN-Connect:

A federated FAIR platform enabling large-scale analysis of high-value cohort data connecting Europe and Canada in personalised health



euCanSHare:

An EU-Canada joint infrastructure for next-generation multi-study heart research



EuCanImage:

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



GDI:

Federated European infrastructure for genomics data



Healthy Cloud:

Defining the strategic agenda for the European Health Research and Innovation Cloud



IC2PerMed:

Integrating China in the International Consortium for Personalised Medicine



INTERVENE:

International consortium for integrative genomics prediction



ISIDORe:

Research infrastructure services for rapid research responses to COVID-19 and other infectious disease epidemics

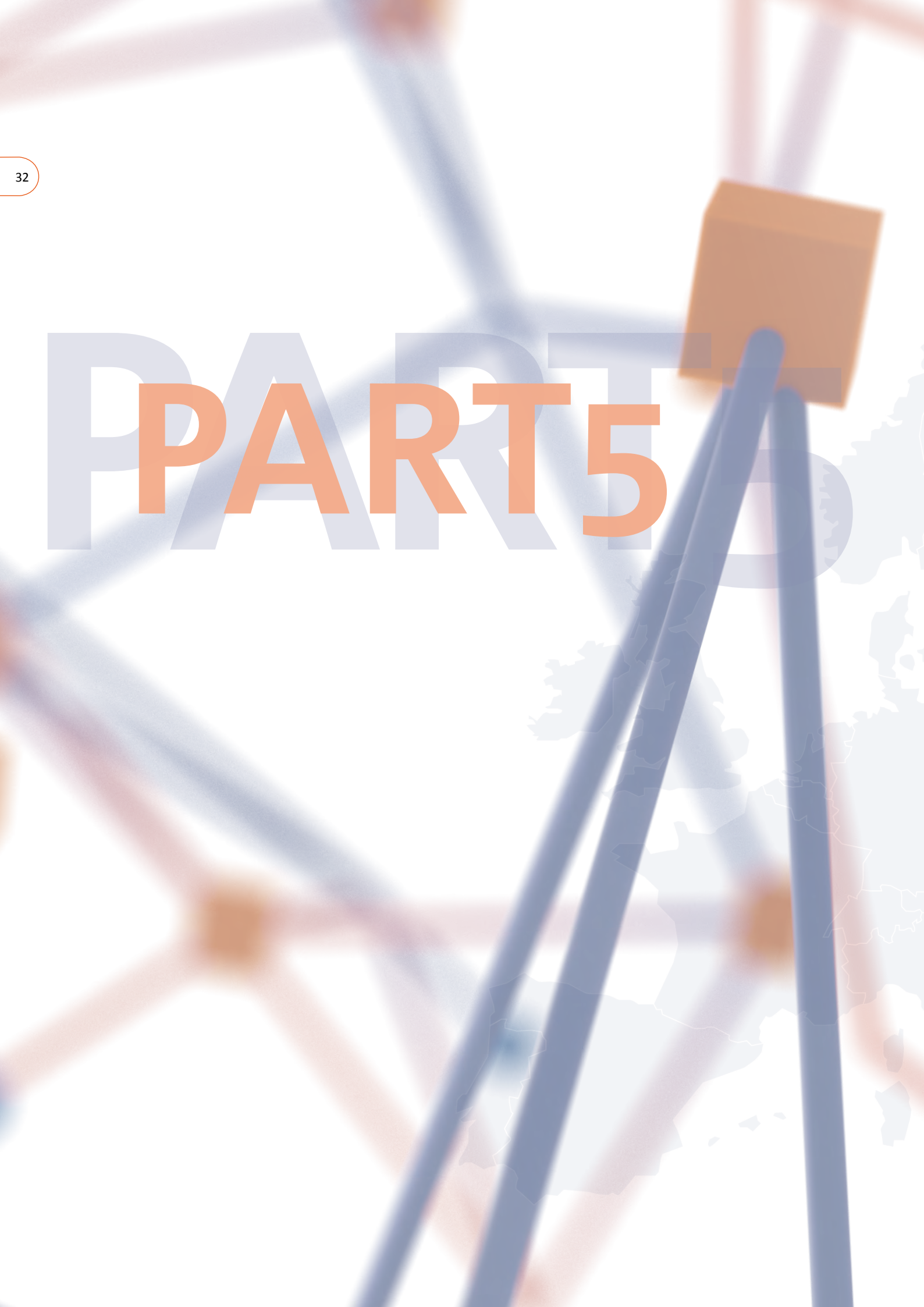


PROPHET:

Personalized prevention roadmap for the future Healthcare.



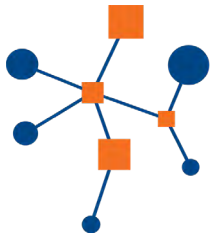
PART 5





National Nodes

2023



BBMRI·at

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Österreich /
Austria /
Autriche /

BBMRI.at comprises the Medical Universities of Graz, Vienna, Innsbruck, Salzburg, the JKU Linz and the University of Veterinary Medicine with their biobanks. Two other universities bring in IT and ELSI expertise. BBMRI.at develops the Austrian biobanking research infrastructure and links it to the European community. Focus is to increase close cooperation and harmonisation between biobanks and foster research collaborations using samples/data and expertise. BBMRI.at partners harbour 22+ million human and animal samples with associated data to support university and industrial research. BBMRI.at was established in 2013 and is funded by the Federal Ministry of Education, Economy, and Research. More at bbmri.at



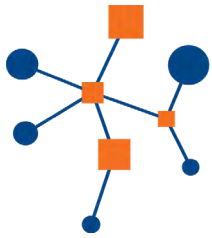
Achievements 2023

Areas of Expertise

- 1. Quality management:** (QM) & services: Developing/ implementing ISO/CEN pre-analytics standards; QM-cross-audits; training/webinars; BSL-3-facility building/operation; high-risk pathogen-containing material biobanking, NGS
- 2. Data management:** Data quality; high-capacity digitalisation of tissue slides (whole-slide-imaging) & AI; trusted data environment and access model; Catalogue/Biobank-Editor development; input to BBMRI-ERIC Directory/Negotiator development
- 3. 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

- 1. Harmonisation & standardisation:** Leading "ISO 18701 human specimens for microbiome DNA" development; continuation of remote QM-cross-audits; concept for user requirements assessment brought to BBMRI.QM; Initiation of Austrian-Cohort-Initiative and *Austrian-Cohort-Research-Days* organisation
- 2. Data management:** Online-Donor-Portal mock-up available, new data access model and "trusted environment for patient data" tested with other BBMRI-ERIC nodes; complementing biobank samples with digital whole-slide-images; Animal Model Bio-material and data collection pilot finalised
- 3. Stakeholder and user information and engagement:** Multiple grants and industry collaborations with BBMRI.at partner contribution accepted; new BBMRI.at website, lighthouse and other outstanding Biobank cohorts presented online; numerous scientific publications with biobank/BBMRI.at contribution, presence in public media; hosting Europe-Biobank-Week IT-Roadshow; biobanking education (e.g., Biobanking courses and MSc programme); stakeholder interviews on biobanking finalised/results published





BBMRI·be

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Belgie /
Belgique /
Belgium /
Belgien /

35

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 and three biobank user partners. More at bbmri.be



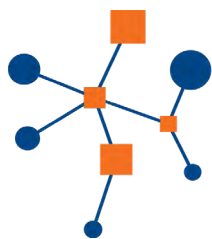
Areas of Expertise **Top 3**

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

Achievements **2023** **Top 3**

1. **Development** of 11 guidelines and SOPs to support biobanks in the quality improvement process towards ISO 20387 accreditation, within the framework of the B3-ISO project (*High quality BioBanking in Belgium: the road towards ISO 20387 accreditation*)
2. **Development** of informed consent modules for extracted & artificial material in accordance with the latest update of the Belgian biobank law
3. **Launch** of the new stakeholder-oriented BBMRI.be website (www.bbmri.be) and related communication materials to inform patients and researchers about biobanks





BBMRI·bg

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

България /
Bulgaria /
Bulgarien /

The Bulgarian National Node of BBMRI is based at Molecular Medicine Centre, Medical University of Sofia, hosting the biggest national biobank with various clinical research collections. The biobanking network involves biobanks and collections in two of the biggest Medical Universities in Sofia and Plovdiv. The Ministry of Education and Science supports BBMRI.bg in the frame of the National Roadmap of Research Infrastructures. Biobanking is done in a research and diagnostic setting with collection, processing, and storage of various types of samples, such as tissue, serum, plasma, DNA and RNA, cell lines and associated clinical, and demographic data. More at mmcbg.org

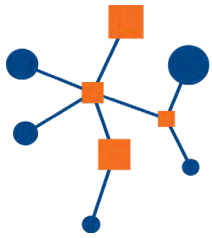
Achievements 2023

Areas of Expertise

1. **Research biobanking** in oncology
2. **Clinical biobanks** for research in rare diseases
3. **National expertise** in QC and ELSI issues

1. **The Ministry of Education and Science** provided support of 2.11 Mio Euro in 2023 for the development of the BBMRI.bg and capacity building. Part of the funding is to foster biobanking and the collection of referent national healthy cohort and the generation of WGS data. More than 400 participants from Sofia and Plovdiv were recruited in 2023 and DNA isolated and stored in the biobanks of BBMRI.bg for the pilot 1,000 Bulgarian genomes project.
2. **The National Science Fund** supported research teams to tackle the societal challenges posed by the COVID19 pandemic. Valuable sets of more than 440 patient's clinical data and DNA, 190 serum samples were gathered to investigate the host/virus interaction and severity of the disease, and to study the cellular and humoral immunity.
3. **BBMRI.bg and the research infrastructure NUCBTR** is the backbone for the implementation of substantial parts of the projects granted to established researchers and their groups through the Strategic research and innovation program of MU-Sofia and MU-Plovdiv, Pillar 2: "Establishing a network of research universities for Accelerating Economic Recovery and Transformation through Science and Innovation Programme", Bulgarian Recovery and Resilience Fund.





BBMRI·cy

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Κύπρος /
Κίβρις /
Cyprus /

We are the Biobank of Cyprus serving biobanking needs of the general population as well as of separate disease entities. It is one of the five pillars of the biobank.cy Centre of Excellence in Research and Innovation, funded by the EU (Horizon 2020), the Cyprus Government and the University of Cyprus. More than 9,000 volunteers have been enrolled, providing personal and health data, accompanied by DNA, plasma, serum, and urine in most cases. More at biobank.cy



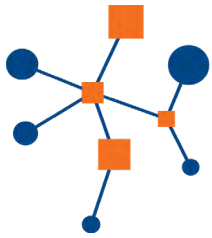
Top 3 Areas of Expertise

- 1. We have established SOPs** for high-quality biobanking with ISO:9001 and preparing for ISO:20387.
- 2. Our setting provides expertise** in IT and bioinformatics, statistics, data analytics, molecular and cell biology, and human genetics/genomics.
- 3. We use REDCap and Openspecimen** as our BIMS.

Top 3 Achievements 2023

- 1. Completed** more than 1,000 Cypriot Exomes for the first time (CYPROME), as the Cypriot reference DNA/genome
- 2. Completed** records of more than 9,000 Cypriot participants, including general population
- 3. Succeeded** in partnering with various groups in Cyprus and abroad (including BBMRI-ERIC, Broad Institute of MIT and Harvard), for developing funded research projects, based on our biobanking capacity in Cyprus





BBMRI·cz

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Česká Republika /
Czech Republic /
Tschechische Republik /

38

Since 2023, this infrastructure has eight members, including specialised medical institutions (3) and universities cooperating with faculty hospitals (5). Our biobanks store material from donors diagnosed with cancer, rheumatological diseases, diseases associated with haematopoietic 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. More at bbmri.cz



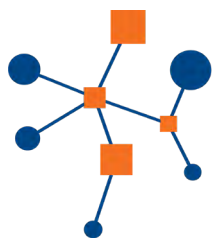
Areas of Expertise **Top 3**

1. **Standard biobanking** services
2. **Digital and molecular pathology** with a focus on liquid biopsies
3. **Analysis** of exosomes and circulating DNA

Achievements **Top 3** 2023

1. **BBMRI has grown** with two new partners in 2023: The Biobank of the *Institute of Haematology and Blood Transfusion (IHBT)* and the CELSPAC Biobank of the RECETOX Research Infrastructure at Masaryk University.
2. **In terms of quality management**, all biobanks in BBMRI.cz continued to prepare for the implementation of the requirements of the European Standard EN ISO 20387:2021 (Biotechnology – Biobanking – General requirements for biobanking) with the exception of the MMCI biobank, which is the only one in the Czech Republic to already have received this accreditation so far.
3. **A data catalogue** integrating biobanking, clinico-pathological and sequencing data (data.bbmri.cz) was launched as a pilot phase with the aim of making BBMRI.cz data available for secondary use in research.





BBMRI·dk

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Danmark /
Denmark /
Dänemark /

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The Danish National Node is in its initial phase. Three meetings have been conducted, and the structure of the Node is being established. The Danish working groups will be aligned with BBMRI's interest areas: IT services & Research, ELSI services & Research, Biobanking Development, Public Affairs & Stakeholders engagement, Outreach, Education & Communications and Quality Management. Members of Expert Groups, Working Groups and Taskforces are also up for nomination. More at bbmri-eric.eu/national-nodes/denmark



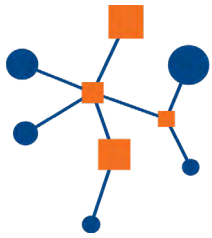
Achievements 2023

Areas of Expertise

1. **IT - Biobank Register**
2. **Sample collection**, both clinical and research biobanks
3. **Use of biobank samples** in combination with health register data

1. **Forming the National Node**, preparing terms of reference for the National Node and joining BBMRI-ERIC as an Observer State
2. **Political awareness**; a National Biobank Analysis has been conducted
3. **Strong collaboration** between biobanks with official establishment of the Danish Biobank Network.





BBMRI·ee

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

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The *Estonian Biobank* (EstBB) is part of the Institute of Genomics of the University of Tartu, with a population-based, prospective and longitudinal biobank. The EstBB maintains and manages the biobank by storing the biological samples of participants – mainly DNA, plasma, and buffy coat cells – and periodically renewing and updating the health information from relevant national registries. The biobank consists of more than two million biological aliquots and health records from over 210,000 participants representing about 20% of Estonia's adult population. All 210,000 participants have been genotyped with GSA microarrays (Illumina) and metabolomics data from Nightingale Health. More at genomics.ut.ee

Eesti /
Estonia /
Estland /

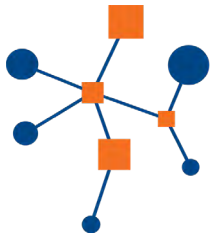
Achievements 2023

Areas of Expertise

1. **Sample and data** collection
2. **Integration** of electronic health records
3. **DNA** analysis

1. **The Estonian Biobank actively engaged** in BBMRI WG QMS meetings, contributing to the development of self-assessment surveys, and transitioning standards, focusing on ISO compliance and quality system organisation.
2. **We have made the Estonian Biobank dataset fully accessible** through the BBMRI-ERIC search engine *Federated Platform* (via BC Link), where one can see what data is available and assemble study cohorts. Requests for access to data can be submitted based on assembled cohorts.
3. **In the ELSI working group**, we contributed to creating a European consensus on issues related to return of result (Vears, D. F. *et al.* (2023): 'A practical checklist for return of results from genomic research in the European context', *European Journal of Human Genetics*).





BBMRI·fi

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

BBMRI.fi is a research infrastructure comprising ten biobanks in Finland. BBMRI.fi is the Finnish National Node of the European-level BBMRI-ERIC (*Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium*). Finnish Biobanks Cooperative – FINBB has coordinated BBMRI.fi since 2020. FINBB was appointed to this role by the Ministry of Education and Culture. More at bbmri.fi



Suomi /
Finland /
Finland /

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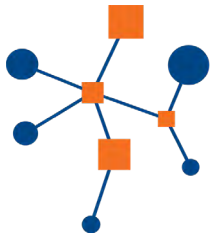
Areas of Expertise

- 1. National one-stop shop biobank services** for researchers through Fingenious® services which includes Availability, Request and Recruit Services. More information: www.fingenious.fi
- 2. High-quality sample collections** with associated clinical data derived from EHRs and study / population cohorts and expert data analysis capabilities
- 3. Capability and processes** to return biobank study results to participants



Achievements 2023

- 1. Fingenious.fi** - the gateway to Finnish biobanks and biomedical research is enhancing international collaboration with over 1,000 researchers from 25 countries, over 400 projects conducted and >1,000 scientific publications in peer-reviewed journals.
- 2. Large biobank study FinnGen** is proceeding as planned. Already >500,000 samples collected and genotyped.
- 3. Helsinki Biobank** developed and piloted a process for returning genomic information via *MyBiobank* digital service to participants carrying pathogenic variants of *BRCA1*, *BRCA2* and *PALB2*. Participants were also asked in *MyBiobank* acceptance to transfer results to healthcare for validation and possibly proactive treatments. The pilot is now extended to all Finnish hospital biobanks and the cost-effectiveness of returning information evaluated by creating a specific health economical assessment model. The preliminary results are indicating that benefits to individuals and healthcare system are higher than the additional costs delivered by the overall process.



BBMRI·de

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Deutschland /
Germany /
Allemagne /

The *German Biobank Node* (GBN) is the umbrella organisation of academic biobanks handling human biospecimens and associated data in Germany. Coordinated by the GBN, 36 academic biobank sites and one IT development centre have joined forces in the *German Biobank Alliance* (GBA). Advancing biomedical research and laying the groundwork for reproducibility, the GBA biobanks establish uniform quality standards and make their human biosamples and associated data available for biomedical research throughout Europe. GBN is funded by the German *Federal Ministry of Education and Research* (BMBF). More at bbmri.de



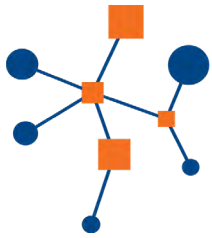
Achievements 2023

Areas of Expertise

- 1. Partner biobanks have great expertise** in quality management and participate regularly in friendly audits as well as proficiency tests conducted within GBA.
- 2. Their strength in IT** enables biobanks to connect to the overarching *Federated Platform* of BBMRI-ERIC and thus provide information via the *Sample Locator*.
- 3. A standardised informed consent** is established at all GBA sites, which means that samples/data can potentially be widely used for health research.

- 1. Increasing Europeanisation:** GBN's *Sample Locator* was integrated into BBMRI-ERIC's *Federated Platform*. GBN successfully participated in the application for the EU project EvolveBBMRI. In addition, GBN worked intensively with partner Nodes on an overarching QM manual and on a film for researchers.
- 2. Biobank accreditation:** The NCT Tissue Bank Heidelberg is the first German biobank to be accredited to DIN EN ISO 20387. It was strongly supported by the GBN QM programme, in particular with "friendly audits".
- 3. Learning opportunities:** A starter kit for biobanks in the development phase has been added to the GBN training portfolio. A wide range of webinar recordings and certificates of attendance have also been included. GBN has published a very successful board game: "Biobanking Challenge".





BBMRI·gr

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Ελλάδα /
Greece /
Griechenland /

43

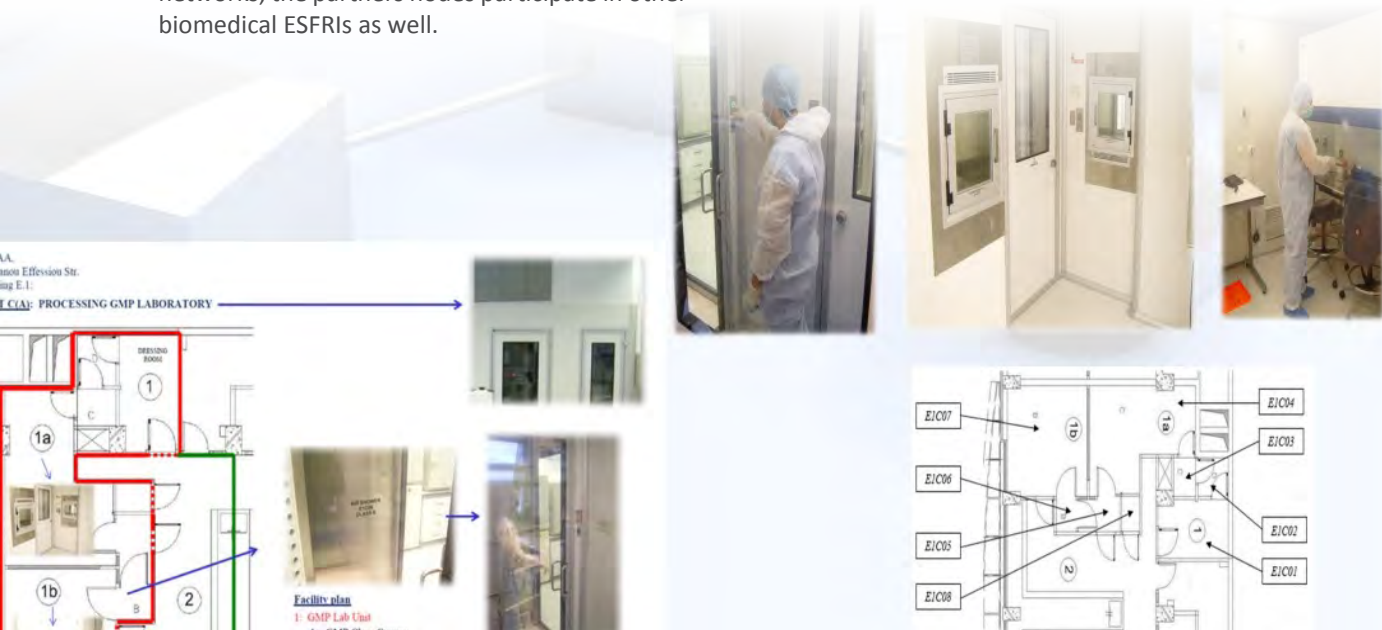
BBMRI.gr integrates collections of biological resources and associated expertise into a key resource for users in academic institutions and in the pharmaceutical and life science industries, contributing directly to innovation. BBMRI.gr is coordinated by the *Biomedical Research Foundation of the Academy of Athens* (BRFAA) and partners are University Hospitals and Research Centres, combining expertise, technological infrastructure and knowledge in thematic fields that ensure complementarity and multidisciplinary. The participating biobanks range from specialised small clinical to large-scale, population-based cohorts available in the different nodes, comprising collections of both disease specific e.g., oncology, Parkinson's disease, viruses, bacteria and a population biobank. More at bbmri-eric.eu/national-nodes/greece

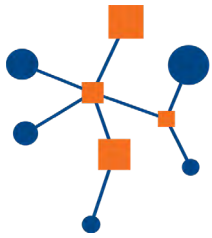
Achievements 2023

- 1. SOPs have been introduced** in local biobanks and internal guidelines have been provided in order to achieve harmonisation.
- 2. During 2023 effort was put on database harmonisation** and IT-infrastructure Information Technology (IT). Requirements analysis and specification. Design and original implementation of BIMS for the national network. The IT-infrastructure of BBMRI.gr consists of a network using the hub-and-spoke topology to connect the different nodes, geographically spread through Greece. The necessary IT-concepts were created, together with architectural components and prototypical solutions for an adequate and effective support of a federated network. For the software of the central node, the use of the MOLGENIS platform has been chosen.
- 3. A biobank of 30,000 samples** of healthy people joined BBMRI.gr.

Areas of Expertise

- 1. State-of-the art research capacity** in genomics, transcriptomics, proteomics, metabolomics, statistics, bioinformatics, data management and integration, bioethics, and societal sciences
- 2. Access to biomedical resources** in Greece and medical expertise for innovative diagnosis and treatment
- 3. Major research actions**, via the BRFAA, at European level, like *The Genome of Europe* and other networks, the partners nodes participate in other biomedical ESFRIs as well.





BBMRI·hu

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Magyarország /
Hungary /
Ungarn /



The Hungarian Biobank Node (HBN) is the umbrella organisation of the largest biobanks in Hungary (University Debrecen, University Szeged, University Pecs, Semmelweis University, South-Pest Centrum Hospital, Richter Gedeon Ltd. and the Paediatric Oncohaematology Network) and represents the Hungarian research community within BBMRI-ERIC. It was established in 2021 and supported by the Hungarian Research and Innovation Office and is the primary contact in Hungary for all stakeholders involved in biobanking. The biobanks of the HBN are collecting several types of biospecimen and associated data elements. Members of the HBN are harmonising their quality standards and establishing federated data sharing within the network, aiming to implement FAIR principles as the foundation of the process. Our sites adhere to the highest ethical standards when acquiring specimens for their collections, and protection of donor identity is assured.

HBN catalyses scientific discovery through the networking of resources aimed at the collection and distribution of different human biospecimen and clinical data. HBN believes that biobanks have a strategical importance in the future of data driven precision medicine. We are engaging all stakeholders relevant to biobanks – from researchers to patients. HBN provides researchers with a wealth of resources to facilitate their research, including medical records and clinical data sets (when available), as well as access to quality metrics and best practices used by each site. More at bbmri.hu

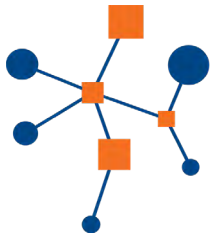
Areas of Expertise

1. **Rare** disorders
2. **Cardiovascular** disorders
3. **Oncohaematological** disorders

Achievements 2023

1. **Preparation** of the data warehouses of the member biobanks for federated data sharing
2. **Drafting** of the implementing decree of the Hungarian Biobank Act to regulate the operation of the Hungarian biobanks
3. **Development** of the framework for the joint consent statement of the members of the Hungarian Node





BBMRI·iarc

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

International Agency for
Research on Cancer/World
Health Organisation
(IARC/WHO)

45

The *International Agency for Research on Cancer/World Health Organisation* (IARC/WHO) is the executive research agency of the WHO with a specific focus on cancer. It is a globally leading research organisation in developing strategies and recommendations for cancer prevention, guideline creation for global health and a leading institution in biobanking research. More at iarc.who.int

Achievements 2023

Areas of Expertise

1. **Biobanking standards** and guidelines

2. **International biobanking network** with a focus on *Low and Middle Income countries* (LMICs); The network is called BCNet

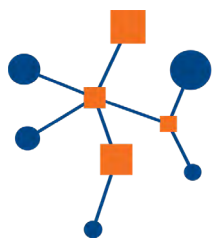
3. **Research on biobanking**, including new laboratory techniques and ethics.

1. **Complete move and validation** of biobanking activities, into new, purpose-built facilities. The new IARC building is located within the Gerland region of Lyon, France, in the proximity of the WHO Academy and a number of French national, academic institutions and pharmaceutical companies.

2. **Over 20 major publications**, many in high-impact international scientific journals, e.g., *Cancer Cell*, *BMJ*, *The Lancet Regional Health — Southeast Asia*, and others.

3. **Achieving the IBISA French National label** as a first step of the process towards ISO 20387 accreditation.





BBMRI·it

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Italia /
Italy /
Italien /

46

The Italian node of BBMRI (BBMRI.it), 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 rely on the use of collections of biological resources. BBMRI.it includes the 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 requests related to quality matters. More at bbmri.it

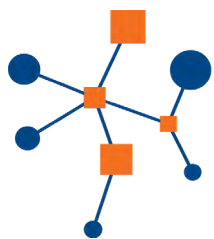
Achievements 2023

Areas of Expertise

- 1. Quality Management (QM):** QM training and support to biobanks; Support to implementation of ISO 20387 standard; Healthcare integrated biobanking
- 2. ELSI** with a specific focus on co-production of knowledge as well as stakeholder and user engagement
- 3. 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

- 1. Support** for the implementation of quality standards and ISO 20387 accreditation / certification by accredited body
- 2. Development** of criteria for secondary use of biological material residual from previous clinical activities. Establishment of BBMRI.it “Hands on Old Collections” working group involving 15 biobanks with institutional endorsement. It included a community of practice approach, co-design rationale and tools for old collections overview and mapping
- 3. Implementation** of a Digital Maturity Framework for Biobanking





BBMRI·lv

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Latvija /
Latvia /
Lettland /

47

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

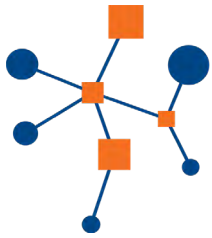
Achievements 2023

Areas of Expertise

1. **Biological samples** of population-based and disease-specific collections, survey data and information retrieval from health care system
2. **Large-scale sequencing** (genome, transcriptome, exome, metagenome) and digitalisation of biological samples in national scale “-omics” projects
3. **Activities** in ELSI and quality management on national and international level

1. **Launching implementation of the Latvian Genome Reference project** under the “European Million Genomes Initiative” (1+MG). In 2023 the recruitment of 3,500 participants for Latvian Genome Reference creation started, accompanied by whole genome sequencing and the development of genomic data storage and processing infrastructure in Latvia. This will serve as foundation of future personalised medicine development in Latvia.
2. **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 into force in Latvia; participation in the working group for development of national regulation for secondary data use for research.
3. **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 others.





BBMRI·lt

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Lietuva /
Lithuania /
Litauen /



The National Cancer Institute of Lithuania coordinates the BBMRI.lt infrastructure in partnership with Vilnius University, Vilnius University Hospital Santaros Klinikos, 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 nvi.lt/biobank

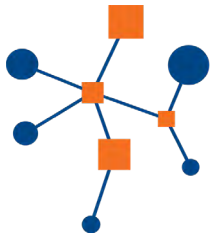
Achievements 2023

Areas of Expertise

1. **Lithuania** moved from BBMRI-ERIC Observer to Full Member.
2. **In the field of rheumatology**, an injectable chondroitin sulphate-thiamine hydrogel biomimetic framework has been developed that effectively protects the cartilage of the knee joint from mechanical stress. Significant studies have also been carried out on the use of electrostimulation in cartilage regeneration processes.
3. **Santaros Klinikos played a key role** in a national prospective cohort study investigating the immunogenicity and clinical effectiveness of mRNA vaccine boosters against the SARS-CoV-2 Omicron variant in patients with haematological malignancies. They published the first biobank-related research article, contributing to the field of biobanking.

1. **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
2. **NGS, proteomics, and metabolomics** methodologies alongside integrated digitalisation processes to explore various diseases and population-based health concerns
3. **High-capacity pathology data digitalisation** of whole slide images; AI solutions





BBMRI·mt

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Repubblika ta' Malta /
Malta /

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BBMRI.mt is represented by the Centre for Molecular Medicine and Biobanking within the University of Malta. The Malta BioBank is the first national archive of biological samples. It houses a population bank and a clinical bank with specific collections. The population bank has a very large collection of random Maltese neonates, pooled neonatal samples, and samples from multiple births and senior citizens. The clinical bank has specific collections such as the Globin Bank, the Coeliac Collection, the Parkinson's Collection, the Diabetes Collection and a small collection of other rare disorders from the genetics services. The main project of the biobank is *StudjuDWARNA*, a population genomics biobank that aims to expand and conduct genetic epidemiology research in the Maltese population. This Maltese Genome Project targets 1 % of the population regarding their origins, mobility, epidemiology, pharmacogenomics and immunogenetics for gene discovery research. The Malta BioBank is a founding member of ITHANET (thalassaemia network), Euro-BioBank and RDCONNECT as well as of BBMRI. It seeks to expand the scope of biobanking in Malta and the Euro-Mediterranean region. More at um.edu.mt/cmmb

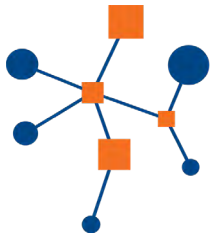
Areas of Expertise

1. **Population** biobanking
2. **Preanalytical** quality control
3. **Population** genomics/bioinformatics

Achievements 2023

1. **In 2023 we launched the national population biobank**, named StudjuDWARNA (Dwarna means 'about us' in Maltese). The Maltese population has a unique genetic architecture, reflecting its shared genetic ancestry with European and Middle Eastern populations. Against this background, StudjuDWARNA aims to conduct a comprehensive evaluation of the genomes of Malta. This will be achieved through analysis of a nationally representative cohort, obtained from DwarnaBio.
2. **DwarnaBio is 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.
3. **DwarnaBio will collect and store** biological samples and associated clinical data from volunteers, to be used by collaborative research at the University of Malta. StudjuDWARNA will perform genomic sequencing and analysis of a reference Maltese collection unselected for disease. It will aim to explore the association between genomic architecture and both rare and common diseases, and eventually to relate genomic findings to clinical outcomes in longitudinal studies. StudjuDWARNA will also enable the construction of a reference Maltese genome, which will be a powerful tool for health research.





BBMRI·nl

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Nederland /
Netherlands /
Niederlande /

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 federated national nodes of BBMRI, EATRIS, and ELIXIR, and works towards a shared, ESFRI-overarching, international-grade service portfolio. BBMRI.nl facilitates harmonised collection, management, and distribution of health records, images, and biomaterials originating from a wide range of registries, cohorts, data- and biobanks. More at bbmri.nl

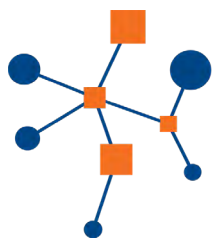
Achievements 2023

Areas of Expertise

- 1. Procedures, Guidelines, and Standards:** Procedures and standards for health data are (further) developed and aligned, followed by regional and local implementation.
- 2. Support and Services:** The services for data findability and accessibility are improved and widely implemented through one-stop shops, training, education and the national ELSI service desk.
- 3. Knowledge Dissemination:** The dissemination of relevant knowledge for biobanks and collections occurs through events, websites, and a network of experts.

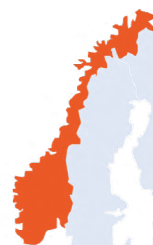
- 1. The 1st national Biobanks & Collections Day**, held on November 9th in Amsterdam, attracted more than 170 participants who discussed biomaterial processing, data handling, and ELSI developments related to patient-centric biobanking.
- 2. Two national projects** have been started aiming to harmonise the pre-analytic process (“Dutch biobanking standard”) and the consent procedures (“Mutual recognition”) for biobanks.
- 3. 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.





BBMRI·no

The European research infrastructure for biobanking and biomolecular resources in health and life sciences



Norge /
Noreg /
Norway /
Norwegen /

51

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

Over the last years, Biobank Norway has increased the number of users exponentially, offering a wide range of well described, richly annotated bio-specimens and corresponding health related data, 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-profile publications. More at bbmri.no

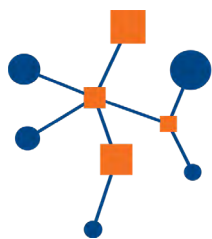
Areas of Expertise

1. **Initiating and running** population-based and clinical biobanks
2. **Digitised biobank data** – secure solution for handling of sensitive big data
3. **Integrating data from multiple sources**, such as national and local registries, electronic health records and population studies, mostly accessed through one national entry point

Achievements 2023

1. **Start of new project period** – Biobank Norway 4
2. **Application sent to the Research Council** of Norway for establishing a national handling infrastructure for sensitive data, based on FAIR-principles and secondary use of health data
3. **ISO 20387 Accreditation forum** and internal partner revision procedures established





BBMRI·pl

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Polska /
Poland /
Polen /

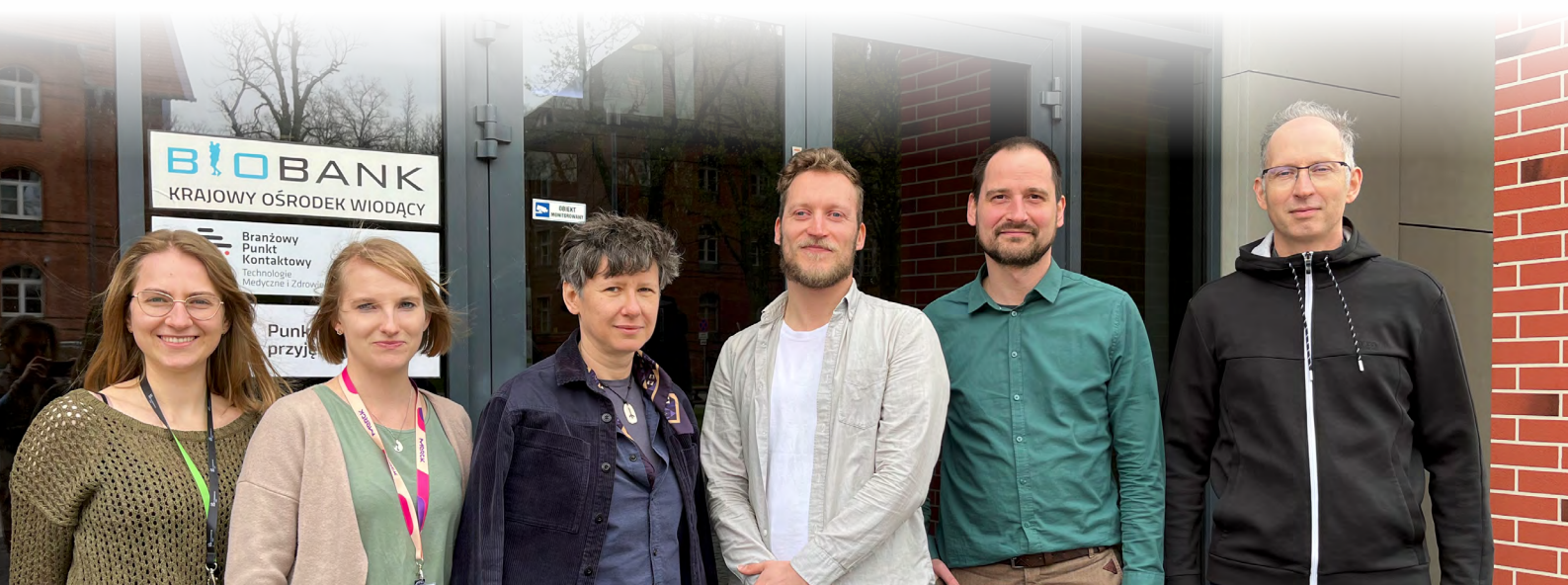
The Polish national node coordinates the activities of the Polish biobanking community and its integration to the BBMRI-ERIC European infrastructure. Our Node is responsible for internal and external communication, contact with BBMRI-ERIC, representation of the biobanking community before national and foreign stakeholders, and promotion of participation of Polish experts in BBMRI-ERIC initiatives and working groups. The node brings together a lot of experts from Polish biobanks and other institutions related to biobanking. The result of the first years of the node's work is, among other things, the establishment of the Polish Network of Biobanks, whose primary task is involving associated biobanks in the activities of the European BBMRI-ERIC infrastructure. More at bbmri-eric.eu/national-nodes/poland

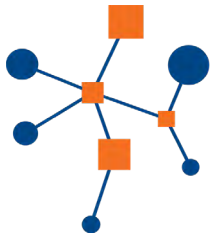
Achievements 2023

Areas of Expertise

- 1. Collaborative biobanking** with a research dimension: ability to bridge biobanking and disease research with focus on histopathological data acquisition and analysis specifically tailored to research projects
- 2. Advisory role** for the medical staff on best practices for collecting and preparing biological samples for biobanking in accordance with the latest QMS requirements
- 3. Digital pathology and digital biobanking** (including multi-layer approaches for machine learning applications): Knowledge of digital histopathology data generation, computational pathology/image quantification and analysis, systems for digital slides management/remote sharing

- 1. Securing funding** from the National Medical Research Agency 2023 open call for Regional Digital Medicine Centres. Six of National Node Institutions received funding: Wrocław Medical University, Łukasiewicz – PORT, Medical University of Białystok, University of Łódź, Medical University of Gdańsk and Medical University of Lublin with seven members of BBMRI.pl (PSB)
- 2. Four peer-reviewed scientific publications** with joint impact factor >47 (including: *Nat. Commun.*, *Clin. Cancer Res.*) and two publications in Quality and ELSI field, first in Springer Nature Publishing Group ("*Manual of Biobank Quality Management*") and second in Bioethics ("*Biobanking of human biological material and the prohibition of commercialisation of the human body and its parts*")
- 3. Launching of new postgraduate educational programme:** MBA in Healthcare integrated with Clinical Trials and Biobanking.

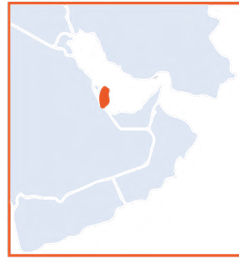




BBMRI·qa

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

رطق دلود /
Qatar /
Katar /



The Qatar Biobank National Node is a pillar of Qatar precision health institute, sets global standards in biobanking and diagnostic testing, compliant with ISO 20387:2018 and CAP accreditation, dedicated to revolutionising personalised medicine in Qatar. By hosting comprehensive studies, including a longitudinal population cohort and targeted disease-specific cohorts, we integrate deep phenotyping, whole genome sequencing, and extensive medical record data. This multifaceted approach enables us to explore the interconnections between genetics, lifestyle, and environmental factors, aiming to uncover insights that lead to tailored healthcare solutions. Our mission is to advance medical research, enhance disease prevention and improve healthcare outcomes thus setting new standards for global health research and personalised medicine.

More at qphi.org.qa

Achievements 2023

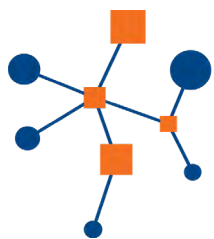
53

Areas of Expertise

- 1. Epidemiology**, where we conduct in-depth studies on how lifestyle and environment influence health across populations.
- 2. Genomic Research**, diving into the genetic foundations of diseases through whole genome sequencing; and Bioinformatics, leveraging sophisticated analytical methods to decode vast biological datasets, advancing the frontier of personalised medicine and tailored healthcare solutions
- 3. Expertise in biobanking** and precise biological sample handling is available, ensuring high-quality, standardised quality assurance practices are in place

- 1. In 2023, Qatar Biobank marked significant advancements**, underscoring our dedication in forcing biomedical research forward at both national and local levels. A major milestone was the initiation of a tissue biobank in partnership with Hamad Medical Corporation, which oversees most governmental healthcare services in Qatar. This strategic collaboration has significantly enriched our repository of biological samples, enhancing our research capabilities.
- 2. We successfully centralised multi-institutional disease cohort studies.** This initiative streamlined the collaboration and data sharing among Qatar's leading research institutions, maximising the utility and impact of our collective health data.
- 3. Our major achievement involved enrolling 40,000 participants** in a longitudinal study, thereby compiling the most extensive dataset in the region, inclusive of whole genome sequences, medical records, and detailed phenotypic information. This endeavour has not only positioned us at the forefront of genomic research in the region but also provided critical insights into genetic factors influencing health in Qatar, greatly advancing the field of personalised medicine. This milestone reflects our deep commitment to leveraging research to improve healthcare outcomes.





BBMRI·si

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Slovenija /
Slovenia /
Slowenien /



54

The Slovenian national node BBMRI.si consists of all three Slovenian public universities, University Medical Centre Maribor, and University Clinic Golnik. More at bbmri-eric.eu/national-nodes/slovenia

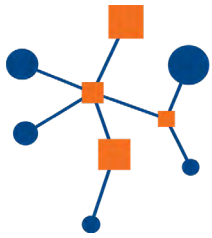
Areas of Expertise

1. **Autoimmune** disorders
2. **Glioblastoma**
3. **Rare** diseases

Achievements 2023

1. **Inclusion** of University Clinic Golnik into BBMRI.si
2. **Inclusion** of the National Institute of Biology into BBMRI.si
3. **Assuring** a small amount of stable governmental funding





BBMRI·es

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

España /
Spain /
Spanien /

55

The *ISCIII Biomodels and Biobanks Platform* (P_ISCIII_BB) is a structure from the Institute of Health Carlos III (ISCIII) and acts as the Spanish National Node in BBMRI-ERIC. It is currently composed of 42 units and another 20 adhered units. The P_ISCIII_BB has been organised into four scientific-technological HUBS, which include: Biobanks, Organoids, Animal Models and 3D printing, to promote and increase scientific-technological resources in biomedical research. Such a structure allows the handling and supply of biological samples, as well as associated clinical data. The number of units for each scientific-technological HUB includes: 56 Units in the Biobanks HUB, 27 Units in the animal model HUB, 25 Units in the Organoids HUB and 21 Units in the 3D printing HUB. More at isciiibiobanksbiomodels.es/en



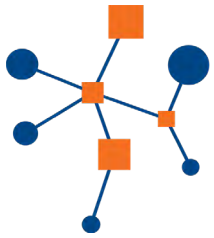
Top 3 Achievements 2023

Top 3 Areas of Expertise

- 1. ELSI:** The P_ISCIII_BB accounts to ELSI experts ensuring state-of-the-art guidance and training as well as consultations with researchers at the national level and worldwide. In 2023, the P_ISCIII_BB received and responded to 11 ELSI-themed consultations through the P_ISCIII_BB helpdesk allocated on the website.
- 2. IT Tools & Quality Management:** The P_ISCIII_BB coordination focuses on the implementation of IT tools and workflows for national Virtual Catalogues, centralising specimen collections for research. In 2023, these tools supported 81 sample availability reports, 34 surveys, and 30 consultation reports. The catalogue includes 47 COVID-19 collections (69,552 samples) and 452 Rare Disease collections (106,166 samples). A dedicated team also ensures quality management in biobanking and biomedical research, supported by the Quality Working Group.
- 3. COMMUNICATION AND OUTREACH:** P_ISCIII_BB continuously increases the visibility of its services and developments through an intense activity in coordination. These activities are also supervised by ISCIII. Building on our units, the P_ISCIII_BB works in the promotion and engagement of congresses, educational programmes and symposia portfolio. The activities include a total of 421 courses, participation in more than 1,400 national projects and participation in more than 1,400 dissemination activities, among others.

- 1. The Biobanks and Biomodels Annual Assembly 2023** highlights the efforts of the three national ISCIII Platforms (*Platform for the dynamisation and innovation of the industrial capabilities of the NHS - ITEMAS, the Clinical Research Support Platform SCReN, and the Biobanks and Biomodels Platform*). The event aimed to foster national collaborations and engage European Platforms and Networks, particularly the EU AMRI alliance. The ISCIII Platforms' workshop to support R+D+I in Biomedicine and Health Sciences was held from October 18-20, 2023, in Cádiz, with virtual participation from Jens Habermann (DG BBMRI-ERIC).
- 2. Launch of new functionalities** in the BackOffice for closing online requests
- 3. Preparation and launch** of the national catalogue of Rare Disease and COVID19 samples, which has a total of 106,166 rare disease samples and 69,552 COVID19 samples, as well as the update of the catalogue of services of the Animal Model HUB, which has a total of 612 identifiers/services.

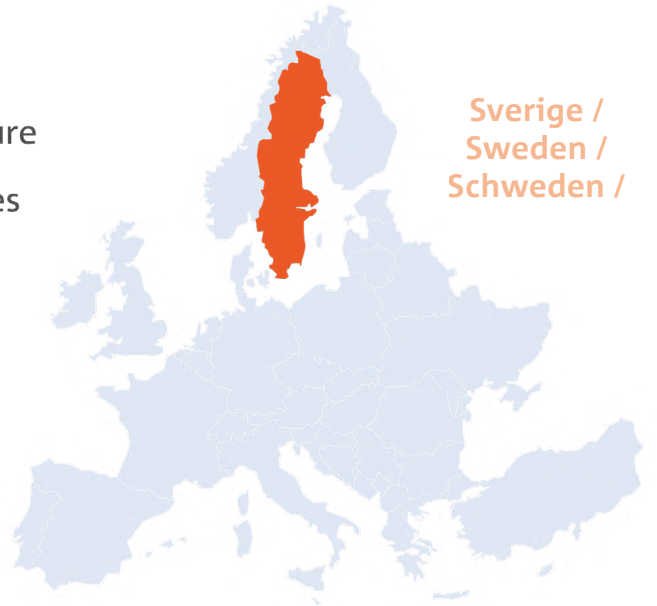




BBMRI·se

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Sverige /
Sweden /
Schweden /



56

Biobank Sweden is not a biobank but a national infrastructure for biobanking where healthcare, academia, industry, and patient organisations collaborate to attain good healthcare and research. The infrastructure aims to provide Sweden with the best conditions for health care and research in the field of biobanking, both nationally and internationally. Biobank Sweden also works to facilitate the application of the Swedish Biobank Act. The work is carried out on behalf of regions/county councils and universities with medical faculties. More at biobanksverige.se

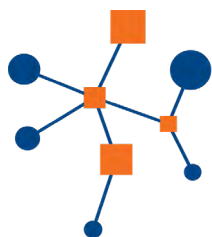
Areas of Expertise

1. **Regulatory** advice and service
2. **Operative** advice and service
3. **A national IT infrastructure for biobanking** including the Swedish biobank registry. Biobank Sweden has a well-developed organisational structure, the first version started in 2004. The structure allows us to collaborate efficiently and achieve results on a national level.

Achievements 2023

1. **The national implementation** of the new Swedish biobank legislation. Biobank Sweden was tasked by all the regions/county councils with leading a joint national project for implementation and interpretation. This was a major focus and permeated all work in 2023.
2. **Support to national research studies** for collection and withdrawal of samples in the health-care integrated biobanking including more than 30 hospitals in Sweden. In 2023 we received funding for a new national project to further improve our possibilities to support national withdrawal projects.
3. **Start of national pathology network** for the facilitation of access to health care samples





BBMRI·ch

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Suisse /
Svizzera /
Svizra /
Switzerland /
Schweiz /

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In Switzerland, many biobanks operate with heterogeneous processes making 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, transparency and the interconnectedness of biobanks and their related data. More at [swissbiobanking.ch](https://www.swissbiobanking.ch)

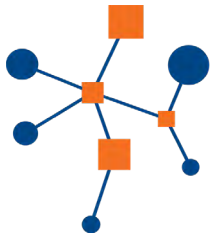
Achievements 2023

- 1. SBP BIMS:** a professional *Biobank Information Management System* developed with DiData to facilitate study configuration by administrators and to offer a SMPL module for intuitive workflow visualisation, integrating datasets for various environments (e.g., Human Liquid, Bacteria, Veterinary).
- 2. A Certificate of Advanced Studies (CAS) in Biobanking:** SBP, with partners including the University of Geneva and Institut Pasteur, is developing a CAS in Biobanking. Supported by Loterie Romande, this pioneering initiative offers online modules covering foundational insights, implementation processes, and professional management. Led by Swiss and international experts, it addresses the critical need for skilled biobanking professionals.
- 3. Cost Calculator for biobanks:** SBP developed the first Swiss Cost Calculator for biobanks, aiming for sustainability and transparency in cost recovery. Developed in collaboration with Swiss biobanking infrastructures, it aids in determining and invoicing costs for pre-analytical services, fostering efficiency and harmonisation within the community.

Areas of Expertise

- 1. Quality and Practice Harmonisation** (through documentation and SBP Labels strategy)
- 2. Interoperability and Data Standardisation** (using SBP Datasets and BIMS)
- 3. Education** (CAS in Biobanking)





BBMRI·tr

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Türkiye /
Türkei /

58

The BBMRI.tr, coordinated by the National Node at Izmir Biomedicine and Genome Center (IBG), is the umbrella organisation of biobanks in Turkey. The regulatory authority is *The Scientific and Technological Research Council of Turkey (TUBITAK) R&D Support and Continuum Management Group (ARGES)*. BBMRI.tr aims to create a collaborative research infrastructure between biobankers, biomedical researchers, clinicians, and patient organisations in Turkey to increase the biobanking capacity in rare diseases, cancer, and infectious diseases. Furthermore, the BBMRI.tr seeks to expand the scope of biobanking in the Euro-Mediterranean region and MENA countries. More at bbmri.ibg.edu.tr

Top 3 Achievements 2023

Top 3 Areas of Expertise

- 1. Rare and undiagnosed diseases:** Clinical expertise on rare diseases and repositories of large consanguineous families, with a particular focus on neurogenetic diseases
- 2. Rare cancers and cancers:** Clinical expertise on hereditary & sporadic solid and haematological cancers and repositories of FFPE, tissue, and blood samples of cancer patients.
- 3. Education** and hands-on training for biobanking.

- 1. The National Standards** for Biobanking in Turkey were completed, which involved harmonisation studies and auditor training for General Requirements for Biobanking, ISO 20387, by the *Turkish Accreditation Agency (TURKAK)*, with the active participation of BBMRI.tr.
- 2. Recruitment of the ERA Chair**, Prof. Dr. Uğur Özbek, as a critical milestone for the RareBoost Project and acceleration of RareBoost activities: Under the leadership provided by Prof. Özbek, several activities related to rare diseases and biobanking have been initiated, including 'Rare and Undiagnosed Diseases Advisory Council,' monthly seminars, recruitment of samples to IBG Biobank, training/networking activities on rare diseases biobanking to increase awareness of clinicians, researchers, industry and public, attracting industry and academic partners, among others.
- 3. International industrial collaborations** for biobanking of samples and data obtained from clinical phase studies were established.







PART 6

Additional Information

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

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 #2 Team (2023)
Belgium	Group picture BBMRI.be (Annual BBMRI.be meeting 3/10/24). Photographer: Kim Vande Look
Bulgaria	Group photo of BBMRI.bg and MMC, 07 December 2023. Photographer: S. Bichev
Cyprus	The CY Biobank team
Czech Republic	The Czech Biobank team
Denmark	A robot in the Danish National Biobank photographed by Novo Nordisk Foundation
Estonia	Prof. Andres Metspalu, Head of the Estonian Biobank from 2000-2024.
Finland	BBMRI.fi biobank day in Helsinki Dec 1 st , 2023
Germany	Meeting of the Steering Committee of the German Biobank Node, its headquarters and Prof. Jens Habermann as special guest. © GBN / Paul Gekeler
Greece	GMP Facility of the BRFAA, Coordinator of BBMRI.gr
Hungary	Expanding Biobank Resources for Rare Disorders at the Hungarian Node
IARC/WHO	The Laboratory Services and Biobank Group at IARC/WHO. Photographer: Xuexun Zhou.
Italy	BBMRI.it National Day
Latvia	Latvian National Biobanking Network event
Lithuania	Final conference at the Government of the Republic of Lithuania on the results and future plans of the EU Structural Funds-funded project “Human Biological Resource Centre”. Photo by National Cancer Institute of Lithuania, Cancer Information and Communication Department
Malta	Launch of StudjuDWARNA - The Maltese population biobank. Photo credit: University of Malta
The Netherlands	1 st Dutch National Biobanks & Collections Day on 9 Nov 2023
Norway	Photo: Oslo University Hospital, Title: biobanking
Poland	Michal Malewicz, NN BBMRI.pl Director, the image presents the PORT Biobank research team with NN BBMRI.pl Director
Qatar	Qatar biobank (QBB) - Qatar precision health institute (QPHI) Team Group Photo. Photographer: Zeid-Edge company
Slovenia	Portrait of Urban Bren, National Node Director of Slovenia
Spain	National Node Representatives in 2023: Scientific Director Dr. Eva Ortega-Paíno and Prof. Nuria Montserrat, Coordinator of the Platform of Biobanks and Biomodels (Institute of Health Carlos III, National Node of BBMRI-ERIC).
Switzerland	The Swiss National Node team. Photographed by Louise Roy.
Türkiye	RareBoost Project Stakeholder Meeting on 22.12.2023 - BBMRI-Türkiye team's efforts to create a strategic plan to boost biobanking of rare disease samples and data. Izmir Biomedicine and Genome Center – IBG.Event: RareBoost Project Stakeholder Meeting. Photographer: Pelin Ulca. Labeled BBMRI-Türkiye members are: 1) Dr. Yücel Erbilgin (Istanbul University, BBMRI.tr CS-ELSI), 2) Prof. Sibel Uğur İşeri (Istanbul University), 3) Dr. Özkan Özdemir (Acıbadem University, BBMRI.tr CS-IT Contact), 4) Prof. Uğur Özbek (Izmir Biomedicine and Genome Center, BBMRI.tr Rare Diseases Contact), 5) Dr. Yavuz OKTAY (Izmir Biomedicine and Genome Center), 6) Dr. Begüm Utz (Izmir Biomedicine and Genome Center, BBMRI.tr Communication officer), 7) Prof. Neşe Atabay (Izmir Biomedicine and Genome Center, BBMRI.tr National Node)

Appendix One

Auditor's report

To the Director General of
BBMRI-ERIC,
Graz

We have completed the audit of the financial statements as of December 31, 2023 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, 2023, 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 assessing whether the statutory requirements were adhered to concerning the preparation of the financial statements.

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

We performed the audit, with interruptions, from March to April 2023 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, 2023, 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, 2023, 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.

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

Responsibilities of 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.

PKF Corti & Partner GmbH
Wirtschaftsprüfer und Steuerberater



Mag. Clemens Corti alle Catene
Wirtschaftsprüfer / Certified Public Accountant

Graz, April 16, 2024

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.

Acknowledgements

We want to thank

Our Headquarters staff
National Node Directors and Biobanks 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 Communications.

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



BBMRI-ERIC[®]

The European research infrastructure
for biobanking and biomolecular
resources in health and life sciences