BBMRI-ERIC®

Work Programme

Contents

42 Central Services & Functions

70 Appendix

01

Executive Summary

For the first time, BBMRI-ERIC's Work Programme has been designed for a three-year period (2022 - 2024).

This allows BBMRI-ERIC to shape its future direction of development and growth in a more strategic and long-term manner, reflecting the needs of our Members. We will also be able to approach our strategic cooperations and to position BBMRI in the European biobanking, health and life science landscape with a longer-term vision.

With this in mind, we will maintain our coordinating role of the ERIC Forum and expand our partnerships within current and future Life Science Research Infrastructures, most notably EU-AMRI, using synergies across health Research Infrastructures. Being a full member of the EOSC Association will allow us to accelerate our service provision and developments substantially, in line with the visions of EOSC, the European Open Data Space, and the European Health Data Space. Hereby, we will continue to focus on the requirements for digitalisation and open science that are relevant for sensitive data management in the health research sector. Moreover, we will contribute to the realisation of precision medicine through a focused research agenda in line with the Mission for Cancer and the 1+Million Genomes Initiative. Our research will address foremost disease areas of cancer, rare diseases, COVID-19 and infectious diseases as well as paediatric diseases while leveraging the potential of novel technologies. This will enable BBMRI to further strengthen its role as a reliable partner and a source of knowledge for addressing the key challenges in health and data sectors that Europe is facing today.

Legend:
- ● Members of BBMRI-ERIC
- ● Observers of BBMRI-ERIC

To achieve these goals, we will conscientiously account for a continued stringent alignment of core and project activities in the coming years in order to foster synergies where possible, to close structural gaps where needed, and to free resources for additional fundamental objectives. BBMRI's value proposition will further excel through an intensified Community Engagement as overarching goal to leverage our community's full potential: starting with our various governing boards, Member States, Observers and National Nodes and affiliated biobank networks, we will reach out further towards BBMRI's various stakeholder groups. This Community Engagement will allow for higher visibility, increased service provision for samples, data and biomolecular resources and novel service value-chains. Networks through our National Nodes, Stakeholder Forum Pillars and Expert Centres together with the refined scope of Outreach, Education & Communications and the reinforcement of Public Affairs will serve as a basis for this overarching goal.

BBMRI Operations

Scientific Affairs

ELSI

IT

QM

Biobank Development

Public Affairs

Today, BBMRI's infrastructure with 23 EU Member States and the International Agency for Research on Cancer (IARC) forms one of the largest health Research Infrastructures in Europe.

" BBMRI's mission is to establish, operate and develop a pan-European distributed research infrastructure of biobanks and biomolecular resources to facilitate the access to resources as well as facilities and to support high-quality biomolecular and medical research."

Central Services & Functions

Finance & Project Management

Outreach, Education Communication

BBMRI has increasingly facilitated sample and data access through our network of National Nodes and biobanks, successfully offering a growing portfolio of services and trainings on ELSI, QM, IT and Biobanking Development, including the successful initiation of a BBMRI Academy offering CME accredited courses. Addressing current needs and EU Framework Programme calls related to, e.g., the COVID-19 pandemic and the Cancer Mission was and is effective in all our core activities as a united effort by our biobanks, National Nodes and Headquarters. In parallel, more than 20 key H2020 projects will continue and further corroborate BBMRI's developments towards BBMRI's future sustainability.

ELSI Services & Research will be a continued backbone of BBMRI. Its service portfolio includes most notably the _Knowledge Base_ and _Helpdesk_, ensuring state-of-the-art guidance and trainings by building on excellence in research. A specific emphasis will remain the development of the _Code of Conduct for Health Research_, which contributes to clarity in GDPR compliance for the health research sector. Based on user feedback, workshops and trainings will further intensify and therewith contribute to our overarching Community Engagement goals.
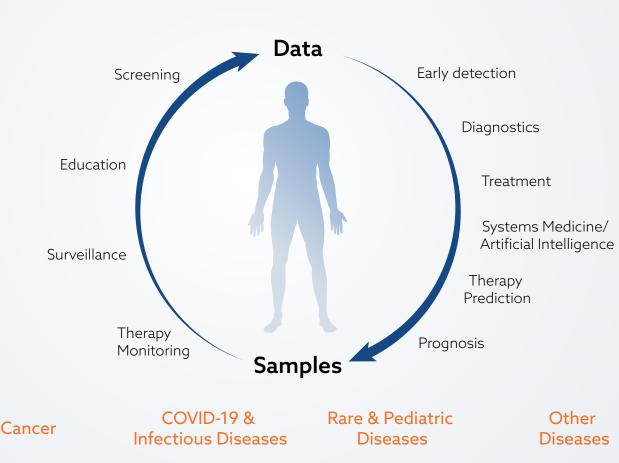
Quality Management Services & Research will further expand on their four pillar activities - _Knowledge Hub, Training/ Support, Auditing and Quality Assurance_,

the latter entailing the definition of quality markers and conceptualization of a proficiency testing programme focusing on liquid biopsies. QM activities will expand towards data quality, the BBMRI.QM Training Curriculum, and the BBMRI Academy, hereby substantially contributing to an intensified Community Engagement. The Headquarters' operations will be further developed according to quality management criteria to streamline and continuously improve our expanding service.

IT Services & Research including **Common Service IT** was restructured and relaunched in 2020. Its key topics will be further developed in 2022 - 2024 including the _Directory_, _Negotiator_, and Helpdesk.

In addition, BBMRI will continue to strengthen its digitalization portfolio by (i) the initiated federated search and analysis platform for sample-level and patient-/donor-level data, (ii) data quality and certification, (iii) expedited access procedures for samples & data, (iv) data pooling, and (v) big data analysis. Furthermore, we will increasingly focus on data of biomolecular resources service provision in line with the development of Transnational and Virtual Access (TNA) within current and future EU grants. These topics will be continuously addressed though an intensified alignment between Common Service IT and the 2021 initiated Task Forces, thereby adding to our overarching Community Engagement activities.

Biobanking Development Services & Research has been newly formed to assist the BBMRI community towards long-term sustainability of both National Nodes and biobanks. Ensuring continued return of investment is becoming a key target for countries investing significant resources to create National Nodes and networks. Thus, sustainability concepts need to be accounted for along the entire maturation phase of National Nodes and biobanks. Hereby, facilitating accelerated sample and data exchange will be aligned with fostering Community Engagement and leveraging novel technology applications.

BBMRI-ERIC fosters Personalized Medicine

Data

Screening

Early detection

Diagnostics

Education

Treatment

Systems Medicine/
Artificial Intelligence

Surveillance

Therapy
Prediction

Therapy
Monitoring

Prognosis

Samples

Cancer

COVID-19 &
Infectious Diseases

Rare & Pediatric
Diseases

Other
Diseases

Public Affairs will continue its leading role liaising with other Research Infrastructures, ERICs, EU institutions and international organisations. We will be further positioning BBMRI within broader EU science policy makers, growing BBMRI membership and developing concepts for affiliates outside the EU. By intensifying activities in our *Stakeholder Forum* within the patient, industry and scientific societies pillars, we will seek continued guidance from all our stakeholders. BBMRI is particularly privileged by the close partnership with our excellent patient advocates and their role in BBMRI's decision-making process. We will further intensify our close alliances with our Member States and Observers at ministerial levels as well as expanding our interactions with the European Commission as part of our Community Engagement.

Outreach, Education & Communications will continuously increase the visibility of BBMRI's services and developments. This will be achieved together with our BBMRI community and various stakeholders through intensified Community Engagement activities. Building upon on our community engaging congress and symposia portfolio, we will promote the *BBMRI Academy* while exploring new avenues on network exchange opportunities at the graduate and post-graduate levels. Together with our National Nodes, BBMRI's communications will be streamlined through the new Task Force Communication & Outreach in which we will conceptualize a marketing strategy to commonly conduct outreach activities towards our stakeholders on international and national levels. In line, success stories will be highlighted while consolidating BBMRI's newsletter and website.

Finances & Project Management remains an essential function for accounting, controlling and resource management. It allows long-term planning of financial activities and resources and plays a key role in the strategic decision-making process. With increasing involvement in numerous EU grants, its project management functions will be strengthened for continued sustainability in financial and human resources aspects.

BBMRI's **Central Office** will consolidate the Headquarters management structure, enabling us to provide the best possible services internally and externally. With a growing community, these activities will become of increasing importance for efficient and transparent operations.

The Work Programme for 2022 - 2024 reflects the continued collaboration and guidance by the entire BBMRI community. On behalf of the Headquarters team, I would like to thank our Members and Observers, National Nodes, and members of our governing bodies, as well as our external partners and collaborators in academia, industry and the public for continued collaboration and guidance that allows BBMRI-ERIC to thrive and thereby enables us to serve our communities. Furthermore, I would like to wholeheartedly invite you all to join forces in pursuing our 2022 - 2024 Work Programme together to address our world's current and future challenges in a concerted and most efficient team effort.

Sincerely,

Prof. Jens K. Habermann, M.D., Ph.D.
Director General BBMRI-ERIC

BBMRI-ERIC National Node Directors

Univ.-Prof. Dr. med. Kurt Zatloukal

National Node Director
BBMRI.AT

Prof. Dr. rer. nat. Michael Hummel

National Node Director
BBMRI.DE

Dr. Annelies Debucquoy

National Node Director
BBMRI.BE

Prof. Andres Metspalu

National Node Director
BBMRI.EE

Prof. Radka Kaneva, Ph.D.

National Node Director
BBMRI.BG

Dr. Eva Ortega-Paíno

National Node Director
BBMRI.ES

Dr. Christine Currat

National Node Director
BBMRI.CH

Marco Hautalahti

National Node Director
BBMRI.FI

Dr. Carolina Stylianou

National Node Director
BBMRI.CY

Dr. Dimitris Thanos

National Node Director
BBMRI.GR

Assoc. prof. Roman Hrstka, M.Sc., Ph.D.

National Node Director
BBMRI.CZ

Prof. Dr. Mária Judit Molnár

National Node Director
BBMRI.HU

Prof. Dr. Marialuisa Lavitrano

National Node Director
BBMRI.IT

Dr. Piotr Zień

National Node Director
BBMRI.PL

Dr. Daiva Dabkeviciene

National Node Director
BBMRI.LT

Prof. Tobias Sjöblom

National Node Director
BBMRI.SE

Dr. Vita Rovite

National Node Director
BBMRI.LV

Prof. Dr. Urban Bren

National Node Director
BBMRI.SI

Dr. Nikolai Pace

National Node Director
BBMRI.MT

Prof. Nese Atabey

National Node Director
BBMRI.TR

Prof. Gerrit Meijer

National Node Director
BBMRI.NL

Dr. Phil Quinlan

National Node Director
BBMRI.UK

Prof. Nine Knoers

National Node Director
BBMRI.NL

Dr. Zisis Kozlakidis

National Node Director
IARC

Prof. Kristian Hveem

National Node Director
BBMRI.NO

02

Scientific Affairs for Biobanking & Biomolecular Resources

Scientific Affairs for Biobanking & Biomolecular Resources of BBMRI-ERIC comprises the core services and developments for the BBMRI community: *Ethical, Legal and Societal Issues; Quality; Information Technology;* and *Biobanking Development.*

These are further supported and interlinked with the *Central Services and Functions for Public Affairs; Outreach, Education & Communication; Finance & Project Management* as well as the *Central Office* as described in chapters 3 and 4.

2.1

Ethical, Legal and Societal Issues (ELSI)

To ensure excellence in providing guidance on ethical, legal and societal issues (ELSI), we operate on the basis of a federated model, in partnership with a network of experts from academia and practice from across the Headquarters, the National Nodes and project partners. Focus areas are recognised in collaboration with European and international ELSI experts and based on user needs identified in projects or *ELSI Helpdesk* requests coming from patient advocacy groups, industry partners or biobankers. Our vision remains to deliver reliable, practical and sustainable services based on state-of-the-art research for the immediate benefit of the life sciences community by setting standards, promoting best practices or enabling a sustainable platform for internal and public knowledge exchange.

2.1.1

BBMRI-ERIC ELSI Services

We support the biobanking and Life Science Research Infrastructure communities by facilitating compliance with regulatory requirements, best practice standards and guidance on ethical, legal, and societal issues. We will continue the activities established in previous years (*Knowledge Base*, Trainings, Expert Groups, Dialogue platform, *Helpdesk*, Ethics Check, Ethics Review, *Code of Conduct*), hereby providing a cornerstone to the overarching Community Engagement activities.

Responsible	Deliverable	2022-2024

Headquarters

ELSI TRAININGS, DIALOGUES & EXPERT GROUPS   ONGOING

- Maintain platforms and expert groups for knowledge exchange among Members and Observers

- Identify and address 'hot topics' (e.g., gender, AI, GDPR implementation, vulnerability, sustainability, citizen science and engagement, research ethics committees, public private partnerships, new legislative acts)

- Implement public training activities, workshops, and webinars, etc. in collaboration with projects and National Nodes, where feasible within the context of the BBMRI Academy

ELSI KNOWLEDGE BASE   ONGOING

- Maintain and improve form and function of this open-access resource platform

- Integrate & promote research project outputs

- Establish new content (e.g., 'how to' guides) in collaboration with national ELSI experts

- Ensure accuracy of existing content and sustainability of service

ELSI HELPDESK   ONGOING

- Provide tailored guidance on a case-by-case basis

- Coordinate (joint) responses to *ELSI Helpdesk* requests

- Maintain internal platform for knowledge exchange across national helpdesks

- Promote national *ELSI Helpdesks* and services

ETHICS CHECK   ONGOING

- Review and, when necessary, propose improvements of the compulsory Ethics Self-Assessment section for research proposals (editorial comments prior to submission)

Responsible   Deliverable   2022-2024

Responsible	Deliverable	2022-2024
	ETHICS REVIEW	ONGOING / DEVELOPING
	• Provide ELSI assessment during a running project (review report)	
	CODE OF CONDUCT FOR HEALTH RESEARCH	
	• Launch public consultation	
	• Prepare submission to DPA/EDPB	
National Nodes	**HELPDESK NETWORK, EXPERT GROUPS AND PROJECTS**	ONGOING
	• Nominate ELSI representatives to expert groups et al. and *ELSI Helpdesk* Network	
	• Provide updates on national ethical, legal and societal issues	
	• Contribute to expert groups and transnational *helpdesk* requests based on relevant ELSI expertise	
	• Propose topics, contribute to (co-)organising joint workshops, webinars and debates, in synergy with national activities	
	• Contribute to proposal and project tasks (e.g., as participant, affiliated partner or via secondment)	

ⓘ

Code of Conduct for Health Research

Considering the complexity of the GDPR, a code of conduct as described in articles 40 and 41 (meant as a set of rules, produced from the bottom up and sector-specific) provides a proper instrument to 'translate' into practice the GDPR provisions. As a regulatory instrument, established bottom-up and scrutinised by the stakeholders concerned, BBMRI-ERIC is committed to develop a Code of Conduct for Health Research. The initiative is a non-exclusive one and it is still open to any possible interested organisation (while being interested does not mean to be obliged to endorse the code).

ⓘ

ELSI Knowledge Base

The BBMRI-ERIC ELSI Knowledge Base is an open-access resource platform promoting know-how on ethical, legal, and societal issues relevant to the life sciences, most notably biobanking. The aims of the BBMRI-ERIC ELSI Knowledge Base are (1) close the knowledge gap by providing practical hands-on guidance and promoting practical know-how for researchers, (2) to provide users with a first orientation on the subject matter, (3) as well as allowing them to explore more detailed information if desired in a self-service manner.

ⓘ

ELSI Helpdesk

The ELSI Helpdesk provides guidance in a customised manner. Much of the information generated from the ELSI Helpdesk will also be beneficial to the wider scientific community. As a publicly funded research infrastructure, it is important that any knowledge generated is shared. Therefore, responses issued through the ELSI Helpdesk may be used to feed into the ELSI Knowledge Base for the use and benefit of the life sciences community and society at large.

2.1.2

Complementary ELSI Development in Projects at Current Stage

The following table provides an overview of how currently active research projects are aligned with the overarching ELSI tasks and as such are integrated in core service developments. More information on the distinct project goals is provided in the overview table at the end of this document. Please note that of all ELSI tasks, 40% are covered by BBMRI-ERIC core budget while 60% are based on grant funding.

Table: Interdependencies between core and project tasks and budget

		RESEARCH & DEVELOPMENT	KNOWLEDGE BASE	ETHICS CHECK	ETHICS ADVICE	ETHICS REVIEW	HELPDESK NETWORK	TRAININGS (WORKSHOPS, WEBINARS, ETC.)	GDPR & ETHICAL COMPLIANCE, CONTRACTS	CODE OF CONDUCT
CORE 40% (2,25 FTE)	TASKS	-	OPS	OPS	-	OPS	OPS*	OPS*	DEV & OPS	CODE & DRAFTING
	CY-Biobank	Dev*	Dev	-	Dev*	-	-	Dev*	-	-
	EOSC-Life	Dev*	Dev	Ops	-	-	-	Dev	-	Coor
	CINECA	Dev	Dev	Ops	-	-	-	Dev	-	Coor
	EUCAN-Connect	Dev	Dev	Ops	-	-	-	Dev	-	Coor
	EUCAN-Image	Dev*	Dev*	Ops*	-	-	-	Dev	-	Coor
	EJP RD	-	Dev	-	Dev	-	-	Dev	-	-
	DIAMONDS	-	Dev	-	-	-	-	Dev	-	-
Projects 60%	**B1MG**	-	Dev	-	Dev	-	-	Dev	-	Coor
	Big Picture	Dev*	Dev*	Ops*	Dev*	-	-	Dev	-	-
	EUCAN-Share	-	Dev	-	Dev	-	-	Dev	-	-
	EOSC-Future	-	Dev	Ops	-	-	-	-	-	Coor
	IC2PerMed	-	Dev	-	Dev	-	-	Dev	-	-
	Healthy Cloud	Dev	Dev	Ops	-	-	-	Dev	-	-
	EPND	Dev	Dev	Ops	-	-	-	Dev	-	-
	Intervene	Dev	Dev	Ops	-	-	-	Dev	-	-
	& others to come									

* = National Nodes involvement; Ops = operations; Coor = coordination; Dev = development; FTE = Fulltime Employee

2.1.3

Milestone and Key Performance Indicators by Headquarters

Milestone Q3 / 2022:

Launch public consultation for the Code of Conduct

Key Performance Indicators:

01.   Number of attendees to which training sessions/webinars/workshops/
      talks etc. were provided to advance the knowledge and awareness on
      ELSI standards and their implementation for practice

Current in 2021	Prospect annually 2022-2024
600	1000

02.   Hours of ELSI-related consultancy, guidance and support in advisory
      bodies, projects, *ELSI Helpdesk* and Ethics Check

Current in 2021	Prospect annually 2022-2024
400	600

*** According to BBMRI-ERIC's overarching KPIs for
Headquarters and National Nodes in alignment
with Member States and EU expectations (ESFRI
guidance) to be revisited.*

2.2

Quality Management (QM)

"BBMRI-ERIC has developed a sophisticated QM service and training offer for biobanks. This service covers the most important cornerstones for improving the performance and competence of biobanks and includes a holistic approach of comprehensive quality management systems for the entire biomedical research pipeline."

The main pillars on which BBMRI.QM Service is built are Knowledge - Training - Assurance - Audit; these are kept at the state-of-the-art through continuous improvement. BBMRI biobanks follow this approach with great enthusiasm; however, the continued strong commitment of the biobanks needs to be fully leveraged for all stakeholders' benefit.

The goal in the coming period of BBMRI will be to leverage biobanks as trusted partners for science and development. Biobanks should become the recognised entry portal for high-quality research projects, which is considered a cornerstone of BBMRI's envisioned overarching Community Engagement activities. To achieve this mission, the biobanks will be requested to implement and work according to the principles of the international standard for biobanking (ISO 20387:2018). All QM Services are available for biobanks to reach this goal.

In a first step, biobanks can apply for a BBMRI Quality Label in the BBMRI Directory, which can be awarded after a positive assessment (audit). The audit programme developed by BBMRI is available to be used for this purpose. Highly developed biobanks will also undergo a 3rd-party accreditation in their countries or – if not available – through member countries that host an accreditation body with that specific ISO portfolio; here too, the BBMRI audit programme can be used in preparation.

The established Working Group QMS (WG QMS), consisting of biobank and QM managers from all Member and Observer countries, will provide support and exchange of experience regarding the implementation and assessment of the biobank standards in biobank operations. Tasks defined in the working group will be implemented. Continuous improvement is essential for the sustainable development of biobanks and will be a key priority for the WG QMS. The Working Group QMS will be open for new QM experts to join, thereby fostering and accelerating knowledge exchange and community engagement. Based on the already introduced concept of the BBMRI.QM training, an all-encompassing training offer, covering all biobank-relevant areas and topics, will be further developed.

The QM Service will further develop the BBMRI Headquarters central quality management system (central QMS) based on the principles of ISO 9001:2015 Quality Management Systems.

ⓘ

BBMRI-ERIC SAS

BBMRI-ERIC Self-Assessment Surveys (BBMRI-ERIC SAS) are unique and customized tools for assessing the organizational performance of the biobank operations. It provides biobankers and researchers with an opportunity to self-evaluate biobanking processes based on criteria set by international standards.

ⓘ

BBMRI-ERIC Quality Label

The BBMRI Quality Label indicates that the biobank's operations and processes are quality assured and quality controlled.

ⓘ

Expert Centres

BBMRI-ERIC Expert Centres are trusted partners, responsible for analyzing samples in the country of origin under internationally standardized conditions providing a broad range of medical and scientific expertise related to the samples, data, and their analysis.

2.2.1

BBMRI-ERIC Quality Management (QM) Services

BBMRI-ERIC *Quality Services* will continue to focus on empowering biobankers and researchers through four pillars: information (Knowledge Hub), education (Training & Support), review (Auditing) and a dedicated Quality Assurance Task Force that will continue to conceptualize work on development of novel biomarkers used for quality characterization of various samples.

Knowledge Hub
BBMRI will strengthen the liaison to several ISO Technical Committees (276, 212, 215) as well as CEN 140 to maintain the information flow from standard development to the biobankers and researchers. BBMRI will actively participate in the revision of the biobank standard ISO 20387:2018 in the best interest of the BBMRI biobank community. The revision period started 2021 and will last until end of 2023.

In addition, all QM expertise provided to, and extracted from, EU and scientific projects are shared within the community via the Knowledge Hub. BBMRI will continue the *BBMRI.QM Newsroom* format on biobank quality-related topics, which has been warmly welcomed by the biobank community. The Newsroom gives biobanks the opportunity to showcase their achievements during the year and increases the visibility of our biobanks to an international audience. Ad-hoc webinars are offered when the need arises, following the example of urgent demand for guidance on specific topics such as pandemic outbreaks.

Training & Support
The training offerings for biobanks and biomedical research will be further expanded with, e.g., modular training courses in the field of *molecular in vitro diagnostics* (e.g., tissue-isolated DNA and FFPE in situ detection techniques), method validation and verification. These offerings will be combined in the *BBMRI Academy* and will represent a contribution from QM among all BBMRI Headquarters related services.

Auditing
BBMRI.QM has successfully established an audit programme which helps the biobanks

to assess their internal quality management system according to the biobanking standard (ISO 20387), as well as with technical standards for various biological material types. This audit programme offers biobanks the opportunity to review quality-relevant aspects of biobank management and, following a positive assessment, BBMRI awards a Quality Label in the Directory. This quality criterion makes biobanks and collections trusted partners in the scientific context and raises the visibility of our top biobanks. Many biobanks are working hard towards this BBMRI Quality Label, and it is expected that the number of quality-controlled biobanks and their collections will increase during BBMRI's Work Programme 2022 - 2024. Thus, BBMRI.QM will continue to provide the performance evaluation of and for the National Nodes according to the audit programme, with self-assessment, remote and onsite audit as follows:

a) Auditing the "Quality Management Systems and General Requirements for Biobanking" according to ISO 20387:2018 and ISO 9001:2015, is an onsite audit service.

b) Auditing "Collection/Sample Handling Processes" according to CEN/TS and ISO is a remote audit service.

The BBMRI audit programme is based on the provision of Self-Assessment Surveys (*BBMRI-ERIC SAS*) which the biobanks can use for their own purposes. Subsequently, biobanks can submit the results of the self-assessment to BBMRI.QM. This is followed by a remote or on-site audit which, if positive, can lead to a BBMRI Quality Label in the BBMRI Directory. On-site audits are offered upon request and can be conducted either by BBMRI-ERIC Headquarters or by national auditors/experts on their behalf and on their terms. Hereby, strong alignments between NNs and HQ activities will be further fostered.

An official conferment of a BBMRI Quality Award for an obtained Quality Label according to ISO 20387 in the Directory will become part of Europe Biobank Week.

An additional activity of BBMRI.QM is the audit of *BBMRI Expert Centres* according to defined QA/QC criteria. BBMRI's aim for increased Community Engagement might also entail the onboarding of new, additional BBMRI Expert Centres.

Quality Assurance
Quality assurance for biobanks is particularly important since it provides the opportunity to monitor the quality and integrity of individual samples. We will address this on two levels:

a) Define and provide biomarkers (intrinsic/extrinsic) that allow standardized assessment of sample quality through engagement in biospecimen research; application of such biomarkers will allow the pooling of samples of comparably high-quality EU-wide and thus foster large-scale cohort studies on, e.g., cancer, rare diseases, paediatrics, and pandemic outbreaks. Here, liquid biopsy samples will be in focus due to their increasing clinical significance.

b) Conceptualize proficiency testing as a service complementing the quality management system implemented in the biobank. Currently, such programmes target nucleic acid purification, single cell isolation and tissue histology. In contrast, EU-wide initiatives addressing liquid biopsies (serum, plasma, urine, and analytes thereof) are lacking and need to be refined considering multi-centre research initiatives.

In addition to liquid biopsies being one common denominator, metabolomics might provide both quality assurance markers as well as standardized technology for proficiency testing – particularly to address factors affecting the preanalytical phase of the biobanking process. For this purpose, in 2021 BBMRI established the Quality Assurance Markers Task Force involving experts and the wider BBMRI community to join forces with academic and industry partners to prepare position papers and seek external grant funding where possible.

Responsible	Deliverable	2022-2024
Headquarters	**KNOWLEDGE HUB:**	ONGOING
	• Maintain liaison to ISO/TC 276, 212, 215 and CEN 140	
	• Participate in the revision of the biobank standard ISO 20387:2018	
	• Conduct QM tasks in funded EU projects as shown on the following page	
	• Provide quarterly QM consultation hours (BBMRI.QM Newsroom) to the community	
	• Provide BBMRI.QM webinars (public) and ad hoc web conferences	
	TRAINING & SUPPORT	ONGOING / DEVELOPING
	• Provide BBMRI.QM training on relevant standards, trainings live and online, training recordings, face-to-face trainings	
	• Provide continuing medical education (CME) and continuing professional development (CPD) credits	

24

Responsible	Deliverable	2022-2024
	AUDITING	ONGOING / DEVELOPING
	• Revise and develop new BBMRI-ERIC Self-Assessment Surveys (SAS)	
	• Access Management to BBMRI-ERIC SAS	
	• Conduct remote and onsite audits, Quality Label in Directory	
	• Report quarterly on performance to the National Nodes	
	• Implement an Integrated Management System (IMS), according to ISO 9001:2015 and ISO 21001:2018	
	• Confer BBMRI-ERIC Quality Award (within Europe Biobank Week)	
	QUALITY ASSURANCE	DEVELOPING
	• Define quality markers in liquid biopsies	
	• Conceptualize proficiency testing of liquid biopsies	
National Nodes	**IN-KIND CONTRIBUTIONS TO SERVICES AND DEVELOPMENTS**	ONGOING
	• All BBMRI.QM Services	
	• All BBMRI-ERIC SAS	
	• Quality assessment according to ISO 20387 & technical standards	
	• Nominate/provide Experts for BBMRI.QM Services (technical experts, auditors, etc.)	
	• Quality assurance scheme development	

2.2.2

Complementary Quality Development in Projects at Current Stage

The following table provides an overview of how the funded projects are aligned with the overarching QM tasks and as such are integrated in core service developments. More information on the distinct project goals is provided in the Appendix. Please note that of all QM tasks, currently 50% are covered by BBMRI-ERIC core budget while 50% are based on grant funding.

Table: Interdependencies between core and project tasks and budget

CORE 50% (2,25 FTE)	TASKS	LIAISON TO ISO AND CEN — DEV/OPS	KNOWLEDGE HUB — OPS*/DEV*	TRAINING & EDUCATION — DEV*/OPS*	AUDIT — DEV*/OPS*	QUALITY ASSURANCE — DEV*
	ConcePTION	-	Dev*	-	-	-
	CY-Biobank	-	Dev*	Dev	Dev	-
	EDIReX	-	Dev	-	Dev	-
Projects 50%	IC2PerMed	-	Dev	Dev	Dev	-
	Diamonds	-	-	-	Ops	-
	ISIDORe	-	Dev*	-	Dev*	-
	EPND	-	Dev	-	Ops	-
	& others to come					

National Nodes involvement; Ops = Operations; Dev = Development; Coor = Coordination; FTE = Fulltime Employee

2.2.3

Milestone and Key Performance Indicators by Headquarters**

Milestone Q4 / 2022:

BBMRI HQ structure conceptualized according
to ISO 9001:2015 and ISO 21001:2018

Milestone Q4 / 2023:

BBMRI Academy structure established
according to ISO 21001:2018

Key Performance Indicators:

01.   Biobank Engagement: BBMRI.QM Newsroom events

Current in 2021   Prospect annually 2022-2024

04   04

02.   Biobank Engagement: Working Group QMS meetings

Current in 2021   Prospect annually 2022-2024

03   06

*** According to BBMRI-ERIC's overarching KPIs for
Headquarters and National Nodes in alignment
with Member States and EU expectations (ESFRI
guidance) to be revisited.*

2.3

Information Technology (IT)

2.3.1

BBMRI-ERIC Common Service IT (CS IT)

Based on the outcomes of the consultations with the National Nodes of BBMRI-ERIC, the second period of the Common Service IT (CS IT) established in 2020 focuses on the following core services: *Directory*, *Negotiator*, Authentication and Authorization Infrastructure (AAI), interoperability work including MIABIS, Helpdesk, and user experience analysis. Other services such as Locator or BIBBOX are to be further developed by the National Nodes and their alliances outside of the CS IT. CS IT is responsible for both development and operation of the core services and also has an increasing role in sustaining operation of services developed in different projects aligned with BBMRI-ERIC strategic priorities, such as cancer, rare diseases, paediatrics, or COVID-19.

Operation of the core services relies on extensive involvement of the National Nodes. CS IT development and operations is done by the National Nodes (CS IT is hosted by DE and contributed to by AT, CZ, FI, IT, NL, PL, UK). In addition, all the National Nodes contribute in-kind in activities, such as Directory data curation for each particular National Node, supporting biobanks from each National Node and monitoring their performance in the Negotiator, or supporting identity validation process in Authentication and Authorization Infrastructure (AAI).

CS IT will target the following key topics in 2022 - 2024:
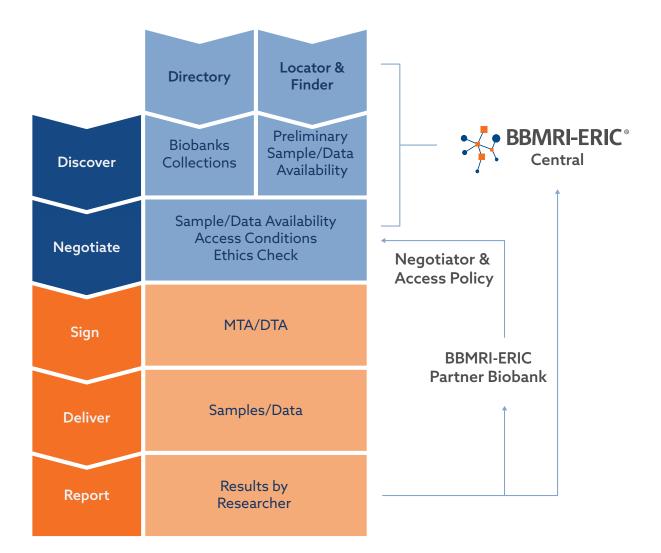
Integrating an increasing variety of biobanking and biomolecular services into the core services. In the recent years it has become apparent that the BBMRI community is providing a much broader portfolio of services than access to retrospective collections of biospecimen and data and that such services – including biomolecular resources domains – need to be made accessible via BBMRI-ERIC's access pipeline. These services include, inter alia, custom prospective data/sample collections, various types of analyses of biological material, data integration and provisioning services.

ⓘ

Discovery tools of BBMRI-ERIC:

In order to make biobanks and biomolecular resources findable, BBMRI-ERIC operates a portfolio of tools: BBMRI-ERIC Directory, Locator and Finder, together with specialized tools such as RD-Connect Biobank and Registry Finder. These tools allow researcher to discover biobanks and biomolecular resources based on their metadata, including aggregate information about donors, available data and samples, or building virtual cohorts and checking availability using privacy-preserving querying of pseudonymized data at source institutions.

ⓘ

Negotiation and access support in BBMRI-ERIC:

Requests issued by researchers are becoming increasingly complex and biobanks and biomolecular resources also need to verify availability of the data and biological material for a particular purpose defined by the researcher. BBMRI-ERIC provides its Negotiator platform that supports researchers and biobankers in this complex communication, allowing to streamline and monitor the whole process effectively.

Implementing support for these services involves defining data models suitable for their characterization, making the services findable in the *Directory* and possibly other relevant discovery services, and facilitating access to them via the *Negotiator platform*. This will be aligned with equivalent tasks in EU granted projects (see interdependency table).

Making CS IT more open and better aligned with activities of National Nodes and integrating IT-related Task Forces into the CS IT. CS IT will work on collecting IT roadmaps of the Nodes and will analyse opportunities for their increased alignment. To facilitate communication across the

Nodes, the CS IT will encourage participation of the broader community from the Nodes in all types of meetings organized by the CS IT. CS IT will also start incorporating the IT-related Task Forces, aligning them to the work planning cycles of the CS IT.

Continuing activities related to interoperability and support for measuring Key Performance Indicators (KPIs).
CS IT will follow the updates of KPIs in the BBMRI-ERIC federated infrastructure and will actively contribute to their development to maximise – where feasible – possible automation of their collections in various services operated by the CS IT or services with which CS IT interfaces.

Responsible	Deliverable	2022-2024

Common Services – IT
(Hosted by National Nodes,
led by BBMRI.de)

DIRECTORY   ONGOING

- Manage operations, data (incl. data quality analysis, documentation and maintenance) and API (Application Programming Interface) documentation and development, and support National Nodes by e.g., through new integration and supporting the resolution of data updating problems

- Continue piloting more detailed information using updated MIABIS CORE 3.0 component (including refined representation of biobank collections) and implement this model into production

- Implement support for describing complex biobank services: piloting/implementation of the data model developed in MIABIS

- Support biobanks updating their Directory data via their Federated Platform connectors (Bridgehead, BCLink, LinkLite, etc.)

NEGOTIATOR   ONGOING

- Manage operations of the Negotiator platform

- Continue implementation of Negotiator 3.0, including flexible generation of request forms based on specifications of individual biobank required data structures, redesign of user interface technology, support for negotiating access to biobank services

- Support KPI generation once defined (see chapter 4.1.1)

AUTHENTICATION AND AUTHORIZATION   ONGOING
INFRASTRUCTURE

- Further support the migration process to LifeScience AAI (dependent on outcomes of EOSC-Life)

- Access Management to BBMRI-ERIC SAS

- Manage operations of the BBMRI-ERIC components of the LifeScience AAI

- Improve identity validation assurance mechanisms for controlling access to human data and contribution and implementation of upcoming standards (e.g., from GA4GH)

Responsible	Deliverable	2022-2024
	INTEROPERABILITY/MIABIS	ONGOING
	• Publish MIABIS Core 3.0	
	• Develop data model for describing portfolio of biobank services (beyond access to retrospective collections of data and biospecimen) and review existing Directory model for describing services specific for COVID-19	
	• Operate Interoperability Forum	
	HELPDESK/RT	ONGOING
	• Maintenance and operations	
	• Support KPI generation	
	USER EXPERIENCE (UX)	ONGOING
	• Perform systematic reviewing for planning purposes: Review of Directory, Negotiator and AAI in collaboration with other WPs; regular and systematic user interface evaluation	
	• Test new releases: Directory, Negotiator and AAI will be reviewed on demand before deployment	
Headquarters	**ADOPT BBMRI-ERIC DATA**	ONGOING
	• Operation of Colorectal Cancer Cohort (CRC-Cohort) hosting, curation, and access	
	FEDERATED PLATFORM	
	• Operation of central components of the Federated Platform	
National Nodes	**DIRECTORY**	ONGOING
	• Responsibility of Directory data quality and data curation for each National Node	
	• Supporting biobanks in understanding how Directory data model works, onboarding biobanks and optimizing their characterization	

Responsible   Deliverable   2022-2024

National Nodes

DIRECTORY   ONGOING

- Responsibility of Directory data quality and data curation for each National Node

- Supporting biobanks in understanding how Directory data model works, onboarding biobanks and optimizing their characterization

FEDERATED PLATFORM

- National Nodes are responsible for building IT and data science capacity to support biobanks in data extraction, processing and integration

- National Nodes should also support biobanks in building internal IT and data science capacities

NEGOTIATOR

- National Nodes are responsible for disseminating information on BBMRI-ERIC Access Pipeline and Negotiator and support biobanks in their onboarding and participation in the Negotiator

- National Nodes are responsible for monitoring access performance of biobanks

AAI TO ADDRESS LACK OF HOME ORGANIZATIONS PROVIDING AUTHENTICATION

- National Nodes are responsible for supporting onboarding biobank/collection representatives in AAI and possibly other users that need elevated level of assurance of their digital identity

INTEROPERABILITY/MIABIS

- National Nodes are responsible for onboarding national experts into the MIABIS working group and into the Interoperability Forum

Responsible   Deliverable   2022-2024

HELPDESK/RT

- National Nodes are responsible for handling helpdesk tickets assigned to respective National Node queue

USER EXPERIENCE (UX)

- National Nodes are responsible for onboarding user representatives into the Common Service IT User Forum

2.3.2

Complementary IT Development in Projects at Current Stage

The following table provides an overview of how the funded projects are aligned with the overarching IT developments and as such are integrated in core service developments. More information on the distinct project goals is provided in the Appendix. Please note that of all IT tasks, currently 30% are covered by BBMRI-ERIC core budget while 70% are based on grant funding.

Table: Interdependencies between core and project tasks and budget

		FINDABILITY	ACCESSIBILITY	INTEROPERABILITY	REPRODUCIBILITY & REUSABILITY	INFRASTRUCTURE	ACCESSIBILITY & INFRASTRUCTURE	REFERENCE TOOLS FOR BIOBANKS	FINDABILITY
		DIRECTORY	NEGOTIATOR	MIABIS	PROVENANCE	HELPDESK	AAI	BIBBOX	LOCATOR
CS IT 30% (1,5 FTE + CS IT)	**TASKS**	OPS / DEV	OPS / DEV	OPS / DEV	- / -	OPS / DEV	OPS / DEV	- / -	- / -
	EOSC-Life	(Dev)	Dev/Use	-	Dev	-	Dev	-	-
	EJP RD	(Dev)/Use	(Dev)/Use	Dev	-	-	-	-	Dev/Ops
	ConcePTION	Dev	Use	-	Use	Dev/Ops	-	-	-
	CY-Biobank	-	-	Use	Use	-	-	Dev/Ops	Ops
Projects 70%	CECOCOEN II	-	-	Dev	Use	-	-	Dev/Ops	Ops
	BY-COVID	Dev	-	Dev	Dev	-	-	-	Dev
	ISIDORe				Dev				
	EOSC-Future	Dev	Dev	Dev					

& others to come

Abbreviations: Ops = Operations; Dev = Development; FTE = Fulltime Employee

2.3.3

Establishing Task Forces with National Nodes by In-kind Contribution & Core Budget

The following Tasks Forces (TFs) are of highest strategic importance for BBMRI-ERIC to facilitate access to samples and high-quality data in an accelerated form to serve our stakeholders sufficiently. Moreover, task forces will complement each other and will secure BBMRI-ERIC's value proposition in accordance with, e.g., the European Open Science Cloud (EOSC), the EU Data Strategy, and the European Health Data Space. TFs are expected to align their work scheduling cycles to the CS IT to ensure joint management of development and operations in the future. The TFs are hosted by BBMRI-ERIC but are led and contributed to by the National Nodes in-kind. The level of involvement by National Nodes can change over time; however, the plan for 2022 - 2024 assumes continuity from 2021 for the already active TFs.

TF on Federated Search & Analysis Platform
The TF will continue implementation of the BBMRI-ERIC Federated Platform. It is currently co-led by UK and CZ and contributed by AT, CH, DE, EE, FI, IT, MT, SE, UK and is expected to broaden participation in 2022 - 2024. This mainly involves extending the amount of onboarded data sources and exploring options for enriching common data models used. The aim is to support search through deep phenotype, clinical and omics data. In collaboration with the CS IT Interoperability Forum, the TF will work on enabling compatibility of the Federated Platform with other widely accepted infrastructures such as Beyond 1+ Million Genomes and other GA4GH compatible infrastructures. The TF will keep exploring possible models for supporting biobanks in populating the data into their local components of the federated system and the European Health Data.

TF on Data Quality and Certification
This TF will work towards developing certification mechanisms on data collection, data preservation/curation, and on data quality control. The data providers (biobanks & biomolecular resources) would have procedures and sustainable models for long-term data preservation and curation compatible with the FAIR and FAIR-Health principles. The data quality would be analysed to the best commonly accessible standards. Again, this will also be integrated into the development of organizational and technical readiness levels (see above).

TF on Expedited Access Procedure for Samples & Data
This TF will explore concepts for accelerated sample & data delivery for requests from academia and industry to allow full use of the federated search & analysis system of biobanks. This will explore opportunities for applying more broadly the mechanisms developed in the ADOPT BBMRI-ERIC project as a part of the CRC-Cohort, where a simplified data access procedure has been designed: the access is realized via BBMRI-ERIC, allowing complexities of access to be handled internally within the Research Infrastructure, hence removing the burden from the requester.

TF on Data Pooling in BBMRI-ERIC
Collecting data centrally within BBMRI, following the foundations built as a part of the ADOPT BBMRI-ERIC project's CRC-Cohort, can be a major asset for BBMRI to serve our stakeholders and the Life Science community overall. The integrated data sets can be quality checked with documented provenance, made compliant with FAIR and FAIR-Health principles and thus readily accessible for effective access to the researchers. The TF will define the requirements of the data collection process (data format and exchange protocols), the construction of the central storage to be usable for data from different BBMRI Member countries, the definition of processes for data modelling and validation, and streamlined data access conditions and regulations. If commercial systems are used for hosting the data, the TF will also investigate licensing issues to allow BBMRI to have the whole data system as a central asset. Based on the challenges identified when building the CRC-Cohort in terms of the costs of collecting and curating high-quality data with documented provenance for research purposes, the TF will also investigate incentive schemes for building this ecosystem and funding schemes to support its initial development.

TF on Big Data Analysis
Analysis of big data, from omics data to digital pathology and radiology, has become an essential task of the more advanced European biobanks, National Nodes and Expert Centres. The goal of this TF is to bring together the groups involved in this domain, share experiences, provide recommendations to the biobanks starting out with such analysis, and to find synergies with project-related activities within the BBMRI-ERIC ecosystem (such as EOSC-Life).

2.3.4

Milestone and Key Performance Indicators by Headquarters**

Milestone Q3 / 2022:

Data model for biobank services piloted in the Directory and supported in the Negotiator

Key Performance Indicators:

01.   Number of users of the Directory

Current in 2021

4709

Prospect annually 2022-2024

6000

02.   Number of requests issued via the Negotiator

Current in 2021

77

Prospect annually 2022-2024

100

*** According to BBMRI-ERIC's overarching KPIs for Headquarters and National Nodes in alignment with Member States and EU expectations (ESFRI guidance) to be revisited.*

2.4

Biobanking Development (BBD)
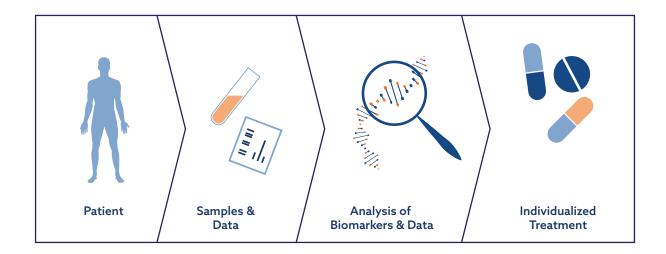
With the continuous growth of BBMRI-ERIC through new Members, BBMRI increasingly faces the challenge to integrate newly established National Nodes and networks into the overall BBMRI community of matured and established National Nodes and affiliated biobanking and biomolecular resources networks. This necessitates an intensified and accelerated support for new Observers and Members, including a status quo evaluation, gap analysis and expedited onboarding for all activities across BBMRI's various service domains.

This not only holds true for the respective new National Nodes but also for the community network they are building and coordinating. Simultaneously, mid- and long-term members explore possibilities and concepts to transit their National Node from a project-funded development phase towards project-independent long-term sustainability, hereby seeking advice from BBMRI. While the expertise to address these BBMRI core interests is excellently represented within our community, it has not been synchronized nor crystallized into formal service provision. The current growth of BBMRI-ERIC in an increasingly changing and challenging Research Infrastructure ecosystem requires precise measures to support to the fullest the backbone of BBMRI-ERIC: our National Nodes and affiliated biobank networks across all maturation levels. This will be facilitated through BBMRI's Scientific Affairs Biobanking Development.

Biobanking Development aims to assist the community and actively work towards long-term sustainability of both National Nodes and biobanks. Thus, ensuring continued return on investment is becoming a key target for countries investing significant resources to create National Nodes and networks. Sustainability concepts need to be accounted for along the entire maturation phase of National Nodes and biobanks.

Such concepts are, however, dependent on the surrounding ecosystem, exploring the biobanking market, as well as exploring and establishing scientific relationships with stakeholders including BBMRI Expert Centres and industry. These will be key priorities to fully leverage accelerated sample and data exchange, promoted and facilitated by BBMRI's existing services and tools (e.g., Directory, Federated Search & Analysis Platform, and Negotiator).

At the same time, we will foster Community Engagement activities and leverage novel technology applications (e.g., Genomics Medicine, Proteomics & Metabolomics, Artificial Intelligence & Imaging), therefore boosting the overall impact of BBMRI as a Research Infrastructure. Yet another key component for the development and sustainability of National Nodes and biobanks are knowledge exchange activities that will be facilitated e.g., through Member State specific workshops and/or via the BBMRI Academy. These scientific and business-oriented services will thus support our BBMRI National Nodes, biobanks, stakeholders and end-users for the development and sustainability of providing samples, data, and biomolecular resources.

| Patient | Samples & Data | Analysis of Biomarkers & Data | Individualized Treatment |

2.4.1

BBMRI-ERIC Biobanking Development Services

We provide services and activities to develop and sustain National Node and biobank operations in BBMRI Member States on various levels as depicted in the table below.

Responsible	Deliverable	2022-2024
Headquarters	**NATIONAL NODE/BIOBANK DEVELOPMENT & SUSTAINABILITY** • Provide technical support via consultations to new members in developing their National Node and national network • Develop sustainability models for National Nodes/ biobanks together with BBMRI community, e.g., though activities in Task Force NN Operations & NNs'/Biobanks' Sustainability • Provide expertise and trainings in the field of biobanking, either through member-specific workshops or via BBMRI Academy	ONGOING / DEVELOPING

Responsible	Deliverable	2022-2024
	VISIBILITY AND ACCESS TO SAMPLES AND DATA • Facilitate clinical and technological aspects of negotiation process for sample and data requests • Supervise and facilitate negotiations between end users and biobanks • Organize workshops where biobanks meet with industrial partners to investigate potential collaboration (i.e., individual meetings, planned workshops during EBW) • Align with other European initiatives that link biobanks and industry (i.e., via collaboration with EIT Health, ESBB, National Nodes)	ONGOING
	PROMOTE SAMPLE/DATA USE THROUGH UTILIZING NOVEL TECHNOLOGIES & ENGAGING BBMRI EXPERT CENTRES • **Genomics Medicine** to enable precision medicine particularly in cancer and rare diseases while contributing to the EU's 1+Million Genomes Initiative • **Proteomics/Metabolomics** to enable deep phenotyping for precision medicine (e.g., through liquid biopsies) and new avenues for sample quality assurance (e.g., by defining quality assurance markers or conceptualizing proficiency testing via Task Force Quality Assurance)	ONGOING / DEVELOPING
National Nodes	**IN-KIND CONTRIBUTIONS TO SERVICES AND DEVELOPMENTS** • Collaborate on Task Force 1 - Quality Assurance Markers development; establish proficiency testing in biobanking • Collaborate on Task force 7 - National Node operations & NNs'/Biobanks' sustainability	ONGOING

2.4.2

Complementary Biobanking Development Activities in Projects at Current Stage

The following table provides an overview of how the funded projects are aligned with the overarching Biobanking Development activities and as such are integrated in core service developments.

More information on the distinct project goals is provided in the Appendix. Please note that of all tasks, currently 20% are covered by BBMRI-ERIC core budget while 80% are based on grant funding.

Table: Interdependencies between core and project tasks and budget

	TASKS	NATIONAL NODE & BIOBANK OPERATION MODELS	VISIBILITY & ACCESS TO SAMPLES/DATA	PROMOTING USE OF NOVEL TECHNOLOGIES
CORE 20% (0,2 FTE)	**TASKS**	OPS*	OPS*/DEV*	OPS*/DEV*
Projects 80%	**CY-Biobank**	Dev	Ops	Ops/Dev
	ISIDORe	Dev	Ops	Ops/Dev
	& others to come			-

*Abbreviations: *National Nodes involvement; Ops = Operations; Dev = Development; Coor = Coordination; FTE = Fulltime Employee*

2.4.3

Milestone and Key Performance Indicators by Headquarters**

Milestone Q3 / 2023:

Workshop on biobank sustainability and industry collaborations

Key Performance Indicators:

01.   Provide direct consultations to **new members and Observers:**

Current in 2021

3/Country

Prospect annually 2022-2024

3/Country

02.   Organize match-making workshops between biobanks and industrial partners

Current in 2021

0

Prospect annually 2022-2024

02

*** According to BBMRI-ERIC's overarching KPIs for Headquarters and National Nodes in alignment with Member States and EU expectations (ESFRI guidance) to be revisited.*

Central Services & Functions

3.1
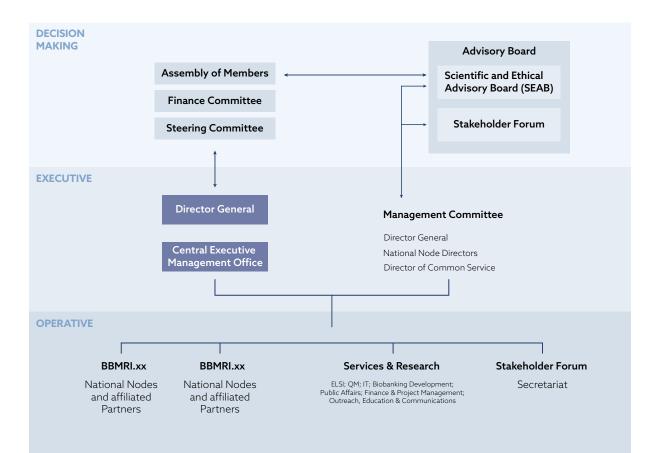
Public Affairs (PA)

3.1.1

BBMRI-ERIC Governance and the Headquarters

BBMRI-ERIC was awarded the European legal status of an ERIC in 2013. Since then, it has set in place and executed a stable governance model, which provides for an efficient decision-making and strategy setting of the organisation. Through its Assembly of Members, the Member States and countries with observer status take decisions on BBMRI-ERIC's future direction and are supported by the Steering Committee. The biobanking community is engaged through their *National Nodes*, whose Coordinators participate in the Management Committee and advise the Director General. In the past period, BBMRI-ERIC has set up also other bodies required by its Statutes, namely the *Stakeholder Forum* and the Scientific and Ethical Advisory Board (SEAB).

For the upcoming period 2022-2024, BBMRI-ERIC will continue to ensure efficient governance of the organisation. Due to continued interest for membership from European countries, we expect that the governance bodies will thus grow too. It will be BBMRI-ERIC's priority to help integrate new Members into the work of its bodies. BBMRI-ERIC will be also looking into intensifying collaboration with the Member States as well as National Nodes across several topics, such as sustainability, cooperation with industry or strategic engagement of biobanks.

DECISION MAKING

Assembly of Members

Finance Committee

Steering Committee

Advisory Board

Scientific and Ethical Advisory Board (SEAB)

Stakeholder Forum

EXECUTIVE

Director General

Central Executive Management Office

Management Committee

Director General
National Node Directors
Director of Common Service

OPERATIVE

BBMRI.xx

National Nodes and affiliated Partners

BBMRI.xx

National Nodes and affiliated Partners

Services & Research

ELSI; QM; IT; Biobanking Development; Public Affairs; Finance & Project Management; Outreach, Education & Communications

Stakeholder Forum

Secretariat

ⓘ

Stakeholder Forum:

The BBMRI-ERIC Stakeholder Forum is the main interface for patient organisations, civil society, industry and academia to interact with the European biobanking universe. It is an integral part of BBMRI- ERIC's governance and culture, where we are engaging in dialogue and exchanging on key issues related to biobanking, such as data protection, informed consent in health research, health research priorities, and other topical questions.

Also, BBMRI-ERIC will aim to further strengthen both the Stakeholder Forum with its three pillars patients, industry and scientific societies as well as the SEAB, ensuring smooth members' rotation and seeking strategic advice as per the Statutes.

Responsible	Deliverable	2022-2024
Headquarters	**ASSEMBLY OF MEMBERS (AOM)**	ONGOING
	• Continuously prepare AoM meetings as per the Statutes	
	• Integrate new Members States into the work of the AoM	
	STEERING COMMITTEE (SC)	ONGOING
	• Prepare SC meetings, preferably monthly and as needed	
	• Ensure smooth hand-over from outgoing Chairs and Vice Chairs to newly elected ones	
	MANAGEMENT COMMITTEE (MC)	ONGOING
	• Prepare MC meetings, preferably monthly and when needed	
	• Continue presentation round of National Nodes	
	• Integrate new National Nodes into the work of the MC	
	SCIENTIFIC & ETHICAL ADVISORY BOARD (SEAB)	ONGOING
	• Prepare SEAB meetings as per the Statutes	
	• Ensure smooth rotation of SEAB members	
	• Seek SEAB advice according to TORs and informing SEAB of key developments	
	• Organise a review of BBMRI-ERIC by SEAB	

ⓘ

Responsible   Deliverable   2022-2024

Responsible	Deliverable	2022-2024
	HEADQUARTERS	
	• Implement internal developments and setting in place new working modes, including SoPs for key internal policies	2023
	• Perform a strategy retreat with MC and SC informed by the HQ internal retreat results	2022
	• Revisit and adjust BBMRI-ERIC overarching key performance indicators (KPIs) if and where needed	Q2 2022
	• Continue to strengthen the HQ central service capacities as needed	
SEAB, SC, MC, AoM, National Nodes	• **All:** Provide guidance, review and approve strategic directions for the organisation	2022-2024
	• **National Nodes:** Cooperate with the Headquarters on the participation in the Task Forces, preparation of KPIs, as well as provide support relating to other BBMRI strategic operations as necessary	

3.1.2

BBMRI-ERIC's relations with Member States and development of strategic partnerships

BBMRI-ERIC Member States are the core funders of the organisation, and it is BBMRI-ERIC's aim to ensure the communities represented in the Member States are served efficiently. BBMRI-ERIC's cornerstone services of ELSI, QM, IT, and Biobanking Development play a central role in this respect. In addition, BBMRI-ERIC aims to build strategic partnerships in the Member States that will further advance accessing samples, data and biomolecular resources in Europe. In collaboration with the National Nodes, BBMRI-ERIC will also aim to strengthen its Stakeholder Forum, engaging with patient organisations, industry, and scientific societies.

To truly reflect its European nature, BBMRI-ERIC would like to expand its membership to those EU and Horizon Europe associated countries which are not yet Members. In addition, BBMRI-ERIC will be considering close partnerships with countries outside Europe, where biobanking/biomolecular resources is well developed or where there is national support for developing the sector.

For BBMRI-ERIC relations with the EU bodies, in particular the European Commission are of key importance, as the Framework Programmes have so far served as a crucial co-funder of services and developments and helped to integrate the biobanking community. In addition, it will be BBMRI-ERIC's priority to engage in strategic dialogue with other ERICs and ESFRI, capitalise on its membership in EOSC, as well as to engage with other pan-European organisations in the area of biobanking and biomolecular resources.

Responsible	Deliverable	2022-2024

Headquarters

MEMBER STATES   ONGOING

- Stay in close contact with Member States' ministries to ensure smooth collaboration

- Arrange visits of the Director General to the Member States as needed

- Stay in close contact with the National Nodes to ensure smooth collaboration

- Prepare organisation wide KPIs

- Engage in workshops, retreats and other collaboration activities within Member States

- Continue expansion of BBMRI-ERIC membership with the EU and Horizon Europe associated countries and closely work with their biobanking communities

NON-MEMBER STATES   ONGOING

- Develop strategic collaboration with selected countries outside Europe and, where appropriate, explore avenues to membership

- Define processes for possible membership of non-European countries

- Implement public training activities, workshops, and webinars, etc. in collaboration with projects and National Nodes, where feasible within the context of the BBMRI Academy

STAKEHOLDER FORUM   ONGOING

- Continue to develop Patient Pillar by expanding its membership across BBMRI-ERIC Member States, and continue engaging the members in BBMRI activities, in particular webinars and workshops

- Continue to develop the Industry Pillar by engaging more industry and industry organisations

- Initiate and develop the Scientific Societies Pillar by identifying and engaging key scientific societies and identifying areas of priority

- All pillars will be supported by close involvement of all HQ teams and National Nodes.

Responsible	Deliverable	2022-2024

47

RELATIONSHIPS WITH THE EU, ERICS, ESFRI AND OTHER INTERNATIONAL AND EUROPEAN BODIES IN THE AREA OF BIOBANKING & BIOMOLECULAR RESOURCES

ONGOING

- Further strengthen BBMRI-ERIC's **relations with the EU bodies, in particular with the European Commission**, and also through its membership in *EOSC*, where BBMRI-ERIC will provide advice through policy papers, surveys, Task Force engagements, speaking in conferences, and other means when appropriate

- Further strengthen BBMRI-ERIC's relations with other **ERICs and ESFRI**, including within the *EU-Alliance of Medical Research Infrastructures (EU-AMRI)*

- Further link to the cluster of *Life Science* Research Infrastructures

- Engage in **new strategic alliances in the European and international biobanking and related arena**, for example *ESBB*, EVAg, ECRAID, ISBER, EuroBioBank as well as other international and European organisation (EMA, OECD, EIROforum), as appropriate

| SC, AoM, National Nodes | • Providing information and collaborating on activities related to Member States, EOSC Association and on the European level | ONGOING |

3.1.3

Complementary Public Affairs Development in Projects at Current Stage

The following table provides an overview of how the funded projects are aligned with the overarching strategies and partnerships. More information on the distinct project goals is provided in the Appendix. Please note that of all tasks, currently 70% are covered by BBMRI-ERIC core budget while 30% are based on grant funding.

Table: Interdependencies between core and project tasks and budget

		HQ INTERNAL INFRASTRUCTURE	GOVERNING BODIES	MEMBER STATES AND PROSPECT MEMBERS	STAKEHOLDER FORUM	SUSTAINABILITY	RELATIONS WITH EU, EOSC, RIS & INTERNATIONAL ORGANISATIONS
CORE 70% (1,5 FTE)	**TASKS**	✕	✕	✕	✕	✕	✕
	ERIC Forum	-	-	-	-	-	✕
	EOSC-Life	-	-	-	-	-	✕
Projects 30%	EPND	-	-	-	-	-	✕
	BIG PICTURE	-	-	-	✕	-	✕
	& others to come						

Abbreviations: FTE = Fulltime Employee

3.1.4

Milestone and Key Performance Indicators by Headquarters**

Milestone Q3 / 2023:

All three Stakeholder Forum pillars are established

Key Performance Indicators:

01.   Number of meetings and visits with the Member States

Current in 2021   Prospect annually 2022-2024

5   15

02.   Number of interactions with the EU, RIs and stakeholders

Current in 2021   Prospect annually 2022-2024

20   40

03.   Number of Representatives in the Stakeholder Forum

Current in 2021   Prospect annually 2022-2024

22   40

*** According to BBMRI-ERIC's overarching KPIs for Headquarters and National Nodes in alignment with Member States and EU expectations (ESFRI guidance) to be revisited.*

3.2

Outreach, Education & Communications (OEC)

One of the goals of BBMRI-ERIC is to increase the visibility of our services and developments regarding samples, data, and biomolecular resources of the BBMRI community. This can only be achieved together with and within our community (NNs, biobanks, and partners) as well as with all our stakeholders (see BBMRI Stakeholder Forum). Outreach, Education & Communications will foster this within the next three years' Work Programme through intensified Community Engagement activities at different levels.

3.2.1

Community engaging events

Europe Biobank Week (EBW) in partnership with ESBB has become a renowned event providing education, promoting networks, and building community identification. We will build on the experiences of the past years and plan to restart our successful face-to-face congress format from 2022 onwards. We will also explore additional exchange and community-building formats, e.g., a continuation of the successful International IT Symposium conducted in 2021 and other topic-specific events.

3.2.2

Community engaging education

In addition, we will continue to grow our _BBMRI Academy_ started in 2021 to promote community building based on educational content exchange and networking. The new BBMRI Academy will not only be available to the entire biobank community, but will also address related disciplines in biomedical research, universities, hospitals, and laboratories. In this way, the competences of the biobanks will be promoted and the perception and attractiveness of the biobank services within their legal and/or parent institutions will be increased. For special BBMRI training formats, continuing medical education (CME) credits are offered; these training formats have been reviewed and accredited by the Accreditation Council for Continuing Medical Education (EACCME®). Course participants can thus acquire credits for continuing medical education (CME) and continuing professional development (CPD) and prove continuing education in their respective institutions. The BBMRI Academy will thus build up a holistic array of trainings in the next period that includes live and recorded online trainings, as well as face-to-face trainings and will take up current and urgent training needs from the community. The development of the BBMRI Academy will follow the principles of the International Standard for 'Educational organizations - Management systems for educational organizations - Requirements with guidance for use' ISO 21001:2018.

Aligned to our scientific events and BBMRI Academy activities, we seek to conceptualize inaugurating a Scientific Journal – in partnership with _ESBB_ – with and for our community, hereby fostering knowledge exchange, Community Engagement and increasing the visibility of services and achievement of the broader biobank community in Europe and beyond. The first step will be performing market research to assess levels of interest among potential target groups and identify the optimal positioning for such a journal, given sufficient interest and resources.

3.2.3

BBMRI-ERIC Communication and Outreach

To increase the recognizability of BBMRI-ERIC, the *National Nodes*, and biobanks, we will work to improve a consistent corporate identity. A toolbox of logos, colour codes, presentation templates and document templates will be updated and provided to all National Nodes for ease of use. In line with the actions taken on the QM, ELSI and IT pages on our website in 2021, we will progressively align the content and layout of the website. Expanding our recently added pages for training and events with easy-to-find entries will further promote our scientific and educational activities. We see the BBMRI Academy offerings as ideal vehicles for reaching a broader audience of biobankers and biobank users and will develop concepts for increasing participation in our trainings, for example with targeted ads on LinkedIn.

To help streamline and align BBMRI's communication, we will initiate a Task Force Communication & Outreach together with our National Nodes (to which they can send a dedicated communications staff member if available or any representative). This TF will also plan and conduct together with the National Nodes and affiliated biobanks our outreach activities to BBMRI's various stakeholder groups being individuals (e.g., patient advocates, scientists, clinicians) or institutions (universities, university hospitals, scientific societies,

companies). This Community Engagement will allow for higher visibility, increased service provision for samples, data and biomolecular resources and novel service value-chains. These activities will further leverage BBMRI biobanks' value proposition as trusted and well-recognised entry portals for high-quality research projects and biomedical developments. In line, we will be marketing the *Directory*, Federated Platform, and *Negotiator* to biobanks and researchers and promote cohorts related to cancer, rare diseases, paediatrics, and COVID-19/infectious diseases. While ensuring consistent corporate identity among the National Nodes and aiding in branding where needed, a close interaction with the Task Force Success Stories will highlight the impact of biobanking.

We will also continue to promote BBMRI's services and trainings through joint initiatives such as the Life Science Research Infrastructures (LS RIs), for whom we manage the website, social media accounts and lead outreach efforts, as well as EU-AMRI (see Public Affairs).

Overall, press releases to media and posts on social media/blogs will support the communication with stakeholders and the public. Hereby, alignment across BBMRI's service domains and the National Nodes is a sine qua non condition.

3.2.4

Marketing

Communication, branding, and environment research are instrumental in marketing the developed services that are offered by BBMRI-ERIC. This shall truly increase the visibility and valorisation of all our services including facilitating access to samples, data, and biomolecular resources. Within the

next Work Programme, we will investigate and develop an overarching marketing concept dedicated to BBMRI's core services, developments and overarching values based on the conclusions of the retreat envisioned together with the National Nodes, Steering Committee, and Headquarters in 2022.

Responsible   Deliverable   2022-2024

Responsible	Deliverable	2022-2024
Headquarters	**COMMUNITY ENGAGING EVENTS**	ONGOING
	• Organise **Europe Biobank Week (EBW)** in partnership with ESBB	
	• Organise **International Biobank Conference Doha, Qatar**, as supporting partner in 2023	
	• Possibly organise a follow-up on the **International IT symposium** in line with BBMRI CS IT and IT related task forces among others	
	• Organise other events alone or in collaboration	
	COMMUNITY ENGAGING EDUCATION	ONGOING / DEVELOPING
	• Continue the existing training and education services	
	• Continue and expand our BBMRI Academy as overarching, formalized and CME accredited education programme	
	• Conceptualize inauguration of scientific journal	
	COMMUNICATION & OUTREACH	ONGOING / DEVELOPING
	• Adapt and develop corporate identity to ensure that all communication channels and materials feature a consistent design	
	• Regularly update the toolbox for National Nodes of BBMRI-related communication resources (e.g., PPT templates)	
	• Update and adjust website appearance and content if and where needed, e.g., landing page for IT to align with QM/ELSI or dedicated pages for events and trainings including BBMRI Academy	
	• Initiate & administer Task Force Communication & Outreach	
	• Conceptualize & conduct intensified outreach to patient & public, clinicians & scientists, universities, university hospitals, scientific societies, and industry	

Responsible	Deliverable	2022-2024
	• Consolidate and expand communication via website, newsletter, and social media network (e.g., Twitter, LinkedIn)	
	• Lead and co-lead communications in joint initiatives such as the Life Science Research Infrastructures (LS RIs, where we manage the website and communications) and EU-AMRI	
	MARKETING	ONGOING / DEVELOPING
	• Investigate and develop overarching BBMRI-ERIC marketing concept	
	• Create media content together with National Nodes to highlight key services and providers with National Nodes and community	
National Nodes, Biobanks, Community, SC	• Provide information and collaborate on activities related to events, education, communication & outreach as well as marketing	ONGOING

3.2.5

Complementary Outreach, Education & Communications Development in Projects

The following table provides an overview of how the funded projects are aligned with the overarching events, communications, and marketing activities and as such are integrated in Headquarters' core services. More information on the distinct project goals is provided in the Appendix. Please note that of all Outreach, Education & Communications tasks, currently 50% are covered by BBMRI-ERIC core budget while 50% are based on grant funding.

Table: Interdependencies between core and project tasks and budget

CORE 50% (1,3FTE)	TASKS	MANAGE WEBSITE, SOCIAL MEDIA — COOR, OPS, DEV	OUTREACH ACTIVITIES — COOR, OPS, DEV	NEWSLETTER — COOR, OPS, DEV	MARKETING — COOR, OPS, DEV	PRODUCE PR CONTENT — COOR, OPS, DEV	SUPPORT TRAININGS & EVENTS (E.G., EBW) — COOR, OPS, DEV
	RI-VIS	-	Coor/Ops/Dev	-	Ops	-	Coor/Ops/Dev
	EOSC-Life	Coor/Ops/Dev	Coor/Ops/Dev	Coor/Ops/Dev	Coor/Ops/Dev	Coor/Ops/Dev	Dev
	ERIC Forum	-	Coor	-	Ops	-	Coor/Dev
	CY-Biobank	-	Dev	-	-	-	Ops/Dev
	EUCAN-Connect	-	Dev	-	-	-	-
	euCanSHare	-	Ops	-	-	Dev	-
Projects 50%	EJP RD	-	Ops	-	-	-	Coor/Ops/Dev
	CETOCOEN II	-	Ops	-	-	-	-
	DIAMONDS	-	Ops	-	-	-	-
	IC2PerMed	-	Dev	-	-	Dev	-
	CINECA	-	Ops	-	-	-	Dev
	Big Picture	-	Ops	-	-	Ops	-
	ISIDORe	-	Ops	-	-	-	-
	BY-COVID	-	Ops	-	-	-	-

& others to come

Abbreviations: Coor = Coordination; Ops = Operations; Dev = Development; FTE = Fulltime Employee

3.2.6

Milestone and Key Performance Indicators by Headquarters**

Milestone Q1 / 2022:

Launch of Task Force Communication & Outreach

Key Performance Indicators:

01.   **Number of followers on social media channels**

Twitter followers in 2021

2747

Prospect annually 2022-2024

3000-3600

02.   **Number of visitors on the website (average/month)**

Current in 2021

3891

Prospect annually 2022-2024

4300-5200

*** According to BBMRI-ERIC's overarching KPIs for Headquarters and National Nodes in alignment with Member States and EU expectations (ESFRI guidance) to be revisited.*

3.3

Finances & Project Management (FPM)

Financial management is essential for the long-term planning of financial activities and resources and plays a key role in the strategic decision-making process. Finance & Project Management is responsible for the development, implementation, and review of operational and financial procedures and covers the entire range of functions necessary for achieving financial sustainability of the organization.

With the growing portfolio of externally funded projects each year, effective project management ensures that BBMRI-ERIC can lead each individual project from the initial proposal phase to a successful completion. Project management requires an in-depth understanding of various project objectives, skilled planning and forecasting, assessing project risks and opportunities, as well as communication and collaboration with the team and project stakeholders. BBRMI-ERIC strives for the continuous improvement of its project management system for the benefit of BBMRI-ERIC as a whole.

3.3.1

BBMRI-ERIC Finance & Project Management Services

Responsible	Deliverable	2022-2024
Headquarters	**FINANCE & PROJECT MANAGEMENT** • Prepare the annual budget in accordance with the Work Programme while balancing the forecasted expenses with the anticipated income received through the annual membership fees, project overheads and other generated income • Regularly monitor the financial plan by accounting (e.g., for daily transactions, costs analysis, management of cash flow) that translates into comprehensive financial reports • Prepare annually the external financial audit • Regularly prepare financial reports and forecasts of all EU projects involved by monitoring project budget spending and supporting project resource planning • Process incoming invoices and issuing outgoing invoices • Prepare monthly payrolls for all employees based in Austria • Support payroll process for employees based outside Austria	ONGOING

Responsible	Deliverable	2022-2024
	• Calculate personnel costs for externally funded grants	
	• Submit financial reporting to the European Commission	
	• Liaise with local financial and legal authorities	
	• Manage time tracking system in compliance with Austrian labour law and project requirements	
	• Support HR activities (onboarding, drafting employment contracts and service agreements, maintaining personnel reports)	
	• Back office financial support to the entire team	
	• Provide overall project management of research projects and proposals	
	• Liaise with project partners and stakeholders on all levels	
	• Perform administrative and organizational tasks	
	• Perform effective resource planning and risk analysis	
	• Regularly monitor project progress and performance	
	• Perform controls to ensure project goals and milestones are achieved, while adhering to the planned deadlines and budget	
	• Drive internal project communication with interdisciplinary teams	
FC, SC, AoM, National Nodes, Biobanks	• **FC, SC, AoM**: Provide guidance and approve according to statutes and governance	ONGOING
	• **National Nodes & biobanks**: Providing information and collaborating on all administrative related matters, particularly regarding EU grants	

3.3.2

Milestone and Key Performance Indicators by Headquarters

No Milestones or KPIs are defined as Finance & Project Management administratively supports all milestones/KPIs across topic domains.

04

Central BBMRI-ERIC Headquarters Office

BBMRI-ERIC Headquarters Team

Alexander Fürbass
Systems Administrator

Andrea M. Wutte
Head of Quality Management

Barbora Halmová
Head of Finance & Project Management

Daniela Krasser
Quality Manager

Eleanor Shember
Head of Outreach, Education & Comm.

Erica Andrade
Finance Officer

Eva García Álvarez
IT Scientist & Project Manager

Heimo Müller
IT Senior Scientist

Ilaria Colussi
ELSI/Data Protection Specialist

Irene Schlünder
Senior Legal Expert

Jana Pavlic-Zupanc
Head of Public Affairs

Jens K. Habermann
Director General

Joanna Pucher
Executive Assistant

Joanna Vella
Quality Manager

Kaya Akyüz
ELSI/Scientist

Konrad Lang
IT Lead Developer & Service Operator

Kurt Majcen
IT Scientist & Project Manager

Luc Deltombe
Media Relations Specialist

Łukasz Kozera
Scientific Programme Manager

Maike Tauchert
Quality Manager

Melanie Goisauf
ELSI/Senior Scientist

Michaela Th. Mayrhofer
Head of ELSI

Mónica Cano Abadía
ELSI/Senior Scientist
Gender, Equality & Diversity Specialist

Nadja Palko
QM Representative

Nayari Castillo-Rutz
ELSI/Project Manager

Petr Holub
Head of IT/CIO

Rudolf Wittner
IT Scientist

Sabrina Melcher
Research & Outreach Assistant

Sara Casati
ELSI/Bioethicist

Sara Crockett
Communication Specialist

Ulrike Rohrer
Human Resources Specialist

Viridiana Beltrán Venegas
Senior Administrative Assistant

The BBMRI-ERIC Headquarters has reached a size where it is beneficial to consolidate the management structure to provide the best possible service to the National Nodes and all relevant stakeholders externally but also internally.

The satisfaction of stakeholders or customers in general as one of the most important benchmarks requires a strengthening but also a customer-oriented sharpening of administrative activities. To this end, the BBMRI-ERIC Headquarters will further develop the management system based on the principles of ISO 9001:2015 Quality Management Systems – Requirements (central QMS). Integrated into the central management are important cornerstones such as data protection. Ensuring and complying with the GDPR and other Union or Member State data protection regulations, as well as BBMRI's internal policies regarding the protection of personal data, but also cooperating with the supervisory authority (Austrian Data Protection Council) is a basic requirement for BBMRI Headquarters.

Another important cornerstone of central management is legal advice, which, in addition to drafting and revising legal contractual documents, also provides legal opinions and advice on matters concerning BBMRI.

The promotion of gender equality and diversity and reducing discrimination in the workplace is a key concern for BBMRI-ERIC. The coordination of the gender equality plan (analysis, preparation, implementation, and evaluation), which is also a mandatory requirement for applying for Horizon Europe projects, is thus considered at Headquarters level.

The executive assistance/secretariat and system administration are key functions for all central administrative tasks of BBMRI-ERIC. These functions maintain internal and external communication and coordination with BBMRI-ERIC stakeholders and governing and partner bodies of BBMRI (National Nodes, Management Committee, Steering Committee, Finance Committee, Assembly of Members, biobanks, and affiliated organisations) and internally to all staff. The measurement of customer satisfaction, key performance indicators and the input on improvement strategies are collected in these functions and incorporated into an improvement cycle by the central QMS.

4.1.1

BBMRI-ERIC Central Office Services

Responsible	Deliverable	2022-2024
Headquarters	**CENTRAL MANAGEMENT**	ONGOING / DEVELOPING
	• Introduce central QMS according to ISO 9001:2015 and ISO 21001:2018	
	• Data protection service, concept and provision	
	• Legal advice service, concept and provision	
	• Gender equality plan, concept and provision	
	• System administration, concept and provision	
	• Executive assistance/secretariate, concept and provision	
	• Customer satisfaction measures, concept and provision	
	• Performance measures, concept and provision	
	• Improvement cycle of the central QMS, concept and provision	
	• Determine Standard Operation Procedures (SOPs) for transparent and timely communications	
	• Obtain a matrix of expertise and available/ affiliated experts per National Node to efficiently support knowledge exchange and common grant applications	
	• Develop grant application policies to guarantee BBMRI-ERIC's Headquarters neutrality and to avoid conflicts of interest	
	• Define publication policies for the different stakeholder groups (scientific, communication, etc.)	
National Nodes, SC, FC, AoM, Stakeholder Forum	• In-kind feedback and contributions	ONGOING

4.1.2

Milestone and Key Performance Indicators by Headquarters

Milestone Q1 / 2023:

Matrix of Expertise & Experts across Member States established

Key Performance Indicators:

No KPIs are defined here as the central office administratively supports all KPIs across topic domains.

Funding

To fulfil its commitments and deliver all the activities as described in this Work Programme, BBMRI-ERIC relies on the annual contributions of its Members and Observers.

In addition, BBMRI-ERIC relies on other income generated from the annual *Europe Biobank Week* congress as well as small amounts of income generated from the delivery of services, subletting office space and receiving the host country contribution of Austria. BBMRI-ERIC also reinvests the indirect costs received from external grants to ensure the continuous development of its activities.

The 2022 core budget was created with the sole purpose of ensuring the successful implementation of this work programme. The expenses and income we forecast for the years to come are presented below.

5.1

Expenses

	2022	2023	2024
Rent, maintenance, equipment, consumables	191.600,00	200.850,00	209.100,00
Consulting, subcontracting, tax, and legal advice	115.000,00	119.000,00	122.000,00
Annual conference (EBW)	300.000,00	400.000,00	400.000,00
Business trips and meetings	50.500,00	59.500,00	64.500,00
Federated search IT software licence	221.055,00	175.095,00	140.625,00
EOSC Association membership	10.000,00	10.000,00	10.000,00
Internal restructuring with National Nodes and Steering Committee	15.000,00	-	-
Proposal writing	20.000,00	-	-
Total operational costs:	**923.155,00**	**964.445,00**	**936.225,00**

Staff costs

In addition to the full-time employees (FTE) specified in chapters 2 to 4 of this Work Programme, six additional positions in the central office are covered by the core budget: 1,25 FTE office administration, 1,45 FTE IT administration, 1,85 FTE finances, 0,75 FTE Director General and 0,25 FTE Data Protection Officer. The central office currently oversees and supports 32 employees in total, who work either full- or part-time based on the respective core and/or project budgets.

Staff costs (5,5 FTE) (True costs of employment)	2022	2023	2024
Gross salaries, taxes, social security contributions, insurance	505.762,95	514.360,92	526.191,22

Services

Services (incl. Personnel and development costs)	2022	2023	2024
QM (including 2,25 FTE)	209.807,80	217.577,04	222.879,73
ELSI (including 2,25 FTE)	318.539,41	322.237,58	326.728,71
CS IT (service agreements)	414.273,00	424.102,24	434.731,47
SHF and Public Affairs (including 1,5 FTE)	177.922,40	201.428,58	237.274,87
Biobanking Development (including 0,2 FTE)	27.951,57	59.461,63	78.253,78
Outreach, Education and Communications (including 1,3 FTE)	156.262,85	159.519,34	162.998,44
Total services:	**1.304.757,04**	**1.384.326,40**	**1.462.866,99**
Total expenses:	**2.733.674,99**	**2.863.132,33**	**2.925.283,22**

5.2

Income

Membership contributions	2022	2023	2024
Austria	69.126,96	70.056,64	71.229,14
Belgium	77.693,23	78.803,39	80.203,50
Bulgaria	31.757,79	31.900,17	32.079,73
Cyprus (Observer)	6.753,68	6.769,56	6.789,59
Czech Republic	49.744,74	50.266,07	50.923,57
Estonia	23.051,91	23.116,21	23.197,30
Finland	51.946,05	52.513,76	53.229,75
Hungary	40.900,66	41.235,67	41.658,16
Lithuania (Observer)	7.638,80	7.673,33	7.716,88
Germany	412.590,38	420.756,29	431.054,95
Greece	45.083,12	45.506,24	46.039,86
Italy	223.181,03	227.356,39	232.622,26
Latvia	23.390,85	23.462,29	23.552,39
Malta	21.476,35	21.507,46	21.546,69
Netherlands	115.631,03	117.540,48	119.948,64
Norway	64.897,86	65.738,45	66.798,57
Poland	84.041,95	85.285,87	86.854,67
Slovenia	25.360,06	25.472,98	25.615,41
Spain (Observer)	48.157,28	49.013,86	50.094,17
Sweden	79.020,01	80.158,12	81.593,49
Switzerland (Observer)	29.553,28	30.017,90	30.603,88
United Kingdom	301.805,29	307.637,14	314.992,13
Turkey (Observer)	29.872,69	30.344,05	30.938,51
IARC (Observer)	6.000,00	6.000,00	6.000,00
Total membership fees:	**1.868.674,99**	**1.898.132,33**	**1.935.283,22**

Other Income

	2022	2023	2024
Host country contribution:	100.000,00	100.000,00	100.000,00
Other earnings (including EBW):	370.000,00	490.000,00	490.000,00
EU projects overheads:	360.000,00	375.000,00	400.000,00
Total other income:	**830.000,00**	**965.000,00**	**990.000,00**
Transfer of financial reserves:	**35.000,00**		

	2022	2023	2024
Total income:	**2.733.674,99**	**2.863.132,33**	**2.925.283,22**

06

Appendix

6.1

Overview of Task Forces and Expert Groups

6.1.1

Task Forces

Overall, Task Forces (TF) are groups of interested, volunteering colleagues to work on a particular topic temporarily until the goal of that specific TF has been achieved. The TFs will be based on in-kind contributions by staff of BBMRI-ERIC National Nodes, affiliated biobanks & partners and/or BBMRI-ERIC Expert Centres – hence the wider BBMRI community. The goals and milestones of each TF will be further specified once the TF has been formed and aligned with BBMRI-ERIC's Management Committee. Two co-chairs per TF will be elected while coordination can be supported through the BBMRI-ERIC Headquarters. TFs are open for the wider BBMRI community to join.

TF 1: Quality Assurance Markers

Defines and provides biomarkers (intrinsic/extrinsic) that allow standardized 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 e.g., on cancer, rare diseases, paediatrics, and COVID-19/infectious diseases. We will focus on liquid biopsy samples due to their increasing clinical significance.

TF 2: Federated Search & Analysis Platform

Continues to leverage the initiated federated search & analysis platform that allows an intuitive user-search on sample-level and patient-/donor-level data. This will support the search through deep phenotype, clinical and omics data, speed up the deployment process and allow commercial & non-commercial solutions to compete for implementation operated by and branded by BBMRI-ERIC. We will explore possible models for supporting biobanks in populating the data into their local components of the federated system (called "Connectors" for simplicity) and advise on sample & data integration within three primary proof-of-principle use cases: (a) COVID-19/infectious diseases (partially supported by EOSC-Life), (b) various cancer types (supporting Mission on Cancer, e.g., building on ADOPT), and (c) rare- & paediatric diseases (partially supported through EJP RD). Furthermore, we will define the organizational and technical readiness levels for our members for integration and align with other ESFRI Research Infrastructures (namely ELIXIR).

TF 3: Biobank Data Quality & Certification

Develops certification mechanisms on data collection, data preservation/curation and data quality controlling. Hereby, we will develop sustainable models for long-term data preservation and curation compatible with the FAIR and FAIR-Health principles. We will also define data quality assessment to the best commonly accessible standards and develop organizational and technical readiness levels.

TF 4: Expedited Access Procedure for Samples & Data

Explores concepts for accelerated sample & data delivery for requests from academia and industry and explores opportunities for applying more broadly the mechanisms developed in ADOPT for a simplified data access procedure: the access is realized via BBMRI-ERIC, allowing complexities of access to be handled internally & removing the burden from the requester.

TF 5: Data Pooling in BBMRI-ERIC

Collects data centrally within BBMRI-ERIC (such as in ADOPT), quality checks integrated data sets with documented provenance while being compliant with FAIR and FAIR-Health principles. We will define the requirements on the data collection process (data format and exchange protocols), construction of the central storage for data from different countries, processes for data modelling and validation, streamlined data access conditions and regulations and licensing issues if commercial systems are used. Moreover, we will identify incentive schemes for building this ecosystem and funding schemes.

TF 6: Big Data Analysis

Captures big data, from omics data to digital pathology and radiology, shares experiences, provides recommendations to the biobanks starting out with such analysis and finds and utilizes synergies with project-related activities (such as EOSC-Life).

TF 7: National Node operations & NNs'/Biobanks' sustainability

Collects challenges & solutions for management of established National Nodes and collects strategies / concepts for sustainability including the exploration of new and different funding opportunities (regional funds, foundations, etc). We also seek to support new Members in establishing their National Node and affiliated biobank and biomolecular resources networks.

TF 8: Success / Impact stories

Focuses on COVID-19/infectious diseases, rare- & paediatric diseases, and cancer related success / impact stories and showcases the need for sustainable biobank infrastructures. We will follow up on samples and data used for research projects to highlight academic publications and to write Impact / Success Stories based on research outcomes.

TF 9: Communication & Outreach

Ensures consistent corporate identity, provides support in branding, and streamlines BBMRI communications overall. Conceptualizes and conducts intensified outreach to patient & public, clinicians & scientists, universities, university hospitals, scientific societies and industry. This TF welcomes Communication Managers and/ or other representatives from National Nodes. This TF will also interact closely with the Task Force Success Stories to highlight the impact of biobanking to the fullest.

6.1.2

Expert Groups and Working Groups

Overall, Expert Groups and Working Groups will continue to provide a platform for general exchange among experts addressing selected key topics described in the Work Programme. The Expert Groups are coordinated by Headquarters and build on in-kind contributions by experts from National Nodes, and/or project partners. Expert Groups recruit designated experts from specific fields (e.g., data protection). They are formed and dissolved based on community needs and more agile in contrast to the TFs described above. Their output provides reliable, feasible and practical knowledge on ethical, legal, or societal as well as quality matters and ensures a common knowledge among experts within the community. Ultimately, this results in guidance, best-practices, recommendations, and trainings.

6.2

BBMRI-ERIC's European Projects Involvement in 2022

EDIReX

Start Date
2018
1
FEB

BBMRI Budget
€ 70.558,75

Development of Levels of Assurance for authentication suitable for biomedical research applications

EUCAN-Connect

Start Date
2019
1
JAN

BBMRI Budget
€ 399.326,25

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

euCanSHare

Start Date
2018
1
DEC

BBMRI Budget
€ 104.675,00

An EU-Canada joint infrastructure for next-generation multi-Study Heart research

RI-VIS

Start Date
2019
1
FEB

BBMRI Budget
€ 245.900,00

Expanding research infrastructure visibility to strengthen strategic partnerships

CINECA

Start Date
2019
1
JAN

BBMRI Budget
€ 350.098,75

International flagship collaboration with Canada and Africa for human data storage, integration and sharing to enable personalised medicine approaches

EOSC-Life*

Start Date
2019
1
MAR

BBMRI Budget
€ 2.011.488,75*

Providing an open collaborative space for digital biology in Europe

EJP RD*

Start Date
2019
1
JAN

BBMRI Budget
€ 2.109.997,51*

European Joint Programme on Rare Diseases creates a comprehensive, sustainable ecosystem allowing a virtuous circle between research, care and medical innovation

ConcePTION*

Start Date
2019
1
APR

BBMRI Budget
€ 328.420,00

Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding: validated and regulatory endorsed w ows for fast, optimised evidence generation

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

ERIC Forum

Start Date   BBMRI Budget

2019
1
JAN

€ 181.250,00

Policy and international cooperation measures for research infrastructures

CETOCOEN II

Start Date   BBMRI Budget

2020
1
JAN

€ 600.000,00

Establishing the European Centre of Excellence in Environmental Health Sciences

Diamonds

Start Date   BBMRI Budget

2020
1
JAN

€ 130.000,00

To bring personalised medicine into routine use in EU healthcare systems for diagnosis and treatment of common infectious and

IC2PerMed

Start Date   BBMRI Budget

2020
1
JAN

€ 219.687,50

Integrating China in the International Consortium for Personalised Medicine

B1MG*

Start Date   BBMRI Budget

2020
1
JUNE

€ 157.190,13

Towards access to at least 1 million sequenced genomes in the EU by 2022

CY-Biobank

Start Date   BBMRI Budget

2019
1
OCT

€ 1.285.815,00

Center of Excellence in Biobanking and Biomedical Research and the Cyprus human genome project: Expanding research infrastructure visibility to strengthen strategic partnerships

INTERVENE

Start Date   BBMRI Budget

2021
1
JAN

€ 349.975,00

AI for Genomics and Personalised Medicine

BigPicture*

Start Date   BBMRI Budget

2021
1
FEB

€ 380.000,00

Central repository of digital pathology slides to support the development of artifical intelligence tools

HealthyCloud

Start Date   BBMRI Budget

2021
1
MAR

€ 311.875,00

Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research

EOSC Future*

Start Date   BBMRI Budget

2021
1
APR

€ 262.062,50*

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

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

EuCanImage*

Start Date

2020
1
OCT

BBMRI Budget

€ 310.425,00*

Building a secure and federated imaging platform for next-generation ar intelligence in oncology

BY-COVID*

Start Date

2021
1
OCT

BBMRI Budget

€1.051.947,75*

FAIR and open data sharing in support to European preparedness for COVID-19 and other infectious diseases

EPND

Start Date

2021
1
NOV

BBMRI Budget

€ 313.875,00

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

ISIDORe

Start Date

2022
1
FEB

BBMRI Budget

€ 602.207,50*

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

CanSERV

Start Date

2022
1
SEPT

BBMRI Budget

€ 3.272.758,00

Providing cutting edge cancer research services across Europe

EOSC4Cancer

Start Date

2022
1
SEPT

BBMRI Budget

€ 580.500,00

A European-wide foundation to accelerate Data-driven Cancer Research

Prophet

Start Date

2022
1
SEPT

BBMRI Budget

€ 84.812,50

A PeRsOnalized Prevention roadmap for the future HEalThcare

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