BBMRI-ERIC®

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

ANNUAL REPORT

2022

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PART ONE

EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

The past year has focused on three themes, those of enriching sustainability, community and collaboration.

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

Leading collaboration

As its coordinator, BBMRI-ERIC successfully launched canSERV in September 2022. This project significantly contributes to the acceleration of transnational research in line with the EU Cancer Mission Board recommendations and the defragmentation of ERA.

CanSERV is a major, community engaging, cluster-project of 19 European partners. It sits alongside EOSC4Cancer and UNCAN.EU to which the BBMRI community also contributes substantially. The canSERV Kick Off in Brussels was a public, high level, stakeholder event that included representation from the Commissioner's Cabinet.

The ERIC Forum project successfully closed and BBMRI continued its Secretariat coordination role by leading the development of the ERIC Forum 2 proposal. This follow-up project launches in 2023.

BBMRI-ERIC's contribution to the ICRI conference focused on fostering cross-domain collaboration.

Part of this was celebrating the opening of the CELSPAC Biobank in Brno where BBMRI and EIRENE brought together human and environmental biobanking expertise to better tackle future challenges posed to health by the climate crisis.

BBMRI-ERIC furthered development of the Code of Conduct for Health Research by expert consultations and participating in the newly launched European Health Data Space 2 Pilot project (EHDS2). In the EHDS2Pilot, BBMRI-ERIC leads two Work Packages with IT and ELSI expertise and represents the only RI with an operating Federated Data Platform across its EU Member States.

Increasing sustainability

For the first time, BBMRI-ERIC implemented a three-year Work Programme. This ensures continuous alignment with National Nodes and their community activities. Thus, engagement and communications with member states at Ministry and National Node level have intensified and this served to underpin discussions on the vision for the infrastructure's next ten years.

To support this, the Headquarters team has grown with key appointments made to Public Affairs, Biobanking Development and Outreach, Education and Communications. In addition, strengthening core operations has put BBMRI on a firmer footing to meet future challenges. This is more vital than ever as member states face increasing financial pressures due to the ongoing war in Ukraine, the energy crisis and continent-wide recession. Demonstrating value and impact has become ever more pressing in achieving sustainability.

Strengthening community

Our strong education activities continued throughout 2022 with further EACCME® accredited BBMRI QM Academy training, ELSI Dialogues offered throughout the year and two successful Europe Biobank Week Roadshows in Regensburg and Rome on Quality Management and Paediatrics respectively. The Roadshows are a new concept, driven by the community, and welcomed by delegates and ministries. Director Generals from the Italian Health and Research and Education Ministries took part in the Rome paediatrics event.

Strategic collaborations grew with the launch of the EU-AMRI alliance in Brussels and intensifying BBMRI's relationship with Elixir.

BBMRI-ERIC is delighted to have signed a Memorandum of Understanding with ESBB (European, Middle Eastern & African Society for Biopreservation and Biobanking) which reaches far beyond the former productive relationship in conducting the Europe Biobank Week congress together.

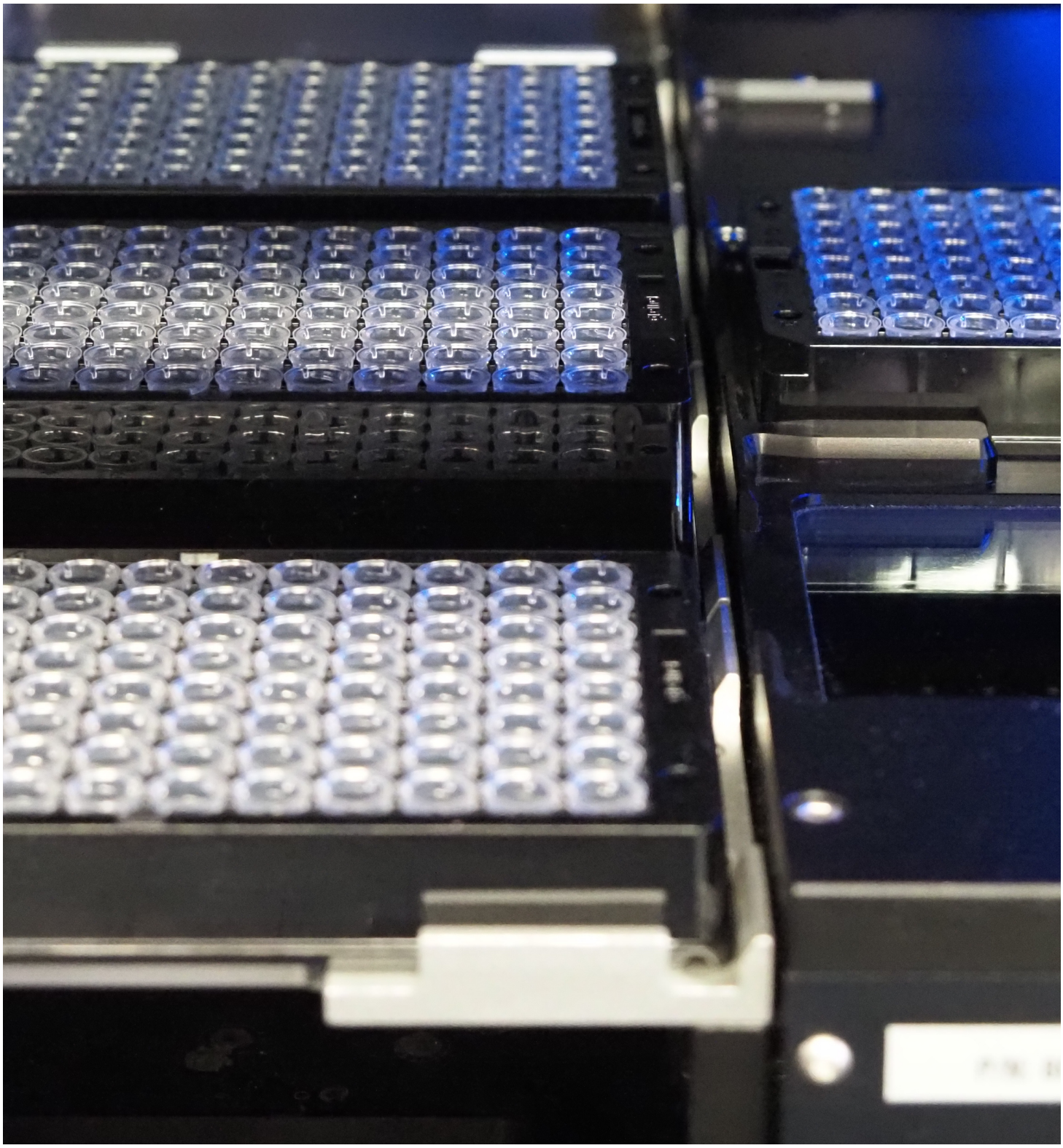
BBMRI further grew in its membership by welcoming the biobanking community from Slovenia which means the infrastructure currently comprises 23 European countries and one international organisation. The Assembly of Members supported the strategic expansion of membership by approving a policy on the admittance of third countries.

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

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

PART TWO

2022 SERVICE ACHIEVEMENTS FOR 2022



PART TWO

SERVICE ACHIEVEMENTS FOR 2022

Common Service IT

The IT infrastructure development and operations provided by the Common Service IT focused on the priorities outlined in the Work Programme 2022-2024. CS IT is based on collaboration between BBMRI-ERIC member states. This provides the necessary expertise, capabilities and capacities to develop and operate core services of common interest to BBMRI-ERIC's community.

Operations

Operations focused on biobank discovery and access facilitation services: the BBMRI-ERIC Directory, Negotiator and Authentication and Authorisation Infrastructure (AAI). The Federated Platform, developed by the respective community-driven task force, has also been supported by the operations team. For the core discovery and access services, CS IT also provided technical support to the Nodes to facilitate their integration. Changes in the underlying service provider infrastructure necessitated migration to a new infrastructure for hosting central data collections, namely the Colorectal Cancer (CRC) Cohort including an extensive archive of histopathological scans of whole slide images (WSIs).

Community driven development

In recent years, BBMRI-ERIC has been actively working on several initiatives aimed at improving the interoperability, usability and accessibility of biobank-related data and resources. One such initiative involved enabling fine-grained collections descriptors of biospecimens and data, and how these were used in previous research projects. This enabled more specific search results in discovery services.

In 2022, this effort resulted in the development of MIABIS (Minimal Information About Biobank data Sharing) Core 3.0, which includes support for data-driven biobanks and adds star-model support to provide in-depth statistics on the availability of data and biological samples. Another activity involved refining the usability of the Directory discovery service, which involved updates to the user interface layout and improvements to indexing speed, search capabilities, and user interface based on several user studies. This effort makes it easier for users to access the information they need from the Directory.

BBMRI-ERIC has also been working to support the heterogenous needs of biobanks by implementing Negotiator 3.0. This has the capability of dynamic and customised access forms based on participating biobanks. Additionally, the organisation has extended Negotiator capabilities to support the integration of access facilitation systems

across Nodes and other infrastructures by designing and implementing APIs for access request exchange. This effort was expanded in synergy with the canSERV project (a collaboration with INSTRUCT-ERIC) and with European Health Data Spaces (EHDS2 aka HealthData@EU) via the EHDS2Pilot project.

Finally, BBMRI-ERIC has been working to enable the integration of a Directory discovery and accessibility mechanism into other data discovery and interoperability resources. This included integration into FAIRsharing.org, the Virtual Platform of European Joint Programming for Rare Diseases (EJP RD), the Covid Data Portal via the BY-COVID project, and discovery and access requesting services of HealthData@EU. These efforts aimed to make biobank-related data and resources more accessible and usable across a wide range of research projects and initiatives.

Collaborating with ELIXIR and INSTRUCT-ERIC led to creating a single identity for European life-sciences researchers by developing LifeScience Authentication and Authorisation Infrastructure (LS AAI). This was supported by the EOSC-Life project and involved extensive user testing of the LS AAI and contributing to its launch in April 2022. BBMRI-ERIC services are scheduled to be migrated to LS AAI in 2023.

Training

CS IT has also provided extensive support and training to the Nodes. For existing nodes, this comprised support of data provision into the Directory and, for those operating relevant national directories, linking into the use of BBMRI's Negotiator service. New Nodes engaged in training that welcomed them into the overall BBMRI IT infrastructure and learned how to gain the most benefit from it.

Advancing the Federated Platform

The Federated Platform implements BBMRI-ERIC Locator, an open-source provision by DKFZ and BBMRI.de Node, and Finder, licensed from BC Platforms and operated solely by BBMRI-ERIC.

The Federated Platform Task Force (FP TF) led by Dr. Dudová (BBMRI.cz) and Dr. Quinlan (BBMRI.uk) worked extensively on finalising these solutions with both providers and onboarding biobanks into it. By December 2022, when the Assembly of Members approved the Federated Platform, the FP TF had enabled privacy-preserving searches of more than 422,000 donors' data. This includes 200,700 entries containing genomic information that could be queried.

Mapping ahead

To further enhance engaged collaboration across Nodes, BBMRI-ERIC has performed an IT roadmap survey resulting in valuable strategic insights that will be presented to the Management Committee and Assembly of Members in 2023. The outcome of the analysis enables better understanding of heterogeneous needs of Nodes, given their different setups.

Projects providing core value

Many important activities utilise synergy between the core funding of BBMRI-ERIC and project funding. Important highlights of such synergies include:

- Finalisation of Part One of the ISO 23494 standard on provenance management to enable trustworthy and machine-readable history documentation of biological material, data, and other research objects, which is due to be published in April/May 2023.

- Implementation of the GA4GH Beacons interface to Federated Platform in collaboration with European Joint Programming for Rare Diseases (EJP RD).

- Implementation support of the Global Alliance for Genomics and Health (GA4GH) Visa and Passports mechanisms in BBMRI-ERIC AAI and LifeScience Authentication and Authorisation Infrastructure (LS AAI) via the EOSC-Life project.

- Development of a new generation of models for machine-readable access conditions to streamline access for data driven applications in collaboration with EJP RD project. This was enabled through development of Data Use Conditions (DUC) and Common Conditions of use Elements (CCE) and piloting these in the Directory.

- Development of guidelines for privacy-preserving sharing of histopathological scans of whole slide images (WSI), supported by the EOSC-Life project and published in Nature Communications in 2023.

- Development of Infectious Diseases Toolkit (IDtk) with the support of the BY-COVID project, providing a knowledge base for Covid-19 related resources.

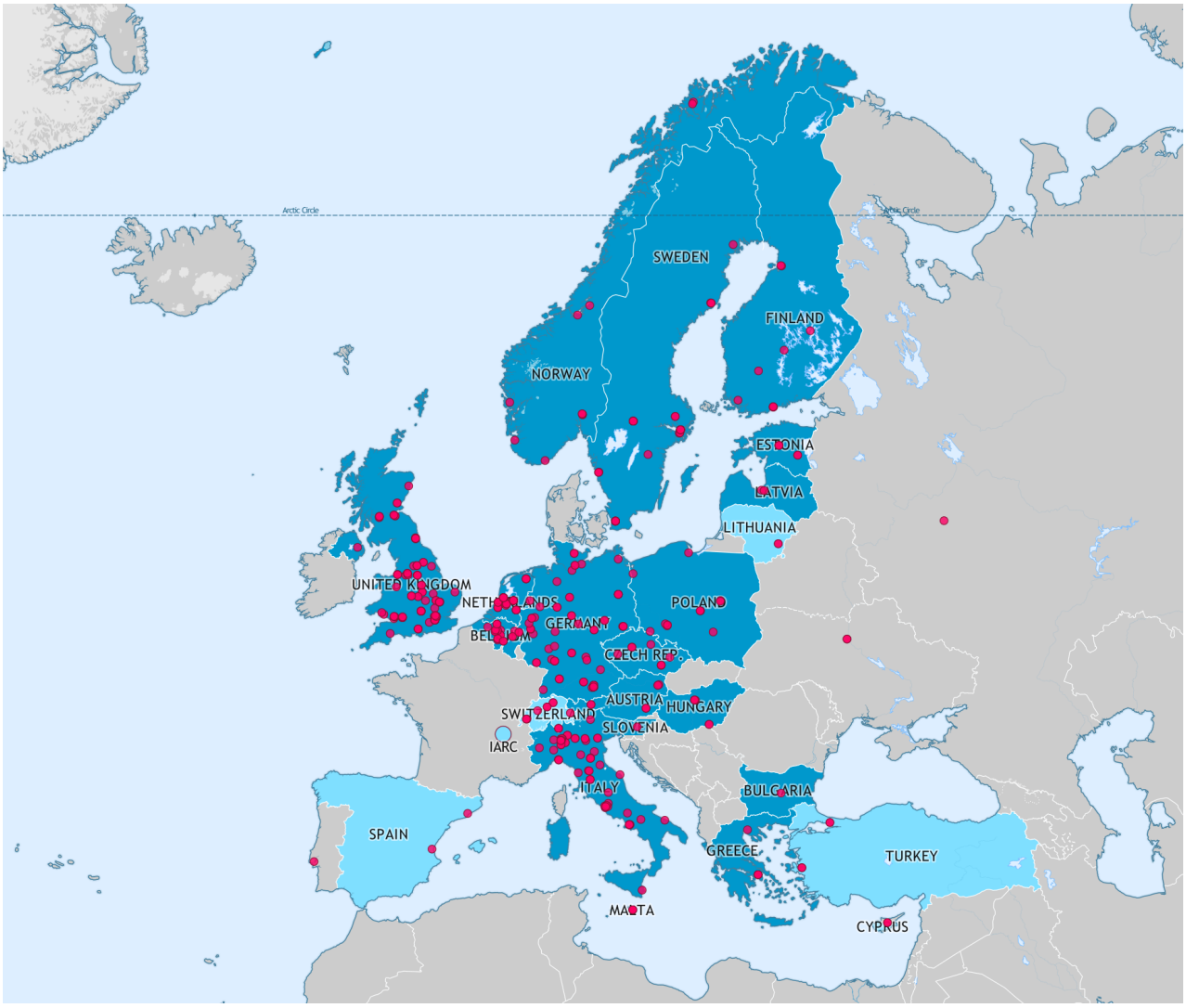


Image: Map of biobanks contributing to the Directory as of December 2022

ELSI Services and Research

Consistent excellence: To ensure excellence in providing guidance on ethical, legal, and societal implications (ELSI), the ELSI Services & Research Department operates based on a federated model, in partnership with a network of experts from academia and practice from across the Headquarters, the National Nodes and project partners.

Its vision remains to deliver reliable, practical, and sustainable services based on state-of-the-art research for the immediate benefit of the health and life sciences communities by setting standards, promoting best practices or enabling a cooperative platform for internal and public knowledge exchange.

Image: ELSI Services & Research

Growing audience

ELSI has more than tripled the audiences reached in 2022, to approximately 3,500 people, including researchers, students, and patient advocates. Following the proven concept of (co-)organising events with National Nodes or project partners or ELSI Dialogues, ELSI has accelerated outreach at scientific conferences and meetings by responding to calls for abstracts and invitations as (keynote) speakers and panelists.

In-demand knowledge

Research project participation amounted to 23 consortia and included nine Work Package and several task leads (e.g., EJPRD, CINECA,

Image: ELSI Word Cloud Christmas Tree containing key words from scientific publications on ELSI topics in 2022.

BigPicture, EOSC-Life, HealthyCloud, EHDS2Pilot, INTERVENE) in which specialists from the Headquarters and/or National Nodes participated alike. Currently, ELSI guidance and research is provided around data privacy, ethics of AI or vulnerability and resulted in 11 scientific publications and various outreach activities.

Practical guidance

The ELSI Knowledge Base aims to close the knowledge gap by translating research findings into hands-on guidance and by promoting 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-serving platform.

Helpdesk network

Focus areas and topics are often identified via ELSI Helpdesk requests. They come from patient advocacy groups, industry partners, biobankers or the wider health and life sciences community. The number of ELSI Helpdesk queries have been measured since 2017. In 2022, the ELSI Helpdesk responded to 134 requests (more than double the amount of 2021), equalling 286 person hours of expertise provided by the team on multidisciplinary topics including GDPR compliance, biobanking with children and gender aspects in research. Whereas some requests can be solved in a few minutes, substantial requests required consultation among the ELSI Helpdesk Network experts. The hours reported correspond to the time of the ELSI experts at the Headquarters alone. In addition, the ELSI Helpdesk Network comprises a diverse group of experts across BBMRI Member and Observer countries and meets quarterly, allowing knowledge transfer across Nodes.

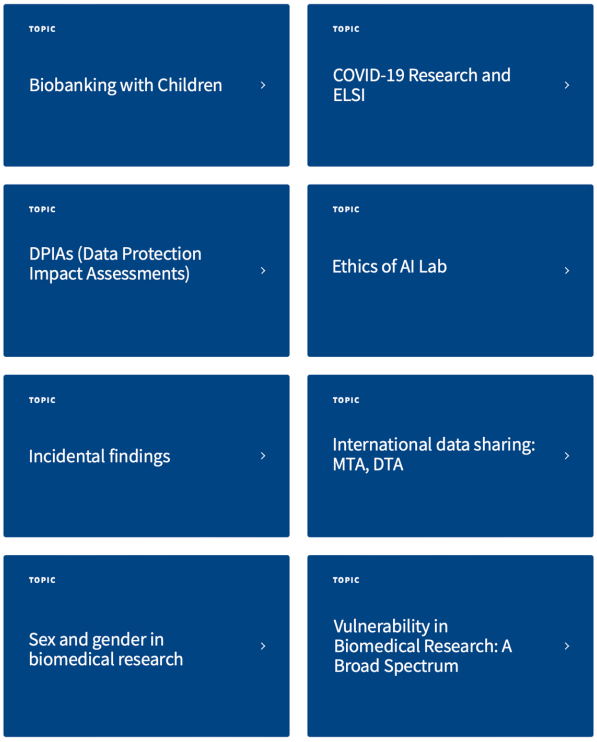


Image: ELSI Knowledge Base topics

Quality Management

During 2022, the Quality Management Department (QM) achieved a high level of community engagement with member and observer countries, and beyond.

Biobankers and biomedical scientists benefited from QM's wide-ranging services incl. Working Groups for QMS, BBMRI.QM Newsroom and training offers, such as the BBMRI Academy for biobanking relevant topics (see image).

Supporting new standards

The QM service has continuously developed its state-of-the-art offer to the community by actively engaging with both standardisation organisations, ISO on the international level and CEN on the European level. Six new biobanking relevant standards were launched in 2022 for which QM provides updates, advice and training to the biobanking community.

BBMRI-ERIC established a collaboration with the European co-operation for Accreditation (EA) that is formally appointed by the European Commission to develop and maintain a harmonised accreditation approach across Europe. To support the training in assessing ISO 20387 that national accreditation bodies undertake, QM contributed to the EU-wide "train the trainer workshop" initiated by EA. 56 technical and lead-assessors from 29 national accreditation bodies joined the two-day workshop.

Auditing for excellence

QM supports biobanks to demonstrate excellence by providing an extensive high quality audit programme, a preliminary stage towards accreditation. Biobanks who complete our Self-Assessment Surveys (SAS) showing compliance with international and European standards are awarded the BBMRI-ERIC Quality Label at biobank or collection level that is displayed in the BBMRI-ERIC Directory.

42	**Webinars available in the field of biobanking**
53	Registrants and access to recordings
1	NEW **BBMRI.QM Academy training** „Frozen tissue collection and biobanking"
113	Participants / 28 countries, recordings available
46	European CME certificates issued - accredited by EACCME®
19	**Awarded Quality Labels in the BBMRI-ERIC Directory, thereof:**
4	ISO 20387 accredited biobanks: ES, IT, PL, FI
4	Other 3rd party certificates: DE (ISO 17020); AT, CY (ISO 9001); NL (ISO 15189)
12	BBMRI audited sample collections and biobanks: SE, CZ
1	**EBW Roadshow** titled "On the Road to High Quality – With Biobanks in the Fast Lane"
165	Attendees in Regensburg, Germany / 21 countries
6	**Meetings of the Working Group for Quality Management**
219	Participants / 22 member countries
4	**BBMRI.QM Newsrooms**
289	Participants / 30 countries, presenting countries: ES, LV, BE, SE

Image: Summary of 2022 Quality Management activities

In 2022, 71 Self-Assessment Surveys have been requested by the community, 1 biobank received a BBMRI-ERIC Quality Label according to ISO 20387 (BBMRI audited), 11 sample collections received a Quality Label according to pre-analytical standards and eight biobanks received (according to their 3rd party certificate) a BBMRI-ERIC Quality Label (4x ISO 20387, 1x ISO 15189, 2x ISO 9001, 1x ISO 17020) in the Directory. Accreditation certificates have been awarded for biobanking competence to Fundación Instituto Valenciano de Oncología (IVO) Biobank (Valencia, Spain); Sezione Dipartimentale (SOD) Biobanca (BMS), Azienda Ospedaliero Universitaria (Pisa, Italy); Wroclaw Medical University Biobank (Wroclaw, Poland); AURIA Biobank, University Hospital (Tyks) and the University of Turku (Finland).

EU projects benefiting from QM expertise

In 2022, QM made a significant contribution to quality-relevant tasks in IMI projects such as ConcePTION and EPND, the H2020 projects EDIReX, CY-Biobank, IC2PerMed and DIAMONDS. Two Horizon Europe projects, ISIDORe and canSERV, have been added to the QM portfolio, addressing some of the EU's key health priorities in the areas of pandemic preparedness and oncology.

We contributed to a successful start of the EPND project by developing a biobanking guideline, which, as it is a public deliverable, will not only benefit the neurodegenerative diseases community, but the entire biobanking community.

QM supported the development of a comprehensive QM and document management system within the CY-Biobank project to ensure fulfilment of ISO 9001:2015 requirements. The resulting certification by the Cyprus Organisation for Standardisation marks a major step in the development of the biobank.cy Centre of Excellence.

Cooperation between the EU and China under the IC2PerMed project continued via a four-part series of virtual roundtables focusing on Personalised Medicine related to biobanking, data, ELSI and quality, as well as the common intersections. The outcome has helped define the requirements for a biobanking collaboration framework between the EU and China.

The EDIReX project received valuable support from BBMRI.QM in monitoring the compliance and local implementation of standards developed for health monitoring, biobanking and quality control in patient-derived cancer xenografts. This project successfully completed in 2022.

Strengthening the Quality community

QM continued to facilitate events throughout 2022 that foster a vibrant and valuable quality management community. This was achieved by:

- **Working Group QMS** meetings, with 219 participants, dealing with topics like user satisfaction, different biobanking issues and important community questions. Due to the success of the WG QMS, an additional WG that deals specifically with biobank standard ISO 20387 and prepares the biobank community for obtaining the BBMRI-ERIC Quality Label has been set up.

- **The QM Newsroom** engaged with 289 participants from our Member and Observer countries, as well as from France, India, Portugal, Uganda, Qatar and the US. Over four virtual meetings addressed quality-related topics under the motto "Get insights from the outside". The quality leads from our National Nodes in Spain, Latvia, Belgium, and Sweden delivered engaging presentation sessions including guest speakers from the ISO Technical committee, Qatar Biobank, IARC and Swiss Accreditation body (SAS).

- **The QM Academy** hosted a webinar with the topic "Frozen tissue collection and biobanking - Pre-analytics, frozen tissue processing, standardisation to increase quality and reproducibility". It was attended by 113 participants representing 28 different countries. QM continued to support participants' ongoing professional development and medical education through the provision of Continuing Medical Education (CME) credits for their active participation in our accredited live educational webinar. In total, 46 European CME certificates were issued on behalf of the European Accreditation Council for Continuing Medical Education (EACCME®). A further 53 people accessed online learning content during 2022.

- **The BBMRI/ESBB "Europe Biobank Week Roadshow**: "On the Road to High Quality – With Biobanks in the Fast Lane" was held in Regensburg, Germany during September 2022. 165 attendees from 21 different countries came for the first face-to-face meeting after two years of COVID-19 travel restrictions. It was a great success and featured keynote speaker Carolyn Compton, a highly regarded professor of life sciences at Arizona State University and professor of laboratory medicine and pathology at the Mayo Clinic.

Biobanking Development

The Biobanking Development (BBD) department is new for 2022 and was involved in the following tasks that cover its main functions and services to the BBMRI-ERIC community:

Supporting new members and observers

In close collaboration with Public Affairs (PA), BBD was involved in the process of welcoming new EU members into BBMRI-ERIC. BBD provided support to Slovenia, Cyprus and Qatar in this respect. We reshaped on-boarding workshops and organised one for Spain in November 2022 that was very well attended by the Spanish biobanking community.

EU projects that benefited from BBD expertise

Since its inauguration in 2022, the Biobanking Development Department has already contributed expertise on the following projects:

- **CY-Biobank** support through collaboration on developing a state-of-the-art biobanking facility. BBD participated in the preparation of a manuscript entitled: 'Implementation of a biobanking cost recovery model, at biobank.cy Centre of Excellence', which summarises all activities related to estimating the costs of running a biobank and preparing biological samples.

- **ISIDORe** benefited from successful provision of sample & data entailing active engagement of 40 biobanks from our community. BBMRI-ERIC was able to prepare and publish an online catalogue of all services provided for the ISIDORe project partners (mainly access to samples and data). This included access to COVID-19 cohorts, control/healthy cohorts and other viral samples that could act as controls for COVID-19 study (available on the ISIDORe project webpage). BBD has also prepared Deliverable 8.4 Guidelines for the calculation of fee-for-sample model. ISIDORe has reviewed 7 applications for access to samples and data via WP8 TNA in 2022.

- **canSERV**: The Biobanking Development Department is strongly contributing to WP10 – Access to human samples and data and WP6 - Accelerated Translation into Personalised Oncology Clinical Practice.

BBD involvement in BBMRI-ERIC Task Forces

The BBD department supported the task force on "Quality Assurance Markers development" (TF1) jointly with the Quality Management department. The aim of this task force 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 prepared in 2022.

BBD involvement in BBMRI-ERIC Tools

The BBD department strongly supported the BBMRI-ERIC Common Service IT department in monitoring the requests submitted by users on the BBMRI-ERIC Negotiator platform.

Additionally, users from the biobanking, scientific, and industry communities were assisted in identifying the samples/data needed for their projects in the BBMRI-ERIC Directory and submitting requests to the BBMRI-ERIC Negotiator on their behalf.

Developing industry links

BBD is leading the Industry Pillar and, in 2022, continued to strengthen collaboration with industry, through BBMRI events and by exploring new collaboration with biotech and IT companies within the BioTechX event in Basel, Switzerland.

These interactions generated bilateral discussion with industry to jointly explore current and future possibilities of tackling the on-going energy crisis by co-developing new solutions to help biobanks reduce their environmental impact, which is in-line with our 2022-2024 Work Programme. Feedback from these events will shape improvements for 2023 activities and events.

At BioTechX, the BBD team strengthened, and built new relationships, with more than 16 biotech companies on potential future collaborations. BBD also aligned with other European Initiatives such as EIT Health Europe that links biobanks with industry to deliver industry-focused biobanking-specific educational workshops. On this front, BBD represented BBMRI-ERIC in the EIT Health matchmaking event in Estonia in December 2022.

BBD, jointly with PA, led the Scientific Societies Pillar to strengthen cooperation with several scientific societies. Close collaboration with ESBB (European, Middle Eastern & African Society for Biopreservation & Biobanking) continued in 2022 and two events were co-organised, the EBW Roadshows on “On the Road to High Quality – With Biobanks in the Fast Lane!” in Regensburg, Germany, September 2022 and on “Paediatric Biobanking and Minor Engagement” in Rome, Italy, October 2022.

Furthermore, a Memorandum of Understanding was signed with ESBB during the first EBW Roadshow in Regensburg.

BBMRI-ERIC continued to be an active member of the European Health Coalition.

Public Affairs

BBMRI-ERIC's membership grows and member interests are supported thanks to Public Affairs.

In 2022, BBMRI-ERIC continued to grow its membership with Slovenia joining as full member. At 24 Members and Observers in 2022, BBMRI-ERIC is one of the largest European Infrastructures in terms of membership. BBMRI-ERIC drove forward discussions with other countries in Europe and there has been a continued and expanding interest towards memberships also from non-EU countries. To meet this demand, BBMRI-ERIC developed a policy for onboarding third countries to the infrastructure. This policy was approved by the BBMRI-ERIC Assembly of Members and applied to the application process of Qatar who joined as of January 2023.

Close contact has been maintained with countries that are interested in joining and those interested in moving from Observer status to full membership, e.g., Cyprus who stepped up to full membership as of January 2023. We have continued our official onboarding process for new members/observers of BBMRI-ERIC by further analysing the needs of each newly admitted country and organised a special workshop for the biobanking community to ensure that new members and observers start developing their national infrastructure and competences based on the targets for the entire research infrastructure. Such workshops are co-organised with the Biobanking Development team.

Relations with existing Member States and observers

The Director General and BBMRI-ERIC senior staff, on invitation, took part in several national meetings of the biobanking communities. In addition, the Director General and Head of Public Affairs and/or Head of Biobanking Development had face-to-face meetings together with the National Node directors and delegates at the ministries of Austria, Belgium, Czech Republic, Estonia, Germany, Italy, the Netherlands, Slovenia and Sweden to align on current and prospect developments nationally and internationally.

Stakeholder Forum

During 2022, BBMRI-ERIC doubled the number of patient advocate representatives in its Stakeholder Forum Patient Pillar. Three meetings of the Patient and Citizens Pillar took place, and the participation of patient organisations was key in organising October's workshop on "Paediatric Biobanking and Minor Engagement" in Rome, Italy. Another important priority for the group was developing closer alignment and engagement in the EU funded project canSERV, which BBMRI-ERIC coordinates. This project focuses on providing cutting-edge research services including socio-economic dimensions and public health measures.

ERIC Forum

As the coordinator of the ERIC-Forum project, BBMRI-ERIC continued to ensure timely and qualitative implementation of project activities. We organised the annual meeting of the ERIC Forum community and key external stakeholders, such as ESFRI, EC and EOSC, and brought together 60 participants from 35 different organisations in a face-to-face meeting in Brussels. Moreover, BBMRI-ERIC was fully engaged in working on the long-term sustainability of the ERIC Forum and was supporting the ERIC Forum and its Chair as the secretariat. BBMRI was nominated by the ERIC Forum to also coordinate the new ERIC Forum

grant application which was successfully submitted in January 2023 and is currently in Grant Agreement stage with an envisioned launch of September 2023. BBMRI-ERIC has become the Vice-Chair of the Life Science Research Infrastructure cluster. These activities not only raised the profile of BBMRI-ERIC within the community, but also with the external stakeholders listed above, which are key also for BBMRI-ERIC's bilateral relations within the European arena.

Key partnerships

BBMRI-ERIC continued its membership in the EOSC Association in 2022 and fostered community engagement in the various EOSC Association task forces. This membership facilitates BBMRI-ERIC's participation and co-building of this key European partnership that will set the ecosystem for hosting and exchange of research data. BBMRI-ERIC continued to build a close partnership with other life-science RIs, successfully conducted its coordinating role of the ERIC Forum project, and maintained its fundamental role in the EOSC-Life project; thereby overall significantly contributing to and sharing its expertise with the rest of the community.

BBMRI-ERIC also increased its engagement with the EU AMRI partners via a high-level Stakeholder Brussels launch event of EU-AMRI in Spring 2022. New venues for partnerships were explored with ESBB (European, Middle Eastern & African Society for Biopreservation & Biobanking), EVAg (European Virus Archive), ECRAID (European Clinical Research Alliance on Infectious Diseases), and ELIXIR. Close relationships with these will continue to be further defined in 2023 while an extended Memorandum of Understanding has been signed with ESBB (European, Middle Eastern & African Society for Biopreservation and Biobanking) during the EBW Roadshow "On the Road to High Quality – With Biobanks in the Fast Lane!" in Regensburg, Germany, September 2022.

Finally, BBMRI-ERIC continued to be an active member of the European Health Coalition.

Outreach, Education and Communications

The Work Programme 2022-2024, with its emphasis on community outreach and engagement, formed the backbone of reshaping Outreach, Education and Communications (OEC) activities this year.

Developing outreach

We refined in-house processes to better serve and amplify National Nodes, biobanks and our wider community. Improvements resulted in higher newsletter engagement, updated web content, precise social media posts published to a regular pattern and updated corporate identity guidelines. A refreshed identity included tweaks to the BBMRI-ERIC logo that now uses an updated and explanatory strapline. This fed into redesigning print and digital communications tools. Finally, OEC expanded content production through shareable audio, video and launched the BBMRI-ERIC Podcast. The podcast showcases success stories from HQ and the biobanking community (episodes on QM, IT and ELSI training) and constitutes a valuable engagement tool for stronger impact storytelling. Combined, this enhances visibility and recognisability - areas that all research infrastructures find a communications challenge.

Supporting projects

Throughout 2022, OEC continued to provide support to 15 EU funded projects where the key role is dissemination and outreach with and beyond each project's target stakeholders. The team continued to play a key role in outreach for the EOSC-LIFE project including management of social media, multiple newsletters and the website. canSERV, a 19-partner consortium project focusing on TNA provision of cutting-edge oncology services, launched in September.

OEC co-leads the Training, Outreach and Stakeholder Engagement work package; the social media channels, website and key communications were active by the end of the year.

Strengthening community

A key milestone was reached on strengthening the community through the launch of the Task Force Nine – Communications and Outreach. This task force brings together National Node communications leads to share good practice, create and pool engagement resources, develop outreach digital skills and shape strategy on better connecting with key stakeholders. Engaging with stakeholders such as patient advocates, scientists, clinicians, and institutions (universities, university hospitals, scientific societies) increases the perceived value of biobanking and therefore, the sustainability of the community.

After two years of online events due to the COVID-19 pandemic, it was pleasing to strengthen the relationship with ESBB through supporting the organisation and communications of two successful, community driven Europe Biobank Week Roadshow education events. "On the Road to High Quality – With Biobanks in the Fast Lane" was held in Regensburg, Germany during September 2022. "Paediatric Biobanking and Minor Engagement", in partnership with the BBMRI-ERIC Stakeholder Forum Patient Pillar, BBMRI.it, the Research Translational (IRCCS) Paediatric Bambino Gesù Hospital, and the paediatric network IDEA, was held in Rome, Italy during October 2022.

SERVICES KPIS SUMMARY

Common Service IT

Directory

642 biobanks connected
3453 collections
32 Countries contributing collections
532 average users per month

Negotiator

2251 collections represented
1178 total users

Locator

13 collections represented
94 unique users

Federated Platform

13 collections represented in Locator
8 collections represented in Finder
422,576 donors in Federated Platform with 200,700 genomes

Quality Management

1 self-assessment survey completion in 2022
11 additional collections with Q-Label
1 additional biobank with a Q-Label

ELSI

Milestone Q1/2022: Code of Conduct Consultation among experts continued.

243 Ethics Checks, ELSI Helpdesk requests and consultations (2017 – 2022)

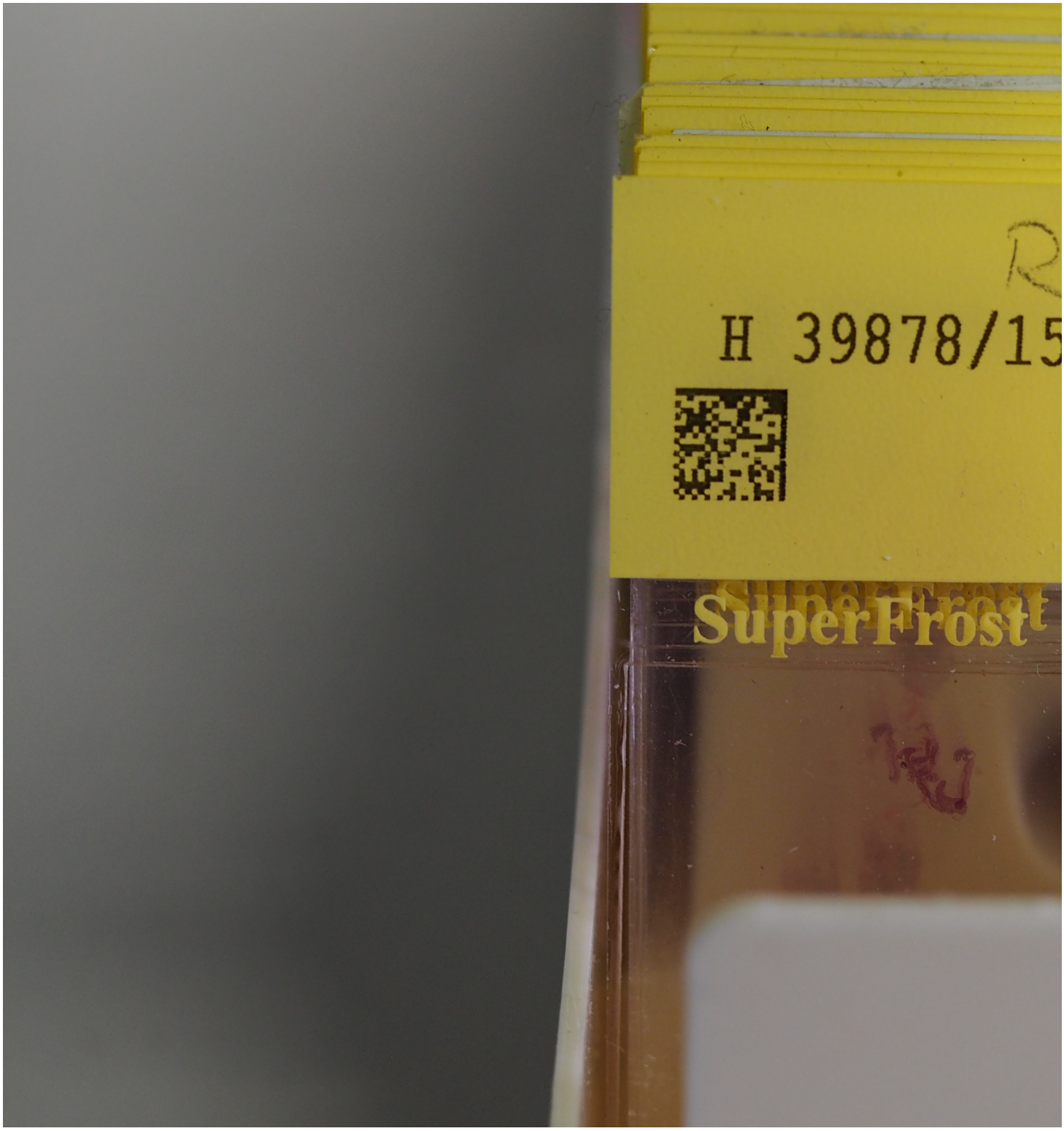
134 requests in 2022 equating to 286 person hours

Donors in the Federated Platform

422,576

PART THREE

FINANCIAL INFORMATION AND PROJECTS



FINANCIAL INFORMATION

Core budget expenditures and allocated competitive research grants.

Throughout 2022, COVID-19 restrictions still impacted the implementation of 25 ongoing research projects, leading to more online communication than face-to-face meetings with the European research community. The impact was a general underspending of travel budgets within the projects.

One of the founding members, the United Kingdom, left the consortium by end of 2022, creating a significant gap in BBMRI-ERIC's core budget for 2023 onwards. This negative impact on the budget was partially compensated by members agreeing to increase the membership fee by 10%. BBMRI also cut out-of-pocket expenses and allocated more resources to project activities. The financial impact was also mitigated by Cyprus becoming a full member and Qatar an observer as of January 2023. These measures meant that the financial stability of the research infrastructure could be secured.

In addition, six new proposals received funding and officially started in 2022 (ISIDORe, canSERV, EOSC4CANCER, PROPHET, GDI, EHDS2 Pilot), securing roughly 5,4 mio € in competitive research grant funding for BBMRI-ERIC and related research infrastructures and service providers with project durations between two and four years.

Profit and loss statement

In EUR	2018	2019	2020	2021	2022
Turnover	3.050.231	4.091.202	3.305.108	3.292.908	3.920.923
Other operating income	1.068	10.882	8.907	7.441	7.537
Material Expenses	-	-	-	-	-
Staff expenses	(1.647.023)	(1.840.023)	(2.143.081)	(2.477.511)	(2.997.450)
Amortization	(35.896)	(31.683)	(30.000)	(54.819)	(52.595)
Other operating expenses	(1.464.964)	(1.676.029)	(847.735)	(758.648)	(849.274)
Operating result	**(96.584)**	**554.348**	**293.198**	**9.371**	**29.142**
Other interest and similar income	-	-	-	-	1.355
Interest and similar expenses	(41)	-	(54)	(204)	(21)
Financial result	(41)	-	(54)	(204)	1.333
Loss from operating activities, Earnings before taxes	**(96.626)**	**554.348**	**293.144**	**9.167**	**30.475**
Taxes on income and revenue	-	-			(339)
Profit of the year	**(96.626)**	**554.348**	**293.144**	**9.167**	**30.136**
Reversal of profit reserves	96.626	-	-	-	-
Allocation to profit reserves	-	(554.348)	(293.144)	(9.167)	(30.136)
Profit carried forward from the previous years	367.775	367.775	367.775	367.775	367.775
Balance sheet profit	**367.775**	**367.775**	**367.775**	**367.775**	**367.775**

Balance sheet

In EUR	2018	2019	2020	2021	2022
Intangible Assets	8.459	5.639	2.820	91.920	68.940
Tangible Assets	55.924	66.339	54.414	41.891	37.777
Fixed Assets	**64.382**	**71.978**	**57.233**	**133.811**	**106.717**
Receivables and other Assets	1.164.191	343.225	299.341	439.425	409.394
Receivables arising from deliveries services	134.301	86.743	93.001	254.117	51.397
Other receivables and assets	1.029.890	256.482	206.340	185.308	357.997
Cash on hand and Bank deposits	1.645.101	2.916.641	2.491.713	2.667.526	9.633.534
Current Assets	2.809.292	3.259.867	2.791.055	3.106.951	10.042.927
Prepaid expenses, deferred charges	13.332	5.031	2.811	3.923	1.453
Assets	**2.887.006**	**3.336.876**	**2.851.099**	**3.244.685**	**10.151.097**
Reserves pursuant to the articles of association	36.674	591.022	884.166	893.333	923.470
Balance sheet profit	367.775	367.775	367.775	367.775	367.775
Investment grants	-	-	-	13.189	9.791
Capital and Reserves	**404.449**	**958.797**	**1.251.941**	**1.274.297**	**1.301.036**
Other accruals	832.308	157.473	68.792	127.273	119.580
Accruals	**832.308**	**157.473**	**68.792**	**127.273**	**119.580**
Liabilities arising from deliveries and services	164.723	226.636	30.026	246.162	220.003
Other liabilities	131.022	385.357	396.798	221.866	312.529
Liabilities	**295.745**	**611.993**	**426.824**	**468.027**	**532.532**
Deferred income	1.354.505	1.608.612	1.103.541	1.375.087	8.197.949
Liabilities and Owner´s Equity	**2.887.006**	**3.336.876**	**2.851.099**	**3.244.685**	**10.151.097**

Cash flow

In EUR	2018	2019	2020	2021	2022
Intangible Assets	8.459	5.639	2.820	91.920	68.940
Tangible Assets	55.924	66.339	54.414	41.891	37.777
Fixed Assets	**64.382**	**71.978**	**57.233**	**133.811**	**106.717**
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The extraordinary cash flow in 2022 of almost 7 mio EUR is mainly due to the prefinancing received for EU projects including canSERV in which BBMRI-ERIC takes the role as coordinator. Over the next two years these funds will be used e.g., 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.

PROJECTS

Projects launched in 2022

PROJECT	BBMRI BUDGET	START	DETAIL
ISIDORe	523,457 EUR (+78 kEUR for AE's)	01.02.2022	The ISIDORe consortium, made of the capacities of European ESFRI infrastructures and coordinated networks, will assemble the largest and most diverse research and service providing instrument to study infectious diseases in Europe, from structural biology to clinical trials.
canSERV	1,652,424 EUR (+1,855 kEUR for TNA services)	01.09.2022	canSERV's mission is to make cutting-edge and customised research services available to the cancer research community EU wide, enable innovative R&D projects and foster precision medicine for patients' benefit across Europe.
EOSC4Cancer	580,500 EUR	01.09.2022	EOSC4Cancer will make cancer genomics, imaging, medical, clinical, environmental and socio-economics data accessible, using and enhancing existing federated and interoperable systems for securely identifying, sharing, processing and reusing FAIR cancer data across borders, and it will offer them via community-driven analysis environments.

Projects launched in 2022

PROJECT	BBMRI BUDGET	START	DETAIL
PROPHET	84,812 EUR	01.02.2022	"PROPHET - a PeRsOnalized Prevention roadmap for the future HEalThcare" will develop a Strategic Research and Innovation Agenda (SRIA) for Personalized Prevention, in order to support the implementation of innovative, sustainable and effective personalized programmes to prevent common chronic diseases.
EHDS2-PILOT	1,010,203 EUR (+68 kEUR for AE's)	01.10.2022	The EHDS2 Pilot project will build and test a first version of European Health Data Space (EHDS) by interconnecting data provider platforms, either national platforms, EU agencies or research infrastructures, in a network of nodes.
GDI	205,440 EUR	01.11.2022	The Genomic Data Infrastructure (GDI) project brings together national agencies, research organisations, and technology providers in 22 countries to provide a cross-border federated network of national genome collections, associated with other relevant data, for advancing data-driven biomedical research and personalised medicine solutions to benefit citizens of Europe.

PART FOUR

NATIONAL NODES

AUSTRIA

Introduction

BBMRI.at comprises public partners, the private Austrian Medical University, the University of Veterinary Medicine with their biobanks, and two other universities (bringing in IT and ELSI expertise). BBMRI.at was established in 2013 and is funded by the Federal Ministry of Education, Economy and Research. More at www.bbmri.at.

2022 KPIs:

Number of biobanks and standalone collections: 4 biobanks (2 additional biobanks under construction)

Number of samples / size of collections: 16,000,000+ (listed in BBMRI-ERIC Directory by Dec 2022)

Number of samples/data used for research: 70,000+

Top 3 areas of expertise

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

2. ***Data management: Data quality; high-capacity digitalisation process & facility for tissue slides***; innovative privacy preserving technologies; digitalisation/whole side imaging & AI; trusted data environment for biobanks and new data access model; BBMRI.at Catalogue/Biobank Editor development; input to BBMRI-ERIC Directory/Negotiator development; BiBBoX.

3. Stakeholder & user engagement: Interviews/discussion groups with different stakeholders (on value of biobanking, data-citizenship); education/training (e.g. on standards & IVDR; Biobanking MSc, and courses); public engagement (e.g. biobank tours, children's courses); Translational Science Forum with industry; conference organisation; online portal for donors.

2022 successes

Harmonisation & standardisation: Contribution to ISO & CEN standards & publication of ISO and development lead of ISO 18701 human specimens for microbiome DNA; events on IVD with Austrian Life Science Clusters, Notified Bodies & Austrian Standards Institute; Implementation of remote cross-audits; concept for sample/data/biobank traceability.

Data management: Establishing concepts for new data access models and "trusted environment for patient data" & discussion at United Nations level; development of pilot projects for Animal Model Biobank; complementing Biobank samples with digital whole slide images.

Stakeholder and user information and engagement: Multiple grants with BBMRI.at partner contribution accepted; several collaborations with industry and biobank contribution to COVID-19 studies incl. numerous publications; biobanking and research technologies around high-risk pathogens; biobanking education (e.g. Biobanking courses and an MSc programme (Med Uni Graz)); strong presence in public media; awareness raised on need for high-quality samples and biobanks at Austrian funding bodies/networks.

Additional comments

Specific strengths of BBMRI.at include:

- Solid community of BBMRI.at partners
- Project leader of and expert contributions to the development of CEN/TS and ISO standards (in CEN/TC 140, ISO/TC 212, ISO/TC 276)
- Pioneering role for QM activities of BBMRI-ERIC (cross-audits, Self-Assessment Surveys, pre-analytic quality standards and courses)

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Specific strengths continued...·

- High-throughput tissue slide digitalisation facility (Med Uni Graz: up to 3,800 slides/day in 6 slide cleaning stations, 9 slide scanners, 2 PB storage)
- Central contact point for sample/data/collaboration requests
- ·SARS-CoV-2: i) Contribution to development and validation of diagnostic SARS-CoV-2 tests (MedUni Wien Biobank); ii) Virus cultures from patient samples established, iii) 25 projects related to new antiviral drugs, diagnostics and decontamination procedures performed in BSL-3 facility (Med Uni Graz); iii) Research using SARS-CoV-2 cohorts (Med Uni Graz)
- Biobank Graz – one of the largest biobanks in Europe awarded with several prizes
- VetBioBank – one of few BBMRI animal biobanks – with quality-marked samples and profound expertise in animal (model) biobanking
- Professional strategy development process at certain biobank partners
- Developing the role of biobanks as key resource provider for developing AI algorithms
- Biobanking university workshops for children and other public engagement activities
- Engagement in context of UN Sustainable Development Goals
- Biobank tours

BELGIUM

Introduction

The scientific participation of Belgium in BBMRI-ERIC was initiated in 2013 by uniting the three existing Belgian network biobank initiatives i.e., Belgian Virtual Tumourbank project assigned to the Belgian Cancer Registry (BVT-BCR), Biothèque de la Fédération Wallonie-Bruxelles (BWB) and the Flemish Biobank Network (CMI).

The activities of BBMRI.be are organised from the coordination office located at the Belgian Cancer Registry. All relevant biobank topics are tackled by more than 60 biobank experts in the six Working Groups of BBMRI.be (IT, ELSI, Quality, Sustainability, Stakeholder Involvement, Networking & Valorisation). Since 2019, BBMRI.be invites all officially recognised Belgian biobanks with translational research potential to join the BBMRI.be network. Currently, our network connects 20 biobanks that are linked to public institutions such as hospitals, universities and research centres and three biobank user partners.

2022 KPIs:

Number of biobanks and standalone collections: 20

Number of samples / size of collections: 3 collections with 1000 samples+; 11 collections with 1,000-10,000 samples; 10 collections with 10,000-100,000 samples; 6 collections with 100,000-1,000,000 samples

Number of samples/data used for research: 195,000

Top 3 areas of expertise

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

2022 successes

Kick off B3-ISO project: In June 2022, BBMRI.be kicked of the B3-ISO project, that was funded within the ESFRI-FED call of BELSPO. This quality improvement program, in which 14 BBMRI.be biobanks will participate, will facilitate the road towards ISO 20387 for the BBMRI.be biobanks. At the same time, an accreditation program will be established together with BELAC (Belgian Accreditation Organisation), ultimately leading to ISO accreditation for our biobanks. In these first months, we have set up the governance structure and performed an online survey to do a first gap analysis and collect expectations/priorities/concerns from the BBMRI.be biobanks as a starting point for the project. Our main goal for the coming year is to develop guidelines, templates and policies and organise webinars to support the biobanks in this process.

New biobank (user) partners: In 2021, two new biobanks (Imec Biobank and Biobank AZ Delta) and one new biobanks user (TEARDRoP) have joined the BBMRI.be network. The biobanks of Imec and AZ Delta have recently been set up in accordance with the Belgian Biobank Law and will benefit from the broad support and exchange of experience in the network. The TEARDRoP consortium was founded to support the translation of new research findings in the field of paediatric oncology to new therapeutic options and aims to support biobanking efforts by setting up practical biobank flows for samples of paediatric oncology.

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Biobank Info Day: On December 1st, BBMRI.be organised, in collaboration with the Jules Bordet Institute and the LUSS (League of health users), a biobank info day to discuss the way biobanks are perceived by patients and citizens. The day was initiated with an introduction to the biobank world, followed by a visit to the biobank of the Jules Bordet Institute. In the afternoon, a focus group was organised to dive in deeper into the essential role of biobanks in research and the importance of cooperation between care institutions, biobank networks and patient's associations.

Additional comments

Press release biobank info day: The Bordet Institute's tumour bank opens its doors to patient's associations. Press release. Dec 1 2022 – link.

BULGARIA

Introduction

The BBMRI Bulgarian National Node is based at Molecular Medicine Center, Medical University of Sofia where it hosts the biggest national biobank with various clinical research collections. The aim of the NN is to establish a national biobanking network that is integrated within BBMRI-ERIC, increase international visibility and further use of the available collections, support high quality technical and ethical standards, and contribute to health research and precision medicine.

At present the biobanking network involves biobank and collections in two of the biggest Medical Universities in Sofia and Plovdiv. Since 2019 the Ministry of Education and Science has supported the establishment of the National Node and biobanking network in Bulgaria in the frame of the National Roadmap of Research Infrastructures. Currently, biobanking is done in research and diagnostic settings and various types of samples are collected, processed, and stored such as tissue, serum, plasma, DNA and RNA, cell lines and associated clinical, and demographical data.

2022 KPIs:

Number of biobanks and standalone collections: 1 biobank, 3 stand-alone collections

Number of samples / size of collections: 25,000+ patients in the biobank

Number of samples/data used for research: 2,500+ *

**The numbers refer to patients whose samples were included in projects active in 2022 at Medical University of Sofia and Medical University of Plovdiv, funded by institutional, national and international projects. More than 50 papers were published in 2022 using data and human samples stored in the biobank as well as the collections of cell cultures and microorganisms.*

Top 3 areas of expertise

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

2022 successes

22 disease collections of samples and data, including rare diseases, cancer, common complex diseases, and COVID-19 from the biobank at Molecular Medicine Center, Medical University of Sofia were added to the Directory of BBMRI-ERIC in 2022.

BBMRI.bg initiated the collection of national reference control samples for the pilot 1,000 Bulgarian Genomes project to contribute to the Genome of Europe (1+MG) project. Support for the development of the BBMRI.bg National Node and capacity building at Medical University of Sofia and Medical University of Plovdiv was received in 2022. Funding of 1.27 mio € was provided by the Ministry of Education and Science to the National University Complex for Biomedical and Translational Research (NUCBTR) and BBMRI.bg as leading national infrastructure on the National Roadmap of Research Infrastructures.

MUTOGRAPHS project: A team from the national node BBMRI.bg, in collaboration with leading clinical specialists from the University Hospital "Tsaritsa Joanna – ISUL", will contribute to the project MUTOGRAPHS by collection and biobanking of tumour tissue samples of kidney and urothelial tract cancers. A Collaborative Research Agreement was signed between Medical University of Sofia and the International Agency for Research on Cancer (IARC) for the purpose of collection of tissue samples for the international project MUTOGRAPHS. The CRUK Grand Challenge large-scale international research project aims to collect mutational signatures of 5,000 cancer samples across the world to advance the understanding of the causes of cancer.

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Additional comments

- BBMRI.bg actively participates in important European initiatives and projects, related to sample and data generation, analysis and storage such as the 1+MG initiative. Medical University of Sofia together with the Ministry of Education and Science are the Bulgarian partners in the European Project "Genomic Data Infrastructure (GDI), funded by DIGITAL EUROPE programme. The project will facilitate the deployment of the national data infrastructure and enable access to genomic, and related, clinical data across Europe.

- BBMRI and the available resources for biobanking were presented at the national forum "Biomedical research infrastructures – drivers of the genomic and personalised medicine in Bulgaria" held on 9-10.12.2022 in Sofia with the participation of more than 100 representatives of all medical universities and faculties in Bulgaria, other research infrastructures in the biomedical field and the Ministry of Education and Science.

- BBMRI.bg and the NN were presented to the public during the European Researchers Night 2022, funded by project SEARCH of Horizon 2022 program.

CYPRUS

Introduction

Cyprus Biobank Node (BBMRI.cy) is overseeing and coordinating biobanking activities in Cyprus under the umbrella of the Ministry of Health and the Deputy Ministry of Research, Innovation and Digital Policy. Cyprus has been an observer to BBMRI-ERIC since 2016 and becomes a full member in 2023 with two biobanks as active members of the node:

biobank.cy: The first biobank of Cyprus was founded in 2011 together with the Molecular Medicine Research Center (MMRC) as an independent research unit, at the School of Pure and Applied Sciences of the University of Cyprus (UCY), a public research and education organisation. It was the result of a successful Strategic Infrastructure proposal, funded by the European Regional Development Fund and the Republic of Cyprus, through the Cyprus Research Promotion Foundation. In 2019, the MMRC team was successful in securing further funding for upgrading to a Centre of Excellence (CoE) in Biobanking and Biomedical Research, biobank.cy (www.biobank.cy), through a Horizon 2020 Teaming program: the CY-Biobank project. The now established CoE funded by the EU, the Government of Cyprus and the University of Cyprus, consists of 5 pillars: the Biobank, the Molecular Medicine Research Center, the Diagnostic Lab, the Education Hub, and the Innovation Hub. All activities aim to collect, analyse, and preserve biological samples and health data in a state-of-the-art biobank and utilise them for scientific, diagnostic, and educational innovation.

2022 KPIs:

Number of biobanks and standalone collections: 1 biobank/ 10 collections

Number of samples / size of collections: 92,000 / Size of collections: from 60 to 3,600 participants

Number of samples/data used for research: 6,564 samples/data sets used for research. 360 Whole Exomes of the general population (preparing to complete 1,000-the CYPROME)

The team aspires to create new knowledge for improving human health and contribute to the prevention, diagnosis, prognosis, and therapy of diseases. Amongst others, the scientific and managerial personnel of the biobank.cy CoE is engaged in constant education and communications activities to the medical community and the public, whilst also developing collaborations in the various biomedical fields. In the meantime, the diagnostics lab has developed, and offers, additional molecular medicine services to serve the medical community and their patients. The Biobank, as a medical research infrastructure, is of horizontal utility, supporting diverse research projects and promoting the discovery of new knowledge to the benefit of patients.

Cyprus Institute of Neurology and Genetics (CING): CING established its own Biobank in 2012 both to support its research/academic activities and to maintain the delivery of high standard specialised services to patients. As a next step, CING would like to develop, streamline, and harmonise its biobanking activities with BBMRI-ERIC, and facilitate the execution of population programmes to achieve optimal clinical biobanking activities. It also aims to promote public awareness of the importance of biobanking in biomedical research whilst working towards personalised medicine and better understanding of aetiology.

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Top 3 areas of expertise

1. Biobanking
2. Genetics-Genomics & Molecular Diagnostics
3. Bioinformatics

2022 successes

Country status application made to change from BBMRI-ERIC Observer to Member.

ISO 9001:2015 certification of the biobank.cy administration.

Completed the first 368 whole exomes of the Cypriot general population (preparing to complete 1,000, the CYPROME).

Additional comments

The biobank.cy Biobank has established biobanking collaborations with various partners, aimed to empower the participation of volunteers and archive data and biospecimens that represent the entire geographic territory of Cyprus. Specific campaigns focus on people with selected inherited diseases.

CZECH REPUBLIC

Introduction

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

2022 KPIs:

Number of biobanks and standalone collections: 6 biobanks

Number of samples / size of collections: approx. 560,000 samples, 60,125 in 2022

Number of samples/data used for research: 8,699 samples and approx. 60,000 related data

Top 3 areas of expertise

1. Offering high-quality human-derived clinical material within the currently applicable European legal landscape for an eligible researcher and eligible industrial collaborator

2. ***Expert knowledge on preparation, cryostorage, and handling of human-derived biospecimens***, derivation of biobanking specimens from diagnostic pathways and modelling specimen and data workflows for new users/participants

3. ***Expert knowledge on the usability of material*** stored in biorepositories to make the best use of precious biological specimen collections, thus preventing irreproducible or meaningless research

2022 successes

Two robotic systems for cryopreservation at Bank of Biological Material (BBM) MMCI were installed and personnel training was completed.

BBM MMCI successfully participated in the CAI pilot project to assess the implementation of the quality management system (QMS) according to the ČSN ISO 20387:2021 Biotechnology-Biobank standard. This resulted in a positive assessment of the established QMS, and the activities carried out in BBM MMCI compliance with the requirements of this standard.

The BBMRI-CZ REVMA collection of 7,500 samples of genomic DNA was awarded the BBMRI-ERIC Q-Label (the requirements of ISO 20186-2:2019). The BBM 1FM CUNI successfully passed re-certification audit of the quality system according to ISO 9001:2015.

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Additional comments

Together with the other LRIs CZECRIN and EATRIS-CZ, we form the backbone of biomedical research in the Czech Republic focused on personalised medicine representing one of the most innovative new concepts in healthcare.

Our activities reflect EU-AMRI - the European Alliance of Medical Research Infrastructures - launched by BBMRI-ERIC, EATRIS-ERIC and ECRIN-ERIC in April 2022 in order to accelerate patient-centric biomedical research. The EU-AMRI Side Event, as a part of the International Conference of Research Infrastructures (ICRI 2022), called “Finding Opportunity Among Health Challenges: Allowing the Space for Research Infrastructures Synergies” was organised. Directors of all three Czech LRIs EATRIS-CZ, CZECRIN and BBMRI.cz gave a lecture. It is also important to note, that we also closely cooperate with other national infrastructures such as the Czech Centre for Phenogenomics with a focus on the development of patient derived tumour xenografts.

GERMANY

Introduction

The German Biobank Node (GBN) is the umbrella organisation of academic biobanks handling human biospecimens and associated data in Germany. Coordinated by the GBN, 37 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). Find out more at bbmri.de.

2022 KPIs:

Number of biobanks and standalone collections: 39 biobanks (22 partners, 17 observers)

Number of samples / size of collections: 13.6 million tissue samples, 20.7 million liquid, 2 million derivates (partner biobanks) *

Number of samples/data used for research: 444,278 *

** Data collected from 21 biobank sites in 2022 for 2021*

Top 3 areas of expertise

1. IT: The GBA IT network facilitates the search for biosamples and associated data across locations in real time (Sample Locator). In 2022, the tools and infrastructure were continuously improved, and expertise contributed to the development of a federated search platform for BBMRI-ERIC. Furthermore, a Germany-wide project was initiated to align biosamples with rich data from patient care collected in data integration centres in all German university hospitals. At the same Time, Sample Locator-associated instances for single biobanks and dashboards for study collections have been made available to the GBA. Moreover, biobank entries in the German Biobank Directory have been thoroughly updated.

2. Quality management: GBN offers a comprehensive quality programme including proficiency tests, internal audits, training courses and services such as a QM manual. In 2022, the fourth proficiency test for tissue biobanking has been conducted. Since implementation of the audit programme to prepare GBA biobanks for accreditation according to ISO 20387, the number of internal audits carried out has risen to 42. A webinar on regulations and best practices for packaging and shipping of biosamples led by community experts, was attended by more than 80 participants.

3. Outreach and communications: GBN has focused its communication activities in 2022 on targeting researchers to increase the use of biobanks. In addition to publishing success stories of research projects working with biobanks, a testimonial campaign has been launched where

renowned researchers promote individual biobanks. In addition, a GBN workshop on "Biobanking in Microbiome Research" brought biobankers and researchers from the field close together.

2022 successes

GBA growth and anniversary: The GBA has again grown in its anniversary year, 2022, with six new observer biobanks joining. This means that the Alliance has more than tripled in size since its inception five years earlier and now comprises around 95% of the German medical faculties. 2022 also saw the first "upgrade": The Central Biobank Erlangen (CeBE) was promoted from observer to partner status.

Community-driven working groups: The successful activities of GBA working groups were significantly intensified in 2022. For example, a model cost catalogue was presented by the WG “Financing”. The "Starter Kit" for biobanks in the establishment phase is about to be published. In addition, new groups have been established, such as the WG “Control Cohorts”. These structures have further accelerated the dynamics in the GBA and promoted cohesion.

Expanding learning opportunities: Further training for GBA employees has been a strong focus of the GBN since its start. In 2022, GBN relaunched its offers on the OpenILIAS learning platform, which now includes a comprehensive online course on DNA isolation, webinar recordings, information about on-site training, and a forum. GBN's online course "Biobanking - Basics for Theory and Practice", available on the edX platform, is now part of the Master's programme "Biomedical Data Science" at the Hannover Medical School (MHH).

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Additional comments

Saving energy was a hot topic in 2022. Therefore, a GBN/GBA team of authors published recommendations on the economical use of -80°C ultra-low temperature freezers, which are typically more energy-intensive. The recommendations were published in German in the Laborjournal and in English on the GBN website.

One of the 28 testimonial banners created for the GBA campaign.

ESTONIA

Introduction

The Government of the Republic of Estonia has prioritised the development of personalised medicine in Estonia. Amendments to the Human Genes Research Act (HGRA) have been undertaken to align the regulation of EBB processing with the needs of personalised medicine. The draft of the HGRA is being prepared by the Ministry of Social Affairs and is waiting for the opportunity to be presented to the Data Protection Inspectorate and the new minister. After institutions coordinate, it goes to the electorate and the National Assembly. The use of our data in personal medicine is regulated there.

The registration of the EBB database in the Administration System for the State Information System (RIHA) environment is underway. The dataset is now officially available, and we are specifying the detailed list of data to be uploaded to RIHA.

The Estonian Biobank Lab in cooperation with the Core Facility of Genomics is accredited according to ISO/IEC 17025:2017 for whole genome genotyping on Illumina genotyping arrays (including DNA extraction) and bioinformatic data analysis (including quality control, phasing and imputing).

2022 KPIs:

Number of biobanks and standalone collections: Estonian Biobank (EBB)

Number of samples / size of collections: Unique biobank participants 211,589, including 3,823 new participants added in 2022. Total number of samples 220,622 (some samples collected in different timepoints. Total number of unique biobank participants genotyped using Illumina GSA arrays 209,786, with a total of 213,184 timepoints genotyped (5,632 added in 2022).

Number of samples/data used for research: 82,588 (9205 DNA and 73,383 plasma) in 38 research projects and participant data used 4,449,288 (3,991,047 phenotype data and 458,241 genotype data) in 88 research projects.

Top 3 areas of expertise

1. Population based biobanking
2. Use the genomics, Polygenic Risk Scores (PRS), in personal medicine
3. Common disease genomics

2022 successes

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Estonian Biobank activity was instrumental for two events in 2022: Tartu University Hospital established a new unit, the "Genetics and Personalised Medicine Clinic" and Institute of Genomics as a coordinator of the Horizon-CSA project "TeamPerMed" was awarded a grant of 30 Mio €.

The whole EstBB cohort was analysed by NMR and metabolomic data were added to the EstBB database.

Estonian Biobank is the richest data contributor to the BBMRI-ERIC federated search platform. Our data is accessible for cohort building and, with special permissions, it is possible to make genome-wide association studies (GWAS) to help partner scientists identify genes associated with a particular disease or other available traits.

FINLAND

Introduction

BBMRI.fi (www.bbmri.fi) is a research infrastructure comprising ten biobanks in Finland. Finnish Biobanks Cooperative – FINBB has coordinated BBMRI.fi since 2020. FINBB was appointed to this role by Ministry of Education and Culture.

2022 KPIs:

Number of biobanks and standalone collections: 10 biobanks

Number of samples / size of collections: Circa 550,000 blood samples from unique participants, 12 million FFPE tissue samples. Other sample types: CSF samples, urine samples, cells, nails

Number of samples/data used for research: Circa 200,000

Top 3 areas of expertise

1. National one-stop shop biobank services for researchers through Fingenious® digital service portfolio, which include:

- Availability of biobank samples and data: Researchers can search sample and data availability from the diagnosis-based (ICD-10) Catalogue-application and the population-based Cohorts-application.
- Researchers can make requests for feasibility studies and access to samples and data in the Requests-application.
- Clinical studies may manage the project with Recruit-application.
- FINBB may coordinate Finnish biobanks preparation and responses to the researcher requests in the Requests-application.
- All organisational and user accounts for researchers and Finnish biobanks are maintained in the Service Platform-application
- Finnish biobanks may share data analytics scripts and practices via cloud-based Shared Data Handling environment. Also, returning data from the research projects may be distributed to biobank in the Shared Data Handling environment.
- Biobank consent givers may be involved in the research studies via the MyBiobank-application.

2. High quality sample collections with associated clinical data derived from EHRs and study / population cohorts

3. Expert data analysis capabilities

2022 successes

Fingenious.fi - the gateway to Finnish biobanks and biomedical research service is enhancing international collaboration. Over 1,000 researchers from 14 countries and almost 400 organisations are using the one-stop-shop service. Over 300 projects have been conducted so far.

Large biobank study - FinnGen is proceeding as planned. Already over 500,000 samples have been collected.

Auria Biobank achieved ISO 20387:2020 accreditation, among the first biobanks in Europe.

Additional comments

The Finnish parliament passed an amendment to the Biobank Act (688/2012. From 1.1.2024 the Biobank Act will expressly stipulate that (Finnish registered) biobanks are entitled to process personal data if the processing is necessary for their tasks listed in the Act, based on GDPR articles 6.1(e) and 9.2(i).

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GREECE

Introduction

Launched in 2004, the Biomedical Research Foundation of the Academy of Athens (BRFAA) is the most recent addition to the Life Sciences Research organisations in Greece. It is located at 3km from downtown Athens and housed in a modern 32,000m2 building. The founding principle of BRFAA is to host both basic and clinical research, thus providing an ideal setting for the emergence of translational activities (Medical Application). BRFAA is one of the few institutes with such character in Europe and is unique for Greece.

2022 KPIs:

Number of biobanks and standalone collections: 10 biobanks

Number of samples / size of collections: Biobank for Parkinson's Disease/BRFAA - 1670 samples. Biobank from DAFNE project/BRFAA – 38,000 samples from healthy donors. COVID-19 Biobank/BRFAA – 1,250 human samples and 62,000 viromes.

Number of samples/data used for research: N/A

The main goal of BRFAA is to achieve excellence in the Biomedical Sciences by recruiting high quality investigators to conduct cutting-edge basic and translational research and to train young researchers in a state-of-the-art facility, which provide a particularly stimulating scientific environment and strong research infrastructures.

A national BBMRI.GR network of existing tissue collections among different institutions to be based in the Biomedical Research Foundation of the Academy of Athens (BRFAA), has been established. Once set in operation, this biobank will comply with the BBMRI-ERIC quality standards. This nationwide endeavour will initiate a new era of biomedical research in Greece, during which large-scale and high-quality biological samples of patients and healthy individuals will be gathered for analysis employing not only latest technologies, such as Next Generation Sequencing (NGS), but also suitable for integrated analyses that will include the full range of omics technologies.

This is necessary to make new treatments possible in the context of Precision medicine. Furthermore, the country's contribution to the BBMRI-ERIC infrastructure and its concomitant compliance with the BBMRI ERIC Code of Conduct aims to create a network of Greek biobanks and connect them with the infrastructure to expedite Greece's integration into the European Research Area (ERA) regulations.

Top 3 areas of expertise

1. Genomics
2. GMP facilities-stem cells
3. Non-invasive small animal imaging in the form of microPET/CT

2022 successes

Inventory of biobanks of BBMRI-GR data and metadata related to the samples.

Implementing Standard Operating Procedures (SOPs) in participating nodes.

Information Technology (IT) requirements analysis and specification. Design and original implementation of BIMS for the national network. Report on control, validation of operation and interoperability of the national network system of biobanks.

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Additional comments

- Expansion of the network, integration of new nodes with disease specific biobanks and further pathology labs.
- At national level, funding of RIs is scheduled, call anticipated within 2023.
- Possible funding request through National Funding.

HUNGARY

Introduction

The Hungarian Biobank Node (HBN) is the umbrella organisation of the largest biobanks in Hungary and represents the Hungarian research community within BBMRI-ERIC, the largest biobank network in Europe. HBN is supported by the Hungarian Research and Innovation Office and is the primary contact in Hungary for all stakeholders involved in biobanking.

Established in 2021, HBN consists of six major biobanks of the largest healthcare providers in Hungary. These biobanks are collecting several types of biospecimens and associated data elements. Members of the HBN are harmonising their quality standards and establishing federated data sharing within the network with the aim to implement FAIR principles as the foundation of the process. HBN 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.

2022 KPIs:

Number of biobanks and standalone collections: 31

Number of samples / size of collections: 2,262,581 in 25 collections

Number of samples/data used for research: 303,078

Top 3 areas of expertise

1. Rare disorders
2. Oncological disorders (oncohaematology, pancreas)
3. Personalised medicine

2022 successes

Uploading data in BBMRI Directory.

Multiple projects in motion within members of the Node in the area of privacy preserving federated data sharing.

Named TOP 50 Research Infrastructure in Hungary.

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ITALY

Introduction

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 relies on the use of collections of biological resources. BBMRI.it includes the National Institute of Health, CNR, 19 universities, 33 research hospitals (IRCCS), 45 hospitals, 14 associations of patients and 97 biobanks, Biological Resources Centres and Collections organised in thematic networks and regional networks with a matrix architecture.

BBMRI.it has developed a web portal, a Help Desk and Common Services for ICT, Quality and ELSI services to support the network. Annually, BBMRI.it Help Desk process a median of 250 requests related to ethical and legal issues and 300 requests related to quality matters. The CS IT adopted the BBMRI-ERIC standards and created the national IT infrastructure developing tools to improve interoperability of research databases. The CS Quality has implemented guidelines/best practices, harmonised operational procedures, developed criteria for the accreditation and certification of biobanks, implemented the quality management system criteria of BBMRI-ERIC in the Italian network and promoted training on the issues of quality. The CS ELSI service supports all stakeholders, from biobanks to the Ethics Committees, from patient associations to researchers and constitutes an innovative liaison between the national node and the European infrastructure.

2022 KPIs:

Number of biobanks and standalone collections: 56 (including 151 collections) in the BBMRI-ERIC Directory, meet quality and ELSI requirements, grant transnational access, and have signed the BBMRI-ERIC Partner Charter. A further 41 biobanks are on their way to meet these criteria.

Number of samples / size of collections: Diseases oriented BBs 2.1mio cases collected. Rare Diseases BBs 175,000 cases collected. Archived Tissue BBs 250mio+ cases collected.

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

Top 3 areas of expertise

1. Quality Management (QM): QM training and support to biobanks; Support in implementing the ISO 20387 standard; Healthcare integrated biobanking.

2. Stakeholder and user engagement: Working groups, dissemination and communication activities were carried out to involve the key stakeholders and to maximise awareness of BBMRI.it's objectives and activities thus enhancing the reputation and visibility of BBMRI.it; contributing to competitiveness and addressing societal challenges; building a strong bond between decision-makers and the scientific community. ELSI with a specific focus on co-production of knowledge as well as on engagement processes.

3. Data management: Secure IT solutions for managing big data and sensitive data; BBMRI.it directory development and input to BBMRI-ERIC Directory.

2022 successes

New national roadmap completed. BBMRI-ERIC Partner Charter signed by 56 biobanks. Support for the implementation of new quality standards. ISO 20387 accreditation of one of the first biobank in Europe.

COVID-19: 22 collections in 19 biobanks, 90,000+ samples/data; 2,900 imaging/data. Development and implementation of wastewater surveillance for early detection of epidemic hotspots to estimate the prevalence of infections and to study SARS-CoV-2 genetic diversity. Biobanking of viral variants.

Biobanking with minors. Matrix for Informed Consent for minors.

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Additional comments

Specific strengths of BBMRI.it include:

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

LATVIA

Introduction

The aim of BBMRI.LV is to provide resources for biomedicine research in Latvia and collaborate with institutions abroad, ensuring knowledge circulation, development and setting of new goals that will encompass international standards, best practices, and promote scientific excellence.

Institutions: Latvian Biomedical Research and Study centre, Institute of Clinical and Preventive Medicine of University of Latvia, Laboratory of Personalized Medicine of University of Latvia, Institute of Biology of University of Latvia, Riga Stradins University Institute of Oncology and Scientific Laboratory of Molecular Genetics.

Top 3 areas of expertise

1. Biological samples of population-based and disease-specific collections, survey data and information retrieval form 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

2022 KPIs:

Number of biobanks and standalone collections: 3

Number of samples / size of collections: Over 60,000

Number of samples/data used for research: Over 2,500

2022 successes

Launch of the Latvian Genome reference development within the framework European 1+Million Genome initiative implementation in Latvia in collaboration with Ministry of Health of the Republic of Latvia. The ELSI framework and data management landscape have been created and the recruitment of participants and sequencing of 3,500 whole genomes from Latvian population will start early 2023. Continuation of the Latvian Microbiome project - a citizen science project, recruiting over 500 participants in the biobank with generated dietary, health information, microbiome sequencing and genotyping data.

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

Participation in the development of more than 30 national-level and seven plus international-level research projects; proposals include areas of diabetes, tumour research, rare disease, omics data, ELSI and other.

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Additional comments

The Latvian National Node of BBMRI-ERIC is actively participating in internationally significant projects and initiatives: European 1+Million Genome initiative, EU4H-2021-PJ2: CanHeal, Million Microbiome of Humans Project, The long-COVID Genetics Initiative and nationally important projects: Paediatric Cancer Initiative, Latvian Microbiome project and National Research Programme BioMedPharm.

LITHUANIA

Introduction

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

Top 3 areas of expertise

1. The NCI Biobank has expertise in handling modern libraries of oncological diseases, developing new freezing technologies for living tissue, and studying molecular cancer biomarkers.

2. Vilnius Santaros Klinikos Biobank (BB VSK) is a disease-specific biobank specialising in preparing and storing viable cells together with complimenting samples and health information to create complete collections related to infectious diseases, haematology and oncology. BB VSK started the collection of samples from CAR-T therapy patients and blood centre donors.

2022 KPIs:

Number of biobanks and standalone collections: 4 licensed premises for the operation of National Biobank storage facilities.

Number of samples / size of collections: In 2022, collected over 50,000 samples in total.

Number of samples/data used for research: Over 800 samples provided for research.

3. Innovative Medicine Center (IMC) biobank collects living tissues and/or isolated living cells obtained during surgeries or other invasive procedures from patient operated for rheumatological, orthopaedic and other pathological indications.

2022 successes

The partners of the Human Biological Resources Centre (HBRC) successfully carried out the preparation of HBRC legislation related to quality management, sample provision, and data protection, and started developing and implementing a unified HBRC IT system and uploaded collections to BBMRI-ERIC Directory. The aim of HBRC project is to join the international research infrastructure, BBMRI-ERIC, while creating a modern infrastructure of the national biobank in Lithuania.

The law of the Republic of Lithuania on the secondary use of health data was published and the description of the data opening procedure was approved.

The partner of HBRC, IMC, has been licensed to provide a biobanking facility.

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MALTA

Introduction

DwarnaBIO, previously known as Malta Biobank, is the national archive of biological samples. It has been recently rebranded and launched to University of Malta academics and researchers. There are active plans to launch DwarnaBIO as the national genomic biobank to the public in the coming weeks. DwarnaBIO is a national initiative led by the University of Malta to establish a central population-based genomic biobank. It represents a major logistical undertaking that aims to deliver a nationally representative collection with consent for multi-omic analysis coupled to biomarker and epidemiological data. Furthermore, DwarnaBIO has provisions for a prospective cohort dynamic consent design to enable assessment of multiple outcomes.

DwarnaBIO overcomes issues with regards to quality management, preanalytical effects and custodianship of existing clinical collections. It will also be the seed for multi-omic longitudinal cohort studies of different clinical outcomes. DwarnaBIO is building towards cross-sector collaboration, specifically with the 1+Million Genomes of Europe initiative and aims to establish a reference

2022 KPIs:

Number of biobanks and standalone collections: 1 biobank, 1 collection underway (reference population collection unselected for disease).

Number of samples / size of collections: N/A

Number of samples/data used for research: N/A

'Maltese Genome' dataset for researchers and clinicians. DwarnaBIO is built around the concept of dynamic consent, facilitated through the DWARNA web portal (https://dwarna.mt/) that acts as a hub connecting the different stakeholders of DwarnaBio: biobank managers, researchers, research partners, and the public. DwarnaBIO will thus establish a reference databank of relevant phenotypic data collected at baseline, with corresponding biospecimen storage with consent for downstream multi-omic analysis and seek to prioritise direct public engagement in research.

Top 3 areas of expertise

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1. Population based biobanking
2. Population genomics
3. Dynamic consent

2022 successes

The Malta Biobank was rebranded and relaunched under the name DwarnaBIO.

Institutional ethics approval has been sought to establish a national reference genomic biobank and is awaiting final approval from regulatory bodies.

Significant investment in human and infrastructural resources to run DwarnaBIO project. This included employment of IT and Quality Management experts and investment in biospecimen management system from Micronic® consisting of barcoded tubes, tracking software and scanners. Standard operating procedures have been drafted, aiming for ISO20387 accreditation.

Additional comments

DwarnaBIO launch is planned for end May 2023, but exact details are to be confirmed. We will inform with further updates.

THE NETHERLANDS

Introduction

During 2022, BBMRI.nl has intensified its collaboration with partner Health-RI to pursue its mission to maximise the use of biosamples, images and data for health research on the prevention, diagnosis, and treatment of diseases. For this, we make sure these resources are available in a FAIR way: Findable, Accessible, Interoperable and Reusable. We do this in compliance with ethical, legal and privacy demands, and with active participation of donors, citizens, and patients.

It is our vision that all collected biosamples, images, and data (from research, healthcare or collected by citizens) will serve research best. Without reinventing the wheel, samples and data will be exchanged and reused for various purposes in an efficient, effective, and meaningful way, and in compliance with ethics, legislation and society's needs and wishes. To contribute optimally to this vision, BBMRI.nl and Health-RI provide:

1. Access to biosamples, images and data
2. Tools to capture, integrate and analyse data, and
3. Support on ethical, legal, and societal implications.

Top 3 areas of expertise

1. Research infrastructure
2. ELSI
3. Biomaterial Quality management

2022 KPIs:

Number of biobanks and standalone collections: 115 biobanks and 528 collections according to the BBMRI.nl Catalogue and the BBMRI-ERIC Directory.

Number of samples / size of collections: Based on the information received from the collection providers, circa 1.5mio of samples deriving from 477 collections are findable.

Number of samples/data used for research: 4 collections have been requested during 2022. The exact number of samples of data included in these requests is unknown.

2022 successes

Tools and services developed within BBMRI.nl with a significant added value for the Dutch research community at large, have successfully transitioned to Health-RI to support science in a sustainable manner.

The ELSI Servicedesk continues to provide support regarding Ethical, Legal, Social Implications to a broad audience in The Netherlands, including scientists, experts, policy makers, and patients. During 2022, the ELSI Servicedesk received more than 10,000 website visits and more than 60 ELSI-related questions. Notably, the ELSI-service desk significantly increased the efficiency of their

support; the duration to answer ELSI-questions decreased from 10 working days in 2019 to 3.2 working days in 2022.

The Request management tool Podium is being used more frequently by the Dutch research community. The number of registered users increased from circa 40 in 2019 to over 200 in 2022. Currently, 70 different organisations make use of this tool to manage and monitor requests for data, images, and biomaterials for scientific use.

Additional comments

Health-RI collaborates with various Dutch ministries to identify and diminish the main obstacles that impede scientific (re)use of data. Together with the national scientific community, eight solutions to these obstacles have been identified.

Furthermore, working plans, supported by the ministries and the national scientific community, have been composed to come to these solutions in the next six years, to resolve the obstacles and stimulate scientific (re)use of data. For more information see this link (In Dutch).

NORWAY

Introduction

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

Top 3 areas of expertise

1. Initiating and running population-based biobanks

2. Logistics for collecting samples for research biobanks integrated with the diagnostic routine

3. Digitised biobank data - secure solution for handling of sensitive, big data

2022 KPIs:

Number of biobanks and standalone collections: 1,752

Number of samples / size of collections: 7,277,797 samples

Number of samples/data used for research: 71,866 samples

2022 successes

Contract for funding of a new project period – Biobank Norway 4 (2023-2027), signed by the Research Council of Norway.

Establishing Biobank OUS – a dedicated biobank infrastructure unit at the University Hospital of Oslo.

The infrastructure has contributed to several publications in high impact journals on the topic early detection biomarkers for cancer of the lung, breast, colon, oropharynx, prostate, malignant melanoma and glioma.

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POLAND

Introduction

The original consortium was created in 2016 by seven scientific partners: LUKASIEWICZ Research Network - PORT Polish Center for Technology Development (Consortium Leader, Leading National Research Center in Biobanking), Medical University of Gdansk, Medical University of Warsaw, Wroclaw Medical University, Medical University of Lublin, University of Lodz and Regional Science and Technology Centre in Checiny. The first BBMRI.pl project consortium operated between 2016 and 2021. In 2022 the preparations for a second project consortium started. The shared vision is to build an integrated, sustainable, state-of-the-art biobanking network in Poland. To achieve this vision, the mission of the biobanking community is to focus on coordination, efficiency, and sustainability in terms of biobank samples.

2022 KPIs:

Number of biobanks and standalone collections: 52 biobanks with more than 50 collections

Number of samples / size of collections: Over 1,000,000

Number of samples/data used for research: 13 projects/11 project sample requests

Top 3 areas of expertise

1. Quality Management Expert Centre

2. Expert knowledge on preparation, cryostorage, and handling of human-derived biospecimens, derivation of biobanking specimens from diagnostic pathways, modelling specimen and data workflows for new users/participants

3. Activities related to QM and ELSI on national level coordinated by NN

2022 successes

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From 2022 all non-commercial clinical trials sponsored by Medical Research Agency must involve biobanking of patient material and be done according to the Quality Standards for Polish Biobanks v.2.00.

In 2022, the new Consortium for the BBMRI.pl 2023-2027 period has been expanded with a new member: Medical University of Bialystok and Centre of Informatics Tricity Academic Supercomputer and network.

Strategic aim: NN has committed to set the course for a "new chapter" in the interaction between the consortium and Polish Biobanking Network – with the aim to incorporate all Polish biobanks into BBMRI.pl network within the next funding round.

SLOVENIA

Introduction

The Slovenian Node BBMRI.SI is very interdisciplinary in its nature. It consists of all three Slovenian public universities: University of Maribor; University of Ljubljana; University of Primorska with the addition of the University Medical Center Maribor. It covers a transdisciplinary array of sciences ranging from medical sciences over natural and life sciences till law and information technologies. The National Node Coordinator is Prof. Dr. Urban Bren.

2022 KPIs:

Number of biobanks and standalone collections: 3 biobanks

Number of samples / size of collections: 30,000 samples

Number of samples/data used for research: 30,000 samples

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Top 3 areas of expertise

1. Autoimmune disorders
2. Cancer
3. Rare diseases

2022 successes

Becoming full member of BBMRI-ERIC***.***

Assuring a small amount of ***stable funding.***

Publication in Nature Chemical Biology***.***

SPAIN

Introduction

The ISCIII Biobanks and Biomodels Platform (P_ISCIII_BB) is a structure from the Institute of Health Carlos III (ISCIII). It currently comprises 41 units and another 23 units adhered under the figure of 'Adhered Biobank'. Through ISCIII, the P_ISCIII_BB acts as the National Node in BBMRI-ERIC.

From its Coordination, the structure of 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: 57 Units in the Biobanks HUB, 18 Units in the animal model HUB, 198 Units in the Organoids HUB and 15 Units in the 3D printing HUB. These units are distributed throughout Spain and represent 16 Autonomous Communities, which include: Andalusia, Aragon, Asturias, Balearic Islands, Canary Islands, Cantabria, Castilla y León, Catalonia, Valencian Community,Galicia, Madrid, Murcia, Basque Country, Autonomous Community of Navarra, Extremadura and Castilla-La Mancha.

2022 KPIs:

Number of biobanks and standalone collections: 57 Biobanks

Number of samples / size of collections: 1,210,241 samples for research, 137,426 donors for 2022

Number of samples/data used for research: 220,477 samples

Top 3 areas of expertise

1. ELSI: The P_ISCIII_BB collaborates with ELSI experts to ensure state-of-the-art guidance and training as well as consultations with researchers at the national level and worldwide. Support from ELSI experts in the HUB of Biobanks is organised from the Coordination of the P_ISCIII_BB by the establishment and supervision of the ELSI working group. Thus, activities are coordinated and centralised, also contributing to the establishment of portfolios of workshops and trainings with the support of the P_ISCIII_BB. In 2022, the P_ISCIII_BB received and responded to 10 ELSI-themed consultations through the P_ISCIII_BB helpdesk allocated on the website.

2. IT tools/catalogues/quality: This is coordinated by P_ISCIII_BB with the goal of establishment and implementation of semi-automatised workflows and solutions for the construction of the national Virtual Catalogues allowing researchers to access and search specimen collections. Support in IT Tools and Catalogues is also gathered through the support of the Catalogue Working group organised by P_ISCIII_BB Coordination. This workflow guarantees the promotion of biobank specimen collections to contribute effectively to research, therapeutic innovation, and precision medicine.

In 2022, **73 sample availability reports** were prepared through the establishment and implementation of IT developments designed and implemented from Coordination. These IT Tools guarantee the centralisation of responses from all P_ISCIII_BB biobanks. Same developments have been crucial for the realization of more than **25 surveys** and **8 consultation reports** from Coordination.

Of equal importance, and to further oversee quality management in biobanking and biomedical research, the P_ISCIII_BB Coordination also collaborates with quality-related experts on issues that ensure quality sample, auditing, and internal training. These activities are developed by the Quality Working group constituted from the P_ISCIII_BB Coordination.

3. Communication and dissemination: The P_ISCIII_BB continuously increase the visibility of its services and developments through intense activity that are also supervised by ISCIII. Building on our units, the P_ISCIII_BB works in promotion and engagement of congresses, educational programmes, and symposia portfolio. Activities related to this area of expertise can be found here:

- A total of **470 courses** have got the involvement of the units from the P_ISCIII_BB during 2022 (including workshops, seminars, training sessions, symposia, among others).

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- A total of **694 national projects** have got the participation of the units from the P_ISCIII_BB during 2022.

- More than **900 dissemination activities**, including dissemination events, leaflets, press releases, radio, talks, articles in non-scientific publications, and social networks, have got the participation from the units of the P_ISCIII_BB.

2022 successes

I Workshop of the ISCIII Biobanks and Biomodels Platform. Thanks to the support of ISCIII, the P_ISCIII_BB organised its first workshop. It was held from 27th to 28th October 2022 in Santander. Organised by the P_ISCIII_BB Coordination, the workshop got operational and scientific support from one of its biobanks acting as local organiser (Valdecilla Biobank from Marqués de Valdecilla Research Institute-IDIVAL). The workshop was also supported by the Ministry of Health of the Government of Cantabria, the City Council of Santander, the University of Cantabria, and Marqués de Valdecilla University Hospital. More than 260 professionals attended which allowed extensive sharing on topics of high interest to the P_ISCIII_BB, a key infrastructure when it comes to guaranteeing quality at national and international level in biomedical research. We also report participation of other ISCIII Platforms, including the ISCIII Clinical Research Support Platform, SCReN (Spanish Clinical Research Network) and ITEMAS to support R+D+i in Biomedicine and Health Sciences. The conference highlighted the added value of networking when opening new opportunities for research and

collaboration, as well as the importance of having quality services as a guarantee to carry out successful studies in biomedicine.

Green light to the project REACT within the call HORIZON-HLTH-2021-DISEASE-04-07. REACT: Aims to define and deepen the mechanisms and variants that may affect the course of respiratory infectious diseases (i.e., respiratory syncytial virus (RSV), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and influenza). The REACT project is led by Statens Serum Institut and works with two P_ISCIII_BB units. Whilst CNIO Biobank leads work package two which is focused on the establishment of prospective and retrospective cohorts, gathering samples and involving the P_ISCIII_BB for the execution of REACT, the IBEC unit leads work package eight on the generation of epithelial organoids, as well as the work package 10 on dissemination and communication activities organisation and implementation.

Publications: A total of 563 publications with mention of P_ISCIII_BB were published in 2022.

Additional comments

P_ISCIII_BB:

- A total of 264 national Patient Associations and platforms have collaborated with P_ISCIII_BB through its units during 2022.
- A total of 44 international patient associations and other international platforms have collaborated with P_ISCIII_BB through its units during 2022.
- A total of 462 courses have been organised by the units of P_ISCIII_BB in 2022, including workshops, seminars, training days, among others.

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- A total of 95 international projects have benefited from P_ISCIII_BB's units during 2022.
- P_ISCIII_BB has participated in the promotion of 997 outreach activities through its units during 2022.
- P_ISCIII_BB has participated in 177 national and 78 international congresses and conferences through its units during 2022.

HUB of Biobanks:

- A total of 1,200,000 samples have been generated for research by the P_ISCIII_BB HUB of Biobanks in 2022.
- Samples were obtained from more than 130,000 donors.
- Among the main areas, we highlight: 273,979 from population samples, oncological diseases with 199,529 samples, COVID-19 with 110,330 samples, neurological and psychiatric diseases with 99,083 samples, although representativeness of most pathologies is available.
- From P_ISCIII_BB in 2022, 69 requests for samples and services have been attended.
- A total of 220,477 samples have been transferred for research, of which 60,237 have been samples from oncological diseases, 44,118 population samples and 24,249 from patients with COVID-19. These assignments have responded to the needs of more than 1,350 competitive projects.

HUB of Animal Models:

- A total of 6 patents have been obtained.
- A total of 181 initiatives related to the use of animals in research have been promoted from the units of the P_ISCIII_BB HUB of Animal Models.
- A total of 2,706 services have been carried out in 2022 by the units of the P_ISCIII_BB HUB of Animal Models.
- A total of 258 training courses have been organised in 2022 by the P_ISCIII_BB HUB of Animal Models. Courses include workshops, seminars, training days, among others.
- A total of 181 scientific entities have collaborated with the P_ISCIII_BB HUB of Animal Models.

SWEDEN

Introduction

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

2022 KPIs: *

Number of biobanks and standalone collections: 450 **

Number of samples / size of collections: Circa 160,000,000

Number of samples/data used for research: 347,385/190,614

** A new routine for tracking KPIs was implemented in 2020.*
*** 450 biobanks managed by 6 regional biobank centres.*

Top 3 areas of expertise

1. National organisation and collaboration: Sweden's national infrastructure is characterised by clear contact points at all levels.

2. Clinical biobanks: A standardised process for collecting, handling and storing samples for research has been implemented across Sweden, and is integrated in the routine healthcare system. Currently 25 hospitals can provide healthcare-integrated biobanking for blood and other liquid samples for research purposes, and more than 120 studies collect samples using the process.

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

2022 successes

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A new Swedish Biobank Act: The current Swedish Biobanks in Medical Care Act (SFS 2002:297) allows human biological material that have been collected and/or stored for healthcare purposes to be used in research and clinical trials if the patient/donor has given consent. However, there has been a growing need for an updated Biobank Act with an expanded scope that simplifies access to samples for researchers while still providing sufficient protection for patients/donors. Biobank Sweden has been a central dialogue partner in the work on the new Swedish Biobank Act (2023:38), which will come into effect on July 1, 2023.

Nordic Biobank Conference: The first-ever Nordic Biobank Conference took place in Gothenburg, Sweden on September 6th-8th, 2022. The theme was "Current trends and challenges in the Nordic countries", and the event was jointly organised by Sweden, Denmark, Finland, Iceland and Norway. The main aim of the conference was to encourage collaboration between the Nordic countries in the field of biobanking. The event was a success, with ~500 participants from 21 countries. The second Nordic Biobank Conference will be held in Trondheim, Norway in 2024.

Developing the Swedish Biobank Registry (SBR): The Swedish Biobank Registry (SBR) was launched during the fall of 2021 as a pivotal cornerstone of Biobank Sweden's fundamental goal to give Sweden the best prerequisites for healthcare and research in the biobanking context. A national sample registry ensures new diagnostics and treatments will be made available to patients, such as in the framework of precision medicine. In 2022, development of the SBR has continued, leading to the implementation of a prototype for searches specifically targeted at research needs. The main focus currently is the development of administrative and regulatory support structures in the system.

SWITZERLAND

Introduction

In Switzerland, biobanks operate with heterogeneous processes, are not registered, making the usability and comparability of samples difficult. Moreover, biobanking practices have greatly evolved over the last ten years, from the individual collection of biological material to professional infrastructures dealing with ethical and legal issues, accessibility and data sharing, interoperability, data protection and quality leading to a huge increase in the costs of biobanking activities. In 2013, the SNSF launched a competitive call for concepts for constituting a national biobanking platform. 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.

SBP strategy is based on a combined approach based on: 1) Documentation supports to provide Swiss biobanks up-to-date technical know-how with specific expertise for the management of their daily biobanking activities; 2) Interactive tools to support biobanks in three critical areas of development (Quality/Harmonisation, Visibility and Interoperability). With its first tool, the Biobank SQAN, SBP evaluates the biobank practices and compliance with the legal/ethical requirements, as well as those applied to ensure the quality of the biobanking processes in alignment with the applicable professional standards (e.g., ISO 20387). With the second, NExT, SBP promotes networks and offers an innovative way to connect biobanks with researchers. This exchange platform is based on user friendliness and ambitious technologies of visualisation to search for samples that could be used in research projects. With the expertise SBP has gained by developing these tools, and their encountered success, SBP is now ready to develop the last missing component, an IT platform dedicated for the daily management of samples and biobanking processes (Biobank Information Management System, BIMS).

Moreover, SBP links Swiss biobanks with the European Biobanking and Biomolecular Research Infrastructure (BBMRI-ERIC) through its Directory to foster biobank networks and increase sharing of information on biological resources. This link with BBMRI Directory is key for Swiss researchers willing to create new partnerships and collaborations with the European network or other BBMRI nodes.

2022 KPIs:

Number of biobanks and standalone collections: 4 biobanks / 46 collections in the BBMRI Directory

Number of samples / size of collections: N/A

Number of samples/data used for research: N/A

Top 3 areas of expertise

1. Quality, Standardisation and Harmonisation
2. IT / Interoperability
3. Education and Outreach

2022 successes

1. Quality, standardisation and harmonisation: Harmonised documentation (e.g., policies, SOPs, templates) in compliance with the European and international requirements and the applicable professional standards. This documentation is the first pillar in SBP Quality strategy to increase the overall quality of research and set the foundation of a harmonised practice at national level. The four newly published documents are:

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

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

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

- MTA 3.0: To better serve biobanks and find the most appropriate support strategy to help researchers access and use biological resources (biological materials and data) more easily and efficiently, SBP has revised its MTA templates (v1.0 and v2.0) to offer a single document (MTA 3.0) that now includes different options and guidance depending on whether or not you share personal data. The contractual setup contains two separate documents: 1) the Project Agreement (PA), which needs to be filled in for each project and contains mostly operative provisions and 2) the Master Legal Instrument (MLI), which contains the legal provisions applicable between the parties that will not be amended (unless the PA provides for an exception). This new template has been developed in collaboration with the Swiss Personalised Health Network (SPHN), the research infrastructure to enable nationwide use and exchange of health data for research. We have worked together to align the new MTA template with the latest version of the SPHN DTUA. Both documents can be jointly or independently used dependent the use case.

2. IT / interoperability: Once sample-related data are comparable and searchable, researchers can assess sample suitability for their project. SBP has worked on two main projects (i.e., the revision of SBP datasets and the concept for a BIMS) to further support interoperability across biobanks.

- ***Datasets:*** The publication in 2018/2019 of SBP datasets (tissue, liquid – human / veterinary and bacteria samples) was an important first step towards interoperability and the standardisation of sample documentation practice. A revised version of these Datasets has been released with the publication of three Core Datasets to better help biobanks in understanding and implementing these DS. These DS will be integrated into the future SBP Biobank Information Management System (BIMS) as the backbone of standardised workflows for each specific biobanking environment.

- BIMS: After selecting DiData as our BIMS provider, SBP is creating a new tool to offer a common basis for harmonisation and sharing of information across Swiss Biobanks, in complement of the already available BIMS in the University Hospitals and on the market. Thanks to its large network, SBP is in the unique situation of understanding specific needs of small biobanks, working on excel sheets and not having the opportunity to switch to a professional BIMS. The three main advantages of the SBP conceptualised BIMS: Considerably affordable system in terms of cost and operation for better compliance with traceability and security requirements, local support system for the establishment and monitoring of biobanks for rapid and available technical integration, highly collaborative and harmonised system for better sample sharing.

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3. ***Education and outreach:*** In 2022, SBP has worked on a new communication strategy to promote its tools, services and expertise to better engage biobanks and researchers. A new website now features the four pillars of support (Quality, Visibility, Interoperability and Education). This approach enabled through specialised communications on our website, via factsheets, newsletters, or through social media to create close links with important actors of the biobanking community, better target the needs of our various partners and tailor our communication by personalizing our messages and offers. With the introduction of 'Education' as a new pillar, SBP is strengthening its strategy to meet the growing need for knowledge in the field which is essential to harmonise "state-of-the-art" biobanking practice and work. The acquisition of basic knowledge will promote common understanding and closer links between Swiss biobanks, researchers, national research infrastructures, ethics committees and society. To support this project, SBP has received a financial support of the Loterie Romande to develop a Certificate of Advanced Studies in biobanking in collaboration with the University of Geneva. For more information on this new pillar and the 2022 developments, please consult our brochure.

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2022
A YEAR IN REVIEW

New website

A brand new website, categorized according to three strategic pillars: Quality, Visibility and Interoperability

Social media

+240

Newsletter subscribers

+140

4 new support documents

- Service Level Agreement Template
- Material Transfer Agreement 3.0
- A Risk Management SOP
- Quality Manual

Loterie Romande

Project support for a **BIMS** and a **CAS in biobanking**

BIMS project

Tender + provider selection + strategy & concept

DiData

SBP Labels progression

+18 VITA Labels

+9 NORMA Labels

+4 OPTIMA Labels

+23 **Registered** in SBP SQAN

Datasets 2.0

CORE Datasets publication

Human Liquid
Human Tissue
Bacteria

Swiss Health Study

SBP helps in coordinating the Swiss Health Study conducted by Unisanté and Bern University. The pilot study is now ready to be deployed at a national level to include a higher number of participants.

TÜRKIYE

Introduction

The BBMRI.tr infrastructure is coordinated by the National Node at Izmir Biomedicine and Genome Center (IBG), and the regulatory organisation for BBMRI.tr is The Scientific and Technological Research Council of Türkiye (TUBITAK) R&D Support and Continuum Management Group (ARGES). The Biobank Node of Türkiye is the umbrella organisation of biobanks in Türkiye. The partner biobanks of BBMRI.tr are Hacettepe University Center for Biobanking and Genomics, Istanbul University, Aziz Sancar Institute of Experimental Medicine Biobank Facility, Acibadem University Rare Disease Biobank Unit (ACU-RDB), Ankara University Brain Research and Application Center Cell Line Biobank and Izmir Biomedicine and Genome Center Biobank.

BBMRI.tr aims to create a collaborative research infrastructure between biobankers, biomedical researchers, clinicians, and patient organisations in Türkiye to increase the biobanking capacity in rare diseases, cancer, and infectious diseases. Furthermore, BBMRI.tr seeks to expand the scope of biobanking in the Euro-Mediterranean region and MENA countries. BBMRI.tr established QM, IT, and ELSI teams to support the network and developed strategies to accelerate Biomedical research via increasing close collaboration, integration, and harmonisation between biobanks in Türkiye to facilitate access to high-quality biospecimens and related data.

2022 KPIs:

Number of biobanks and standalone collections: 5 biobanks

Number of samples / size of collections: HUGEN Rare Diseases Biobank: 46,000 samples (5,900 families). İBG-Biobank: 16,595 samples. AUBAUM Biobank: 15,714 samples. IEM, Rare Disease Biobank: 5,100 samples. ACU-Rare Diseases bioBANK: 1,122 samples

Number of samples/data used for research: HUGEN Rare Diseases Biobank: 645 samples. İBG-Biobank: 676 samples. AUBAUM Biobank: 210 samples. IEM, Rare Disease Biobank: 610 samples. ACU-Rare Diseases bioBANK: 112 samples

Briefly, the BBMRI.tr team has implemented CEN and ISO standards for the accreditation and certifications of biobanks to Turkish Biobanks in collaboration with the Turkish accreditation body TURKAK and organised training sessions on quality management.

Top 3 areas of expertise

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

2. Rare cancers and cancers: Clinical expertise on hereditary & sporadic solid and haematological cancers and repositories of FFPE, tissue, and blood samples of cancer patients

3. Education and hands-on training for biobanking

2022 successes

Completion of National Standard Development for Biobanking in Türkiye by harmonisation studies and auditor training for General Requirements for Biobanking, ISO 20387 by Turkish Accreditation Agency (TURKAK) with the active participation of BBMRI-Türkiye.

The initiation of the İSTisNA project coordinated by Acıbadem University-ACU-Biobank and Istanbul University-Aziz Sancar Institute of Experimental Medicine Biobank Facility aim to develop solution proposals in cooperation with patients and patient associations, scientists, public institutions, and society in the field of undiagnosed and rare diseases, to increase research activities, to bring together stakeholders, to integrate national and international biobanks and to train scientists is initiated with the participation of BBMRI-Türkiye and its partner biobanks.

Establishment of the first international industrial collaboration agreements for biobanking of samples and data obtained for clinical phase studies.

UNITED KINGDOM

Introduction

The UK Node, also known as the UKCRC Tissue Directory and Coordination Centre (TDCC) is hosted by the University of Nottingham and University College London. TDCC has a remit to ensure existing resources are used before more samples are collected - therefore TDCC clearly does not further compound the challenge by collecting yet more samples. This also ensures TDCC is independent from any biobank or collection in the UK and can always act as an “honest broker”.

The sole remit is to make sure existing resources can be discovered and accessed, with a revived drive for transparency across the whole ecosystem. Therefore, we do not and cannot count sample numbers.

We achieve our goal by focusing on the discovery of biobanks, their capabilities, the datasets they can provide and working with industry in a friendly and collaborative environment. All this technical work is underpinned by world leading engagement activities to ensure we understand the requirements of the researchers who are seeking to connect and engage with biobanks to support their research.

2022 KPIs:

Number of biobanks and standalone collections: 279 biobanks and standalone collections representing a total of 834 collections

Number of samples / size of collections: N/A

Number of samples/data used for research: N/A

Top 3 areas of expertise

1. Discovery processes, systems and best practice

2. Engagement of key stakeholders

3. Co-creation and collaboration with industry

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IARC/WHO

Introduction

The International Agency for Research on Cancer (IARC) is the specialised cancer research agency of the World Health Organization (WHO). Created in 1965 in Lyon, IARC's mission is to promote international collaboration in cancer research and understand the causes of cancer. With the support of 27 Participating Member States, the Agency makes an exceptional contribution to the fight against cancer worldwide, by mobilising individuals and organisations around common values and objectives.

IARC is interdisciplinary, bringing together skills in epidemiology, laboratory sciences and biostatistics to identify the causes of cancer so that preventive measures may be adopted, and the burden of disease and associated suffering reduced. A significant feature of IARC is its expertise in coordinating research across countries and organisations; its independent role as an international organisation facilitates this activity.

Aligned with its WHO mandate, IARC has a particular interest in conducting research in low and middle-income countries through partnerships and collaborations with researchers in these regions.

2022 KPIs:

Number of biobanks and standalone collections: 1 biobank, centralised in Lyon, France

Number of samples / size of collections: 6,447,992 (392 projects supported thus far)

Number of samples/data used for research: 5,994,286

Top 3 areas of expertise

1. Cancer research at an international scale
2. Cancer research in resource-restricted settings
3. Research-informed guidelines

2022 successes

Twinning for the Armenian Research Infrastructure on Cancer Research (ARICE) grant, co-led by IARC, has been ranked as amongst the best Twinning programs by the European Research Executive Agency.

Participation in key, EU-funded canSERV project.

Continuing scientific publications in high-impact international journals (Nature Microbiology; Lancet Oncology; Nature Communications; and many others).

Additional comments

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In 2022, IARC/WHO moved into a dedicated, modern building located in the heart of the Gerland Bio-district in Lyon, France. The IARC biobank in the new building has its storage capacity increased to 10mio biological samples. The investment in new premises, more efficient equipment for the storage and processing of samples; in material, logistical and human resources for the operational management of the biobank, but also the implementation of new procedures, processes and educational/training opportunities, are the key towards the development of more extensive local and international partnerships.

PART FIVE

LEGAL NOTICE AND AUDITOR'S REPORT

LEGAL NOTICE

Legal Address

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8010 Graz, Austria
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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, Czech Republic, Federal Republic of Germany, Republic of Estonia, Republic of Finland, French Republic, Hellenic Republic, Italian Republic, Republic of Latvia, Republic of Malta, Kingdom of the Netherlands, Kingdom of Norway, Republic of Poland, Republic of Slovenia, Kingdom of Sweden

Observers

Republic of Cyprus, Republic of Lithuania, Swiss Confederation, Kingdom of Spain, Republic of Türkiye, International Agency for Research on Cancer (IARC/WHO)

Values

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

AUDITOR'S REPORT

APPROVAL OF AUDIT REPORT 2022

Document No AoM/24/4b

Author(s)	BBMRI-ERIC Headquarters
Purpose	Approval of the Audit report 2022
Voting requirement(s)	Statutes Art. 11(9a): The following decisions shall require agreement of at least 75 % of Members present and voting representing at least 75 % of the Members annual mandatory contributions: decisions on the Work Programme and budget
Action(s) required	Decision

PKF Corti & Partner GmbH
Wirtschaftsprüfer und Steuerberater

Wirtschaftsprüfung &
Steuerberatung

Long-form Audit Report

of the Financial Statements
as of December 31, 2022
(Translation)

BBMRI-ERIC
Graz

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Handelsgericht Graz
Firmenbuch Nr. 37316 b
UID-Nr. ATU44527008
WT-Code 801034

Bankverbindungen
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IBAN AT17 2081 5000 4302 9321
SWIFT/BIC STSPAT2GXXX
UniCredit Bank Austria AG (BLZ 12000)
IBAN AT47 1200 0766 1310 2800
SWIFT/BIC BKAUATWW

PKF Corti & Partner GmbH
Wirtschaftsprüfer und Steuerberater

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To the Director General of
BBMRI-ERIC,
Graz

We have completed the audit of the financial statements as of December 31, 2022 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, 2022, 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.

The previous auditor granted access to relevant information about the audited company and about the last audit performed.

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, 2022, 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, 2022, 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 Statements

The Director General is responsible for the preparation of the financial statements in accordance with Austrian Generally Accepted Accounting Principles, for them to present a true and fair view of the assets, the financial position and the financial performance of the Company and for such internal controls as management determines are necessary to enable the preparation of 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.

Comments on the Management Report

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

PKF Corti & Partner GmbH
Wirtschaftsprüfer und Steuerberater

Mag. Clemens Corti alle Catene
Wirtschaftsprüfer/Certified Public Accountant

Graz, April 17, 2023

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.

Appendices

Deloitte.

Möstl & Pfeiffer
Steuerberatungs GmbH

Financial Statements

2022

(Translation)

BBMRI-ERIC

Neue Stiftingtalstraße 2/Stiege B6/OG
8010 Graz

Assets	2022-12-31 EUR	2021-12-31 EUR
A. Fixed assets		
I. Intangible assets		
1. Software	68,940.01	91,920.01
II. Tangible assets		
1. Tools and equipment	37,777.45	41,890.61
	106,717.46	**133,810.62**
B. Current assets		
I. Accounts receivable and other assets		
1. Accounts receivable - Trade	51,396.51	254,117.13
2. Other receivables and assets	357,997.20	185,307.85
	409,393.71	439,424.98
II. Cash in hand and bank balances	9,633,533.54	2,667,526.10
	10,042,927.25	**3,106,951.08**
C. Prepayments and accrued income	**1,452.52**	**3,923.33**
Total assets	**10,151,097.23**	**3,244,685.03**

Shareholder's equity and liabilities	2022-12-31 EUR	2021-12-31 EUR
A. Shareholder's equity		
I. Earnings reserves		
1. Reserves provided for by the articles of association	923,469.78	893,333.43
II. Balance sheet profit	367,775.00	367,775.00
thereof profit carried forward from the previous years	*367,775.00*	*367,775.00*
	1,291,244.78	**1,261,108.43**
B. Investment grants	**9,791.46**	**13,188.72**
C. Provisions		
1. Other provisions	**119,579.58**	**127,273.27**
D. Liabilities		
1. Accounts payable - Trade	220,003.27	246,161.68
thereof with a remaining maturity of up to one year	*220,003.27*	*246,161.68*
2. Other liabilities	312,529.20	221,865.55
thereof taxes	*84.37*	*1,190.72*
thereof social security	*661.76*	*798.96*
thereof with a remaining maturity of up to one year	*312,529.20*	*221,865.55*
	532,532.47	**468,027.23**
thereof with a remaining maturity of up to one year	*532,532.47*	*468,027.23*
E. Accruals and deferred income	**8,197,948.94**	**1,375,087.38**
Total shareholder's equity and liabilities	**10,151,097.23**	**3,244,685.03**

		2022 EUR	2021 EUR
1.	**Net turnover**	**3,920,923.33**	**3,292,908.28**
2.	**Other operating income**		
	a) Other	**7,537.18**	**7,440.85**
3.	**Personnel expenses**		
	a) Salaries	2,520,260.44	2,103,945.08
	b) Social security costs	477,189.73	373,566.24
	aa) statutory social security costs and payroll related taxes	476,300.22	373,289.54
		2,997,450.17	**2,477,511.32**
4.	**Amortisation and depreciation**		
	a) of intangible and tangible assets	**52,594.85**	**54,819.07**
5.	**Other operating expenses**		
	a) Other	**849,273.91**	**758,647.91**
6.	**Subtotal no. 1 to 5 (Operating profit)**	**29,141.58**	**9,370.83**
7.	**Other interest and similar income**	**1,354.50**	**0.00**
8.	**Interest payable and similar expenses**	**21.10**	**203.69**
9.	**Subtotal no. 7 to 8 (Financial result)**	**1,333.40**	**-203.69**
10.	**Taxes on income**	**338.63**	**0.00**
11.	**Net profit for the year**	**30,136.35**	**9,167.14**
12.	**Allocation to earnings reserves**	**30,136.35**	**9,167.14**
13.	**Profit carried forward from the previous years**	**367,775.00**	**367,775.00**
14.	**Balance sheet profit**	**367,775.00**	**367,775.00**

1. Notes to the Financial Statements
for the Financial Year 2022

A. Accounting and valuation methods

1. General principles

The annual financial statements were prepared in accordance with the provisions of Sections 189 et seq. of the Austrian Commercial Code (UGB) in accordance with generally accepted accounting principles and in compliance with the general standard of providing the most accurate possible rendition of net assets, the financial position and operating results of the association.

The annual financial statements were drawn up in compliance with the principle of completeness in accordance with statutory provisions.

When assessing the individual assets and liabilities, the principle of individual valuation was taken into account and a going concern assumed.

The principle of prudence was taken into account by showing only the profits realized on the balance sheet date. All identifiable risks and imminent losses have been taken into account – insofar as legally required.

2. Capital assets

Intangible assets

Acquired intangible assets were valued at cost less scheduled depreciation. Depreciation was calculated on a straight-line basis.

The following useful lives were based on scheduled depreciation:

	Useful life in years
Software	4.00 - 5.00

Property, plant and equipment

The depreciable property, plant and equipment was valued at acquisition or production cost, which was reduced by the scheduled depreciation. Low-value assets up to a value of EUR 800,00 were fully written off in the year of acquisition. Low-value assets up to a value of EUR 800,00, which can be used more than two years were valued at cost less scheduled depreciation. Depreciation was calculated on a straight-line basis over the expected useful life in years.

The following useful lives were based on scheduled depreciation:

	Useful life in years
Tools and equipment	1.00 - 15.00

3. Receivables and other assets

The receivables and other assets have been estimated at nominal value. In case of identifiable individual risks, the lower fair value has been applied.

4. Provisions

Other provisions

In accordance with the prudence principle, other provisions took into account all risks identifiable at the time of drawing up the balance sheet and the amount of or reason for contingent liabilities with the amounts which, according to the best possible estimate, may have to be used to settle the obligation. All provisions have a term of less than one year.

5. Liabilities

Liabilities were stated at their settlement amount.

B. Explanations of the balance sheet and the income statement

1. Remarks on the balance sheet

Capital assets

The development of the individual items of fixed assets and the breakdown of the annual depreciation by individual item are shown in the attached schedule of assets.

Investment grants

	Status 2022-01-01	Allocation	Release	Usage	Status 2022-12-31
Software	12,868.80	0.00	3,217.20	0.00	9,651.60
Tools and equipment	319.92	0.00	180.06	0.00	139.86
	13,188.72	0.00	3,397.26	0.00	9,791.46

Cash-effective income after the balance sheet date:

Other receivables include the following significant income, which only becomes cash-effective after the balance sheet date:

	2022-12-31 EUR	2021-12-31 EUR
Project revenue	245,035.24	22,426.60
other revenues	0.00	89,629.09
	245,035.24	112,055.69

Provisions

Composition and development of provisions:

	Status 2022-01-01 EUR	Usage EUR	Allocation EUR	Status 2022-12-31 EUR
Other provisions				
Other provisions	0.00	0.00	22,541.82	22,541.82
Provision for credit hours	3,382.17	3,382.17	7,416.05	7,416.05
Provision for annual leave	106,091.10	106,091.10	77,621.71	77,621.71
Provision for consulting expenses	17,800.00	17,800.00	12,000.00	12,000.00
Sum provisions	127,273.27	127,273.27	119,579.58	119,579.58

Cash-effective expenses after the balance sheet date

Other liabilities include the following material expenses, which only become payable after the balance sheet date:

	2022-12-31 EUR	2021-12-31 EUR
Payroll expenses	263,602.81	198,913.63
Other operating expenses	42,988.16	19,404.24
	306,590.97	218,317.87

Deferred income statement items

BBMRI-ERIC receives grant payments from the public sector for the coordination and execution of projects. The disbursements of these grant payments are partly carried out at the beginning of the project phases. The grant payments are allocated to the actual expenses incurred and are distributed over deferred income. As in the previous year, deferred income contains these deferred grant payments. The grants include the compensation of direct costs and a lumpsum compensation for overhead costs with an amount of 25% of the incurred direct costs.

Obligations arising from the use of property, plant and equipment not shown in the balance sheet

	of the following financial year EUR	of the following five financial years EUR
Obligations from rental agreements	121,807.00	609,036.00
Previous year	*115.677.00*	*578,385.00*
Total	121,807.00	609,036.00
Previous year	*115,677.00*	*563,357.40*

2. Explanations for the profit and loss account

The profit and loss account was prepared according to the total cost method.

Breakdown of sales

Composition and development of revenues:

	2022 EUR	2021 EUR
Revenues		
Membership fees	1,898,053.76	1,872,513.35
Project revenue	1,852,583.44	1,150,882.41
other revenues	170,286.13	269,512.52
	3,920,923.33	3,292,908.28

3. Expenses for the auditor

The expenses for the auditor attributable to the financial year amount to EUR 5,000 (previous year: EUR 8,800) and relate exclusively to audit services.

C. Other Information

1. Organs and employees of society

In the financial year, the following person acted as Managing Director:

Jens Habermann since 2020-09-01

The average number of employees during the financial year 2022 is 35 (previous year: 26).

2. Other information

COVID-19 pandemic has a direct impact on the environment of BBMRI-ERIC. The management took appropriate measures with the implementation of homeoffice options for employees.

The format of the annual conference (Europe Biobank Week) was modified. All national and international travels to meetings and conferences were suspended and the resources were channelled towards online activities, like webinars and online workshops. The acquisition of new projects and work on current projects will be continued. As a European research infrastructure for biobanking, BBMRI-ERIC received some additional funding from the EU Commission in projects related to COVID-19 research. The management conducts an ongoing review of the current situation and the possible impacts to the association.

Furthermore, BBMRI-ERIC continuously monitors the crisis between Russia and Ukraine and evaluates the potential impact on the organization's business and assets on a regular basis. From today's perspective, no material effects are expected for BBMRI-ERIC.

In summary there are no material financial impacts on the association resulting from the COVID-19 pandemic or the Ukraine crisis. Therefore, at the time of preparing the financial statements, these both crises do not lead to any uncertainties regarding the going concern assumption.

.....
14. April 2023, Jens Habermann

Summary of Fixed Assets

BBMRI-ERIC

as per December 31, 2022

		Purchase/historical costs					accumulated depreciations					Carrying values	
		Status 2022-01-01 EUR	Additions EUR	Disposals EUR	Repostings EUR	Status 2022-12-31 EUR	Status 2022-01-01 EUR	Depreciations EUR	Write-ups EUR	Disposals EUR	Status 2022-12-31 EUR	Status 2022-01-01 EUR	Status 2022-12-31 EUR
A.	Fixed assets												
I.	Intangible assets												
1.	Software	126,178.01	0.00	0.00	0.00	126,178.01	34,258.00	22,980.00	0.00	0.00	57,238.00	91,920.01	68,940.01
II.	Tangible assets												
1.	Tools and equipment	198,793.52	25,501.69	2,880.50	0.00	221,414.71	156,902.91	29,614.85	0.00	2,880.50	183,637.26	41,890.61	37,777.45
		324,971.53	**25,501.69**	**2,880.50**	**0.00**	**347,592.72**	**191,160.91**	**52,594.85**	**0.00**	**2,880.50**	**240,875.26**	**133,810.62**	**106,717.46**

KAMMER DER STEUERBERATER UND WIRTSCHAFTSPRÜFER

General Conditions of Contract for the Public Accounting Professions (AAB 2018)

Recommended for use by the Board of the Chamber of Tax Advisers and Auditors, last recommended in its decision of April 18, 2018

Preamble and General Items

(1) Contract within the meaning of these Conditions of Contract refers to each contract on services to be rendered by a person entitled to exercise profession in the field of public accounting exercising that profession (de facto activities as well as providing or performing legal transactions or acts, in each case pursuant to Sections 2 or 3 Austrian Public Accounting Professions Act (WTBG 2017). The parties to the contract shall hereinafter be referred to as the "contractor" on the one hand and the "client" on the other hand).

(2) The General Conditions of Contract for the professions in the field of public accounting are divided into two sections: The Conditions of Section I shall apply to contracts where the agreeing of contracts is part of the operations of the client's company (entrepreneur within the meaning of the Austrian Consumer Protection Act. They shall apply to consumer business under the Austrian Consumer Protection Act (Federal Act of March 8, 1979 / Federal Law Gazette No. 140 as amended) insofar as Section II does not provide otherwise for such business.

(3) In the event that an individual provision is void, the invalid provision shall be replaced by a valid provision that is as close as possible to the desired objective.

SECTION I

1. Scope and Execution of Contract

(1) The scope of the contract is generally determined in a written agreement drawn up between the client and the contractor. In the absence of such a detailed written agreement, (2)-(4) shall apply in case of doubt:

(2) When contracted to perform tax consultation services, consultation shall consist of the following activities:
a) preparing annual tax returns for income tax and corporate tax as well as value-added tax (VAT) on the basis of the financial statements and other documents and papers required for taxation purposes and to be submitted by the client or (if so agreed) prepared by the contractor. Unless explicitly agreed otherwise, documents and papers required for taxation purposes shall be produced by the client.
b) examining the tax assessment notices for the tax returns mentioned under a).
c) negotiating with the fiscal authorities in connection with the tax returns and notices mentioned under a) and b).
d) participating in external tax audits and assessing the results of external tax audits with regard to the taxes mentioned under a).
e) participating in appeal procedures with regard to the taxes mentioned under a).
If the contractor receives a flat fee for regular tax consultation, in the absence of written agreements to the contrary, the activities mentioned under d) and e) shall be invoiced separately.

(3) Provided the preparation of one or more annual tax return(s) is part of the contract accepted, this shall not include the examination of any particular accounting conditions nor the examination of whether all relevant concessions, particularly those with regard to value added tax, have been utilized, unless the person entitled to exercise the profession can prove that he/she has been commissioned accordingly.

(4) In each case, the obligation to render other services pursuant to Sections 2 and 3 WTBG 2017 requires for the contractor to be separately and verifiably commissioned.

(5) The aforementioned paragraphs (2) to (4) shall not apply to services requiring particular expertise provided by an expert.

(6) The contractor is not obliged to render any services, issue any warnings or provide any information beyond the scope of the contract.

(7) The contractor shall have the right to engage suitable staff and other performing agents (subcontractors) for the execution of the contract as well as to have a person entitled to exercise the profession substitute for him/her in executing the contract. Staff within the meaning of these Conditions of Contract refers to all persons who support the contractor in his/her operating activities on a regular or permanent basis, irrespective of the type of underlying legal transaction.

(8) In rendering his/her services, the contractor shall exclusively take into account Austrian law; foreign law shall only be taken into account if this has been explicitly agreed upon in writing.

(9) Should the legal situation change subsequent to delivering a final professional statement passed on by the client orally or in writing, the contractor shall not be obliged to inform the client of changes or of the consequences thereof. This shall also apply to the completed parts of a contract.

(10) The client shall be obliged to make sure that the data made available by him/her may be handled by the contractor in the course of rendering the services. In this context, the client shall particularly but not exclusively comply with the applicable provisions under data protection law and labor law.

(11) Unless explicitly agreed otherwise, if the contractor electronically submits an application to an authority, he/she acts only as a messenger and this does not constitute a declaration of intent or knowledge attributable to him/her or a person authorized to submit the application.

(12) The client undertakes not to employ persons that are or were staff of the contractor during the contractual relationship, during and within one year after termination of the contractual relationship, either in his/her company or in an associated company, failing which he/she shall be obliged to pay the contractor the amount of the annual salary of the member of staff taken over.

2. Client's Obligation to Provide Information and Submit Complete Set of Documents

(1) The client shall make sure that all documents required for the execution of the contract be placed without special request at the disposal of the contractor at the agreed date, and in good time if no such date has been agreed, and that he/she be informed of all events and circumstances which may be of significance for the execution of the contract. This shall also apply to documents, events and circumstances which become known only after the contractor has commenced his/her work.

(2) The contractor shall be justified in regarding information and documents presented to him/her by the client, in particular figures, as correct and complete and to base the contract on them. The contractor shall not be obliged to identify any errors unless agreed separately in writing. This shall particularly apply to the correctness and completeness of bills. However, he/she is obliged to inform the client of any errors identified by him/her. In case of financial criminal proceedings he/she shall protect the rights of the client.

(3) The client shall confirm in writing that all documents submitted, all information provided and explanations given in the context of audits, expert opinions and expert services are complete.

(4) If the client fails to disclose considerable risks in connection with the preparation of financial statements and other statements, the contractor shall not be obliged to render any compensation insofar as these risks materialize.

(5) Dates and time schedules stated by the contractor for the completion of the contractor's products or parts thereof are best estimates and, unless otherwise agreed in writing, shall not be binding. The same applies to any estimates of fees: they are prepared to best of the contractor's knowledge; however, they shall always be non-binding.

(6) The client shall always provide the contractor with his/her current contact details (particularly the delivery address). The contractor may rely on the validity of the contact details most recently provided by the client, particularly have deliveries made to the most recently provided address, until such time as new contact details are provided.

3. Safeguarding of Independence

(1) The client shall be obliged to take all measures to prevent that the independence of the staff of the contractor be jeopardized and shall himself/herself refrain from jeopardizing their independence in any way. In particular, this shall apply to offers of employment and to offers to accept contracts on their own account.

(2) The client acknowledges that his/her personal details required in this respect, as well as the type and scope of the services, including the performance period agreed between the contractor and the client for the services (both audit and non-audit services), shall be handled within a network (if any) to which the contractor belongs, and for this purpose transferred to the other members of the network including abroad for the purpose of examination of the existence of grounds of bias or grounds for exclusion and conflicts of interest. For this purpose the client expressly releases the contractor in accordance with the Data Protection Act and in accordance with Section 80 (4) No. 2 WTBG 2017 from his/her obligation to maintain secrecy. The client can revoke the release from the obligation to maintain secrecy at any time.

4. Reporting Requirements

(1) (Reporting by the contractor) In the absence of an agreement to the contrary, a written report shall be drawn up in the case of audits and expert opinions.

(2) (Communication to the client) All contract-related information and opinions, including reports, (all declarations of knowledge) of the contractor, his/her staff, other performing agents or substitutes ("professional statements") shall only be binding provided they are set down in writing. Professional statements in electronic file formats which are made, transferred or confirmed by fax or e-mail or using similar types of electronic communication (that can be stored and reproduced but is not oral, i.e. e.g. text messages but not telephone) shall be deemed as set down in writing; this shall only apply to professional statements. The client bears the risk that professional statements may be issued by persons not entitled to do so as well as the transfer risk of such professional statements.

(3) (Communication to the client) The client hereby consents to the contractor communicating with the client (e.g. by e-mail) in an unencrypted manner. The client declares that he/she has been informed of the risks arising from the use of electronic communication (particularly access to, maintaining secrecy of, changing of messages in the course of transfer). The contractor, his/her staff, other performing agents or substitutes are not liable for any losses that arise as a result of the use of electronic means of communication.

(4) (Communication to the contractor) Receipt and forwarding of information to the contractor and his/her staff are not always guaranteed when the telephone is used, in particular in conjunction with automatic telephone answering systems, fax, e-mail and other types of electronic communication. As a result, instructions and important information shall only be deemed to have been received by the contractor provided they are also received physically (not by telephone, orally or electronically), unless explicit confirmation of receipt is provided in individual instances. Automatic confirmation that items have been transmitted and read shall not constitute such explicit confirmations of receipt. This shall apply in particular to the transmission of decisions and other information relating to deadlines. As a result, critical and important notifications must be sent to the contractor by mail or courier. Delivery of documents to staff outside the firm's offices shall not count as delivery.

(5) (General) In writing shall mean, insofar as not otherwise laid down in Item 4. (2), written form within the meaning of Section 886 Austrian Civil Code (ABGB) (confirmed by signature). An advanced electronic signature (Art. 26 eIDAS Regulation (EU) No. 910/2014) fulfills the requirement of written form within the meaning of Section 886 ABGB (confirmed by signature) insofar as this is at the discretion of the parties to the contract.

(6) (Promotional information) The contractor will send recurrent general tax law and general commercial law information to the client electronically (e.g. by e-mail). The client acknowledges that he/she has the right to object to receiving direct advertising at any time.

5. Protection of Intellectual Property of the Contractor

(1) The client shall be obliged to ensure that reports, expert opinions, organizational plans, drafts, drawings, calculations and the like, issued by the contractor, be used only for the purpose specified in the contract (e.g. pursuant to Section 44 (3) Austrian Income Tax Act 1988). Furthermore, professional statements made orally or in writing by the contractor may be passed on to a third party for use only with the written consent of the contractor.

(2) The use of professional statements made orally or in writing by the contractor for promotional purposes shall not be permitted; a violation of this provision shall give the contractor the right to terminate without notice to the client all contracts not yet executed.

(3) The contractor shall retain the copyright on his/her work. Permission to use the work shall be subject to the written consent by the contractor.

6. Correction of Errors

(1) The contractor shall have the right and shall be obliged to correct all errors and inaccuracies in his/her professional statement made orally or in writing which subsequently come to light and shall be obliged to inform the client thereof without delay. He/she shall also have the right to inform a third party acquainted with the original professional statement of the change.

(2) The client has the right to have all errors corrected free of charge if the contractor can be held responsible for them; this right will expire six months after completion of the services rendered by the contractor and/or – in cases where a written professional statement has not been delivered – six months after the contractor has completed the work that gives cause to complaint.

(3) If the contractor fails to correct errors which have come to light, the client shall have the right to demand a reduction in price. The extent to which additional claims for damages can be asserted is stipulated under Item 7.

7. Liability

(1) All liability provisions shall apply to all disputes in connection with the contractual relationship, irrespective of the legal grounds. The contractor is liable for losses arising in connection with the contractual relationship (including its termination) only in case of willful intent and gross negligence. The applicability of Section 1298 2nd Sentence ABGB is excluded.

(2) In cases of gross negligence, the maximum liability for damages due from the contractor is tenfold the minimum insurance sum of the professional liability insurance according to Section 11 WTBG 2017 as amended.

(3) The limitation of liability pursuant to Item 7. (2) refers to the individual case of damages. The individual case of damages includes all consequences of a breach of duty regardless of whether damages arose in one or more consecutive years. In this context, multiple acts or failures to act that are based on the same or similar source of error as one consistent breach of duty if the matters concerned are legally and economically connected. Single damages remain individual cases of damage even if they are based on several breaches of duty. Furthermore, the contractor's liability for loss of profit as well as collateral, consequential, incidental or similar losses is excluded in case of willful damage.

(4) Any action for damages may only be brought within six months after those entitled to assert a claim have gained knowledge of the damage, but no later than three years after the occurrence of the (primary) loss following the incident upon which the claim is based, unless other statutory limitation periods are laid down in other legal provisions.

(5) Should Section 275 Austrian Commercial Code (UGB) be applicable (due to a criminal offense), the liability provisions contained therein shall apply even in cases where several persons have participated in the execution of the contract or where several activities requiring compensation have taken place and irrespective of whether other participants have acted with intent.

(6) In cases where a formal auditor's report is issued, the applicable limitation period shall commence no later than at the time the said auditor's report was issued.

(7) If activities are carried out by enlisting the services of a third party, e.g. a data-processing company, any warranty claims and claims for damages which arise against the third party according to law and contract shall be deemed as having been passed on to the client once the client has been informed of them. Item 4. (3) notwithstanding, in such a case the contractor shall only be liable for fault in choosing the third party.

(8) The contractor's liability to third parties is excluded in any case. If third parties come into contact with the contractor's work in any manner due to the client, the client shall expressly clarify this fact to them. Insofar as such exclusion of liability is not legally permissible or a liability to third parties has been assumed by the contractor in exceptional cases, these limitations of liability shall in any case also apply to third parties on a subsidiary basis. In any case, a third party cannot raise any claims that go beyond any claim raised by the client. The maximum sum of liability shall be valid only once for all parties injured, including the compensation claims of the client, even if several persons (the client and a third party or several third parties) have sustained losses; the claims of the parties injured shall be satisfied in the order in which the claims have been raised. The client will indemnify and hold harmless the contractor and his/her staff against any claims by third parties in connection with professional statements made orally or in writing by the contractor and passed on to these third parties.

(9) Item 7. shall also apply to any of the client's liability claims to third parties (performing agents and vicarious agents of the contractor) and to substitutes of the contractor relating to the contractual relationship.

8. Secrecy, Data Protection

(1) According to Section 80 WTBG 2017 the contractor shall be obliged to maintain secrecy in all matters that become known to him/her in connection with his/her work for the client, unless the client releases him/her from this duty or he/she is bound by law to deliver a statement.

(2) Insofar as it is necessary to pursue the contractor's claims (particularly claims for fees) or to dispute claims against the contractor (particularly claims for damages raised by the client or third parties against the contractor), the contractor shall be released from his/her professional obligation to maintain secrecy.

(3) The contractor shall be permitted to hand on reports, expert opinions and other written statements pertaining to the results of his/her services to third parties only with the permission of the client, unless he/she is required to do so by law.

(4) The contractor is a data protection controller within the meaning of the General Data Protection Regulation ("GDPR") with regard to all personal data processed under the contract. The contractor is thus authorized to process personal data entrusted to him/her within the limits of the contract. The material made available to the contractor (paper and data carriers) shall generally be handed to the client or to third parties appointed by the client after the respective rendering of services has been completed, or be kept and destroyed by the contractor if so agreed. The contractor is authorized to keep copies thereof insofar as he/she needs them to appropriately document his/her services or insofar as it is required by law or customary in the profession.

(5) If the contractor supports the client in fulfilling his/her duties to the data subjects arising from the client's function as data protection controller, the contractor shall be entitled to charge the client for the actual efforts undertaken. The same shall apply to efforts undertaken for information with regard to the contractual relationship which is provided to third parties after having been released from the obligation to maintain secrecy to third parties by the client.

9. Withdrawal and Cancellation („Termination")

(1) The notice of termination of a contract shall be issued in writing (see also Item 4. (4) and (5)). The expiry of an existing power of attorney shall not result in a termination of the contract.

(2) Unless otherwise agreed in writing or stipulated by force of law, either contractual partner shall have the right to terminate the contract at any time with immediate effect. The fee shall be calculated according to Item 11.

(3) However, a continuing agreement (fixed-term or open-ended contract on – even if not exclusively – the rendering of repeated individual services, also with a flat fee) may, without good reason, only be terminated at the end of the calendar month by observing a period of notice of three months, unless otherwise agreed in writing.

(4) After notice of termination of a continuing agreement and unless otherwise stipulated in the following, only those individual tasks shall still be completed by the contractor (list of assignments to be completed) that can (generally) be completed fully within the period of notice insofar as the client is notified in writing within one month after commencement of the termination notice period within the meaning of Item 4. (2). The list of assignments to be completed shall be completed within the termination period if all documents required are provided without delay and if no good reason exists that impedes completion.

(5) Should it happen that in case of a continuing agreement more than two similar assignments which are usually completed only once a year (e.g. financial statements, annual tax returns, etc.) are to be completed, any such assignments exceeding this number shall be regarded as assignments to be completed only with the client's explicit consent. If applicable, the client shall be informed of this explicitly in the statement pursuant to Item 9. (4).

10. Termination in Case of Default in Acceptance and Failure to Cooperate on the Part of the Client and Legal Impediments to Execution

(1) If the client defaults on acceptance of the services rendered by the contractor or fails to carry out a task incumbent on him/her either according to Item 2. or imposed on him/her in another way, the contractor shall have the right to terminate the contract without prior notice. The same shall apply if the client requests a way to execute (also partially) the contract that the contractor reasonably believes is not in compliance with the legal situation or professional principles. His/her fees shall be calculated according to Item 11. Default in acceptance or failure to cooperate on the part of the client shall also justify a claim for compensation made by the contractor for the extra time and labor hereby expended as well as for the damage caused, if the contractor does not invoke his/her right to terminate the contract.

(2) For contracts concerning bookkeeping, payroll accounting and administration and assessment of payroll-related taxes and contributions, a termination without prior notice by the contractor is permissible under Item 10. (1) if the client verifiably fails to cooperate twice as laid down in Item 2. (1).

11. Entitlement to Fee

(1) If the contract fails to be executed (e.g. due to withdrawal or cancellation), the contractor shall be entitled to the negotiated compensation (fee), provided he/she was prepared to render the services and was prevented from so doing by circumstances caused by the client, whereby a merely contributory negligence by the contractor in this respect shall be excluded; in this case the contractor need not take into account the amount he/she obtained or failed to obtain through alternative use of his/her own professional services or those of his/her staff.

(2) If a continuing agreement is terminated, the negotiated compensation for the list of assignments to be completed shall be due upon completion or in case completion fails due to reasons attributable to the client (reference is made to Item 11. (1). Any flat fees negotiated shall be calculated according to the services rendered up to this point.

(3) If the client fails to cooperate and the assignment cannot be carried out as a result, the contractor shall also have the right to set a reasonable grace period on the understanding that, if this grace period expires without results, the contract shall be deemed ineffective and the consequences indicated in Item 11. (1) shall apply.

(4) If the termination notice period under Item 9. (3) is not observed by the client as well as if the contract is terminated by the contractor in accordance with Item 10. (2), the contractor shall retain his/her right to receive the full fee for three months.

12. Fee

(1) Unless the parties explicitly agreed that the services would be rendered free of charge, an appropriate remuneration in accordance with Sections 1004 and 1152 ABGB is due in any case. Amount and type of the entitlement to the fee are laid down in the agreement negotiated between the contractor and his/her client. Unless a different agreement has verifiably been reached, payments made by the client shall in all cases be credited against the oldest debt.

(2) The smallest service unit which may be charged is a quarter of an hour.

(3) Travel time to the extent required is also charged.

(4) Study of documents which, in terms of their nature and extent, may prove necessary for preparation of the contractor in his/her own office may also be charged as a special item.

(5) Should a remuneration already agreed upon prove inadequate as a result of the subsequent occurrence of special circumstances or due to special requirements of the client, the contractor shall notify the client thereof and additional negotiations for the agreement of a more suitable remuneration shall take place (also in case of inadequate flat fees).

(6) The contractor includes charges for supplementary costs and VAT in addition to the above, including but not limited to the following (7) to (9):

(7) Chargeable supplementary costs also include documented or flat-rate cash expenses, traveling expenses (first class for train journeys), per diems, mileage allowance, copying costs and similar supplementary costs.

(8) Should particular third party liabilities be involved, the corresponding insurance premiums (including insurance tax) also count as supplementary costs.

(9) Personnel and material expenses for the preparation of reports, expert opinions and similar documents are also viewed as supplementary costs.

(10) For the execution of a contract wherein joint completion involves several contractors, each of them will charge his/her own compensation.

(11) In the absence of any other agreements, compensation and advance payments are due immediately after they have been requested in writing. Where payments of compensation are made later than 14 days after the due date, default interest may be charged. Where mutual business transactions are concerned, a default interest rate at the amount stipulated in Section 456 1st and 2nd Sentence UGB shall apply.

(12) Statutory limitation is in accordance with Section 1486 of ABGB, with the period beginning at the time the service has been completed or upon the issuing of the bill within an appropriate time limit at a later point.

(13) An objection may be raised in writing against bills presented by the contractor within 4 weeks after the date of the bill. Otherwise the bill is considered as accepted. Filing of a bill in the accounting system of the recipient is also considered as acceptance.

(14) Application of Section 934 ABGB within the meaning of Section 351 UGB, i.e. rescission for laesio enormis (lesion beyond moiety) among entrepreneurs, is hereby renounced.

(15) If a flat fee has been negotiated for contracts concerning bookkeeping, payroll accounting and administration and assessment of payroll-related taxes and contributions, in the absence of written agreements to the contrary, representation in matters concerning all types of tax audits and audits of payroll-related taxes and social security contributions including settlements concerning tax assessments and the basis for contributions, preparation of reports, appeals and the like shall be invoiced separately. Unless otherwise agreed to in writing, the fee shall be considered agreed upon for one year at a time.

(16) Particular individual services in connection with the services mentioned in Item 12. (15), in particular ascertaining whether the requirements for statutory social security contributions are met, shall be dealt with only on the basis of a specific contract.

(17) The contractor shall have the right to ask for advance payments and can make delivery of the results of his/her (continued) work dependent on satisfactory fulfillment of his/her demands. As regards continuing agreements, the rendering of further services may be denied until payment of previous services (as well as any advance payments under Sentence 1) has been effected. This shall analogously apply if services are rendered in installments and fee installments are outstanding.

(18) With the exception of obvious essential errors, a complaint concerning the work of the contractor shall not justify even only the partial retention of fees, other compensation, reimbursements and advance payments (remuneration) owed to him/her in accordance with Item 12.

(19) Offsetting the remuneration claims made by the contractor in accordance with Item 12. shall only be permitted if the demands are uncontested and legally valid.

13. Other Provisions

(1) With regard to Item 12. (17), reference shall be made to the legal right of retention (Section 471 ABGB, Section 369 UGB); if the right of retention is wrongfully exercised, the contractor shall generally be liable pursuant to Item 7. or otherwise only up to the outstanding amount of his/her fee.

(2) The client shall not be entitled to receive any working papiers and similar documents prepared by the contractor in the course of fulfilling the contract. In the case of contract fulfillment using electronic accounting systems the contractor shall be entitled to delete the data after handing over all data based thereon – which were prepared by the contractor in relation to the contract and which the client is obliged to keep – to the client and/or the succeeding public accountant in a structured, common and machine-readable format. The contractor shall be entitled to an appropriate fee (Item 12. shall apply by analogy) for handing over such data in a structured, common and machine-readable format. If handing over such data in a structured, common and machine-readable format is impossible or unfeasible for special reasons, they may be handed over in the form of a full print-out instead. In such a case, the contractor shall not be entitled to receive a fee.

(3) At the request and expense of the client, the contractor shall hand over all documents received from the client within the scope of his/her activities. However, this shall not apply to correspondence between the contractor and his/her client and to original documents in his/her possession and to documents which are required to be kept in accordance with the legal anti-money laundering provisions applicable to the contractor. The contractor may make copies or duplicates of the documents to be returned to the client. Once such documents have been transferred to the client, the contractor shall be entitled to an appropriate fee (Item 12. shall apply by analogy).

(4) The client shall fetch the documents handed over to the contractor within three months after the work has been completed. If the client fails to do so, the contractor shall have the right to return them to the client at the cost of the client or to charge an appropriate fee (Item 12. shall apply by analogy) if the contractor can prove that he/she has asked the client twice to pick up the documents handed over. The documents may also further be kept by third parties at the expense of the client. Furthermore, the contractor is not liable for any consequences arising from damage, loss or destruction of the documents.

(5) The contractor shall have the right to compensation of any fees that are due by use of any available deposited funds, clearing balances, trust funds or other liquid funds at his/her disposal, even if these funds are explicitly intended for safekeeping, if the client had to have anticipated the counterclaim of the contractor.

(6) To secure an existing or future fee payable, the contractor shall have the right to transfer a balance held by the client with the tax office or another balance held by the client in connection with charges and contributions, to a trust account. In this case the client shall be informed of the transfer. Subsequently, the amount secured may be collected either after agreement has been reached with the client or after enforceability of the fee by execution has been declared.

14. Applicable Law, Place of Performance, Jurisdiction

(1) The contract, its execution and the claims resulting from it shall be exclusively governed by Austrian law, excluding national referral rules.

(2) The place of performance shall be the place of business of the contractor.

(3) In absence of a written agreement stipulating otherwise, the place of jurisdiction is the competent court of the place of performance.

SECTION II

15. Supplementary Provisions for Consumer Transactions

(1) Contracts between public accountants and consumers shall fall under the obligatory provisions of the Austrian Consumer Protection Act (KSchG).

(2) The contractor shall only be liable for the willful and grossly negligent violation of the obligations assumed.

(3) Contrary to the limitation laid down in Item 7. (2), the duty to compensate on the part of the contractor shall not be limited in case of gross negligence.

(4) Item 6. (2) (period for right to correction of errors) and Item 7. (4) (asserting claims for damages within a certain period) shall not apply.

(5) Right of Withdrawal pursuant to Section 3 KSchG:

If the consumer has not made his/her contract statement in the office usually used by the contractor, he/she may withdraw from the contract application or the contract proper. This withdrawal may be declared until the contract has been concluded or within one week after its conclusion; the period commences as soon as a document has been handed over to the consumer which contains at least the name and the address of the contractor as well as instructions on the right to withdraw from the contract, but no earlier than the conclusion of the contract. The consumer shall not have the right to withdraw from the contract

1. if the consumer himself/herself established the business relationship concerning the conclusion of this contract with the contractor or his/her representative,

2. if the conclusion of the contract has not been preceded by any talks between the parties involved or their representatives, or

3. in case of contracts where the mutual services have to be rendered immediately, if the contracts are usually concluded outside the offices of the contractors, and the fee agreed upon does not exceed €15.

In order to become legally effective, the withdrawal shall be declared in writing. It is sufficient if the consumer returns a document that contains his/her contract declaration or that of the contractor to the contractor with a note which indicates that the consumer rejects the conclusion or the maintenance of the contract. It is sufficient if this declaration is dispatched within one week.

If the consumer withdraws from the contract according to Section 3 KSchG,

1. the contractor shall return all benefits received, including all statutory interest, calculated from the day of receipt, and compensate the consumer for all necessary and useful expenses incurred in this matter,

2. the consumer shall pay for the value of the services rendered by the contractor as far as they are of a clear and predominant benefit to him/her.

According to Section 4 (3) KSchG, claims for damages shall remain unaffected.

(6) Cost Estimates according to Section 5 Austrian KSchG:

The consumer shall pay for the preparation of a cost estimate by the contractor in accordance with Section 1170a ABGB only if the consumer has been notified of this payment obligation beforehand.

If the contract is based on a cost estimate prepared by the contractor, its correctness shall be deemed warranted as long as the opposite has not been explicitly declared.

(7) Correction of Errors: Supplement to Item 6.:

If the contractor is obliged under Section 932 ABGB to improve or complement his/her services, he/she shall execute this duty at the place where the matter was transferred. If it is in the interest of the consumer to have the work and the documents transferred by the contractor, the consumer may carry out this transfer at his/her own risk and expense.

(8) Jurisdiction: Shall apply instead of Item 14. (3)

If the domicile or the usual residence of the consumer is within the country or if he/she is employed within the country, in case of an action against him/her according to Sections 88, 89, 93 (2) and 104 (1) Austrian Court Jurisdiction Act (JN), the only competent courts shall be the courts of the districts where the consumer has his/her domicile, usual residence or place of employment.

(9) Contracts on Recurring Services:

(a) Contracts which oblige the contractor to render services and the consumer to effect repeated payments and which have been concluded for an indefinite period or a period exceeding one year may be terminated by the consumer at the end of the first year, and after the first year at the end of every six months, by adhering to a two-month period of notice.

(b) If the total work is regarded as a service that cannot be divided on account of its character, the extent and price of which is determined already at the conclusion of the contract, the first date of termination may be postponed until the second year has expired. In case of such contracts the period of notice may be extended to a maximum of six months.

(c) If the execution of a certain contract indicated in lit. a) requires considerable expenses on the part of the contractor and if he/she informed the consumer about this no later than at the time the contract was concluded, reasonable dates of termination and periods of notice which deviate from lit. a) and b) and which fit the respective circumstances may be agreed.

(d) If the consumer terminates the contract without complying with the period of notice, the termination shall become effective at the next termination date which follows the expiry of the period of notice.

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