BBMRI-ERIC's
10-Year Roadmap
for 2025-2035

Environment

Human

Animal

Biobanking for a
Healthier World
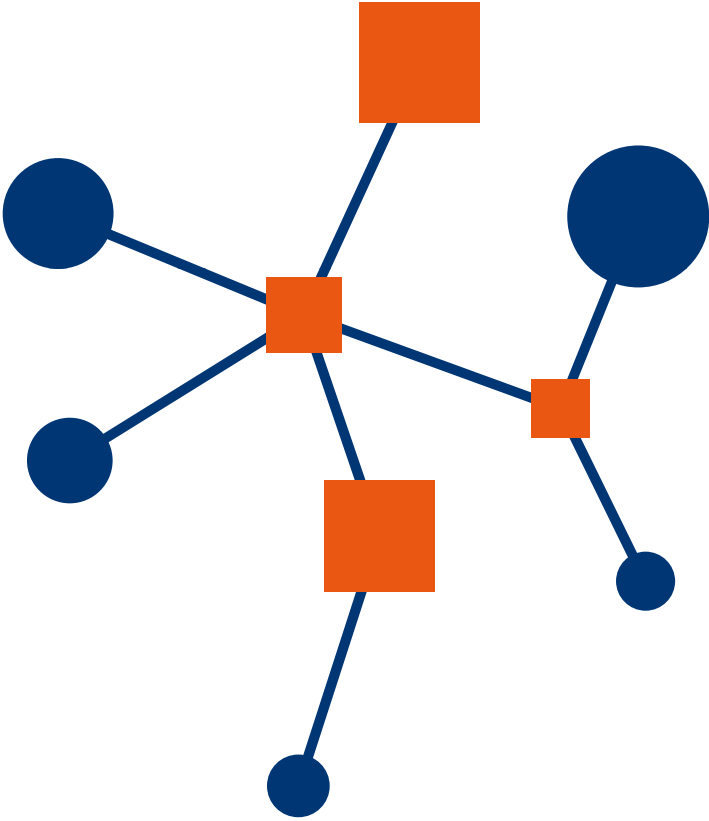
Acknowledgements

The BBMRI-ERIC 10-Year Roadmap has been developed as part of an intensive community engagement and consultation process with **our Member States, National Nodes and Biobanks, Stakeholder Forum Patients and Citizens' Pillar, our Scientific and Ethical Advisory Board and other key stakeholders**. In particular we would like to express our sincere gratitude to **all BBMRI-ERIC Member States and their delegates**, who have enabled this process, provided us with guidance and their dedicated co-creation from the beginning of the journey.

BBMRI-ERIC

Neue Stiftingtalstrasse 2/B/6

8010 Graz, Austria

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Biobanking for a
Healthier World

Preamble

As BBMRI-ERIC enters its second decade of operations, I am delighted to share our new vision for a healthier world with the biobanking community, patients and partners. BBMRI-ERIC has developed its first 10-Year Roadmap, setting out our strategic approach to ensure that biobanking can continue to thrive in the context of Europe's longer-term political, societal, health and infrastructure related developments. Underpinning the Roadmap and its targeted objectives is the overarching imperative to take a "One Health" approach as we believe human, animal and environmental health are deeply interconnected.

The 10-Year Roadmap is intended as a framework to guide BBMRI-ERIC's evolution over the next decade through more aligned activities that will enable us to realise our potential for the benefit of patients, science and society. Through it, we want to empower National Nodes and biobanks to maximise their, and our, collective impact by increasing their level of engagement and leadership to leverage the full potential of biobanking. We developed the Roadmap through an intensive and comprehensive process open to BBMRI-ERIC colleagues from the entire infrastructure. This process included multiple face-to-face workshops, the use of online whiteboard tools, numerous bilateral discussions and significant written feedback.

In this regard, I would like to recognise the invaluable contributions made by colleagues from the National Nodes, Assembly of Members and Headquarters; on behalf of the entire team thank you for the time and effort you have invested.

I also want to recognise the important guidance that we received from our Stakeholder Forum Patients and Citizens' Pillar, and our Scientific and Ethical Advisory Board. I would like to emphasise that this 10-Year Roadmap is meant for the entire infrastructure. We intend that its vision, mission, strategic objectives and operational goals apply to BBMRI-ERIC's biobanks, National Nodes and Headquarters, while closely involving all relevant stakeholders within the Member States, in particular patients, clinicians, scientists and the public. Based on our core values of scientific excellence, equity, diversity, inclusion and fairness, the Roadmap is intended as a framework to support the greater strategic alignment of activities within the biobanking community in Europe. Implementation will, however, be delivered via distinct work programmes - at Member State or EU-level, as agreed by the BBMRI-ERIC Management Committee and Assembly of Members.

We are excited to continue this journey with all of you!

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

Outline

List of Abbreviations

AI	**A**rtificial **I**ntelligence
AoM	**A**ssembly **o**f **M**embers
BBD	**B**io**B**anking **D**evelopment
BBMRI	**B**iobanking and **B**io**M**olecular Resources **R**esearch **I**nfrastructure
CEE	**C**entral and **E**astern **E**urope
EBW	**E**urope **B**iobank **W**eek
EHDS	**E**uropean **H**ealth **D**ata **S**pace
EC	**E**uropean **C**ommission
EDI	**E**quity, **D**iversity, and **I**nclusion
ELSI	**E**thical, **L**egal and **S**ocietal **I**mplications
ERA	**E**uropean **R**esearch **A**rea
ERIC	**E**uropean **R**esearch **I**nfrastructure **C**onsortium
ESFRI	**E**uropean **S**trategy **F**orum on **R**esearch **I**nfrastructures
EU	**E**uropean **U**nion
EUCAIM	**EU**ropean Federation for **CA**ncer **IM**ages
FAIR-Health	**F**indable, **A**ccessible, **I**nteroperable, **R**eusable (incl. ELSI & quality aspects)
GDI	**G**enomic **D**ata **I**nfrastructure
HQ	**H**ead**Q**uarters
IARC	**I**nternational **A**gency for **R**esearch on **C**ancer
ISO	**I**nternational **O**rganisation for **S**tandardisation
IVDR	**I**n **V**itro **D**iagnostic Medical Device **R**egulation
MC	**M**anagement **C**ommittee
MDR	**M**edical **D**evice **R**egulation
ML	**M**achine **L**earning
MS	**M**ember **S**tate
NN	**N**ational **N**ode
OEC	**O**utreach, **E**ducation and **C**ommunications
OECD	**O**rganisation for **E**conomic **C**ooperation and **D**evelopment
QM	**Q**uality **M**anagement
RI	**R**esearch **I**nfrastructure
RRI	**R**esponsible **R**esearch and **I**nnovation
SDG	**S**ustainable **D**evelopment **G**oal
SEAB	**S**cientific and **E**thical **A**dvisory **B**oard
UN	**U**nited **N**ations
WHO	**W**orld **H**ealth **O**rganisation

Introduction to BBMRI-ERIC

BBMRI-ERIC is the European research infrastructure for biobanking and bio-molecular resources in health and life sciences. BBMRI-ERIC has been fully operational since 2013, when it was granted the ERIC status (European Research Infrastructure Consortium) by the European Commission.

BBMRI-ERIC enables the development of innovative technology and processes as a transnational European infrastructure that facilitates responsible access to high quality samples, data and biomolecular resources. We achieve this through multi-disciplinary expertise and service provision, scientific excellence, knowledge exchange and partnerships in health and life sciences.

At BBMRI-ERIC's headquarters, and across the community, our vision and mission for biobanking are advancing by developments in core services and research in the areas of Ethical, Legal and Societal Issues, Quality Management, Information Technology, and Biobanking Development. These core services work in close cooperation with Public Affairs, Outreach, Education and Communications, and Finance and Project Management.

One of the largest distributed ERICs, BBMRI-ERIC encompasses 25 Member and Observer countries. Members and Observers each operate a National Node that interlinks closely with both their bio-bank community on the national level and through BBMRI-ERIC Headquarters at European level. Hence,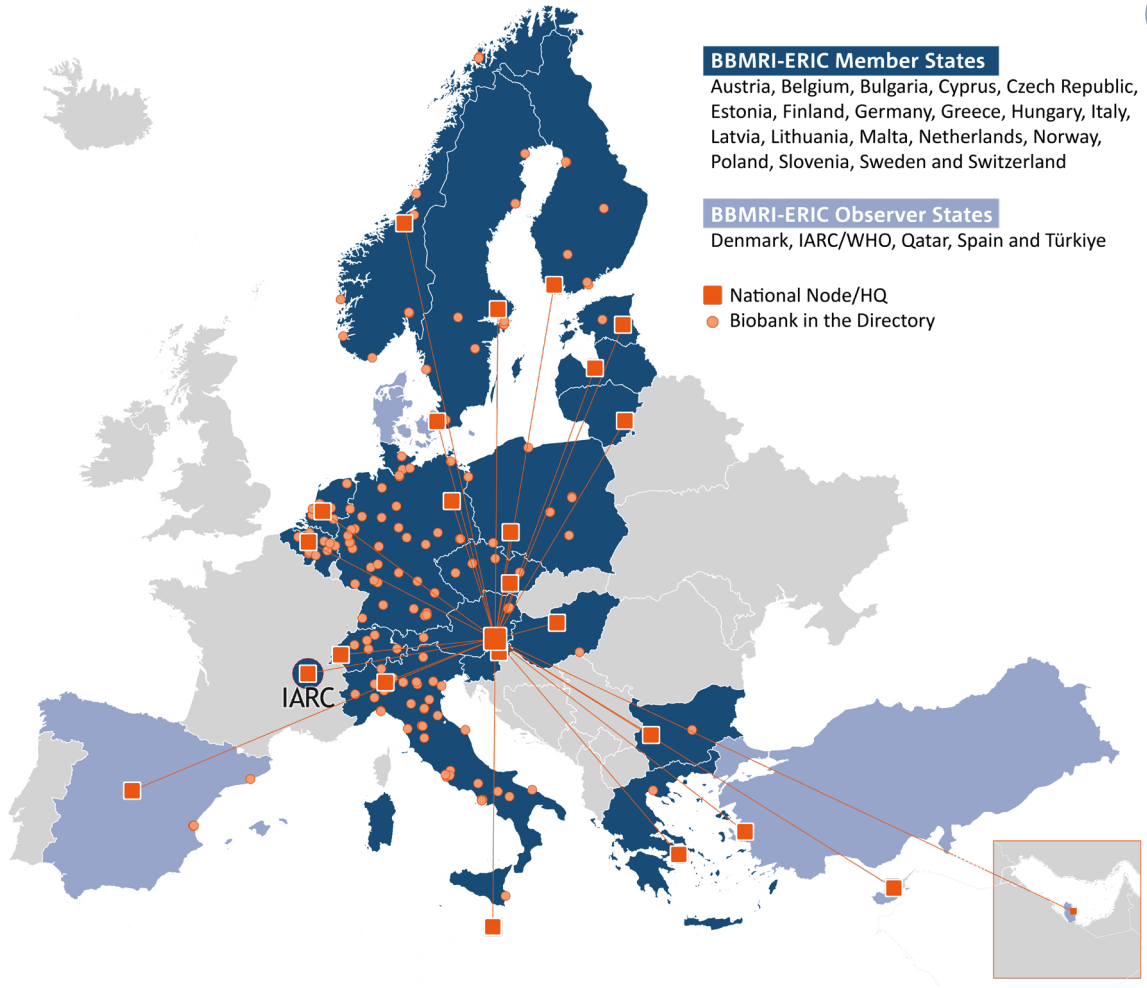 BBMRI's 25 National Nodes, with over 400 biobanks and affiliated partners, Expert Communities for its core services, three Biotechnology Expert Centres and the Headquarters in Graz, Austria, represent our backbone. Research and work in the Member States is coordinated by National Node Directors who are supported by their country's funding bodies.

Samples and data from biobanks in the BBMRI-ERIC network span all disease areas and come from integrated health-care biobanks operating in hospitals and university clinics, as well as from population-based biobanks, and those focusing on human biomonitoring and the environment.

BBMRI-ERIC also plays a major role across Europe by leveraging its expertise in areas funded by the Horizon Europe Framework Programme for Research and Innovation. BBMRI-ERIC has so far engaged its community and partners in more than 28 EU projects in the first decade and is currently active in 23 additional projects. With a co-ordinating role in projects relating to EU priorities such as EU Mission on Cancer or further strengthening of research infrastructures and ERICs, as well as an important role in other projects, BBMRI-ERIC is contributing its core expertise towards structuring the European Research Area.

In this respect, BBMRI-ERIC's federated access and analysis platform has become a strong asset and reference point for EU initiatives such as the European Health Data Space (EHDS) and EUropean Federation for CAncer IMages (EUCAIM) and serves as an example of impact of BBMRI-ERIC

BBMRI-ERIC: The European research infrastructure for biobanking and biomolecular resources in health and life sciences

BBMRI-ERIC Member States
Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Slovenia, Sweden and Switzerland

BBMRI-ERIC Observer States
Denmark, IARC/WHO, Qatar, Spain and Türkiye

■ National Node/HQ
● Biobank in the Directory

IARC

core expertise on EU health and life science research developments. Beyond this, the BBMRI-ERIC core expertise helps researchers and clinicians to accelerate personalised medicine research in general. Importantly, this fully GDPR-compliant service enables access to samples and data of over 5.1 Mio. patients and research participants facilitated by over 400 biobanks across 32 countries worldwide. These reflect various diseases with a focus on cancer, paediatric diseases, infectious diseases, worldwide collections of COVID-19, and rare diseases.

Welcome to the 10-Year Roadmap

Over the past decade, BBMRI-ERIC has successfully developed multidisciplinary expertise and implemented cutting edge services for the biobanking community in Europe to achieve its core mission of facilitating access to samples, data, and biomolecular resources for public benefit. This document sets out BBMRI-ERIC's Roadmap[1] for the next ten years to foster ground-breaking science to benefit not only European patients, the public and economies but to also ensure that the wider interdependence of human, environmental and animal health is fully recognised.

A complex research landscape

Back in 2006, the EU set itself the ambitious goal of constituting research infrastructures across all sciences to benefit researchers in the European Research Area. To do this, it set up *European Research Infrastructure Consortiums* (ERICs) via the ESFRI process. BBMRI-ERIC is proud to be one of the oldest ERICs that also adopts a leadership role in bringing together the 28 ERICs via the coordination of the first and second ERIC Forum projects. Over the past decade, ERICs have evolved, matured their approach and are now looking to further broaden their scope to global activities. These developments rightly reflect the worldwide challenges that the EU faces and the need for comprehensive action.

Today's global challenges are many and complex: geopolitical (e.g. political in-stabilities, Russia's war against Ukraine), economic (e.g. stagnating economies), technological advances (e.g. advancements in personalised healthcare and genomics, the unprecedented development of AI) and environmental (e.g. the climate crisis and biodiversity loss). There are also specific challenges faced by health systems (e.g. rising health costs, digitalisation of health, implementation of EU legislation such as EHDS). Finally, there are challenges related to RIs in particular (e.g. how to optimise our impact, how to make better use of Member State and EU resources, the role of AI, and the datafication process).

Part of the process of developing this 10-Year Roadmap was properly considering these challenges - and some opportunities - that exist in the changing environment in which BBMRI-ERIC operates. As we considered these, it became clear that optimising the impact of BBMRI-ERIC would require us to take a longer-term view through a renewed strategic approach.

Striving towards "One Health"

The health-related challenges are significant. There is a massive unfinished agenda in global health to progress towards the universal health targets enshrined in the 2030 Agenda for Sustainable Development[2]. The *Sustainable Development Goals* (SDGs), including their health targets, are ambitious.

Today, with only five years left for implementation, countries have collectively realised only about 25 % of what they committed to achieve on health. This calls for a new impetus on a European and global level to tackle these health-related challenges. This is supported by the UN and the EU that have both recently re-confirmed the need for the implementation of a "One Health" approach.

For BBMRI-ERIC, as a research infrastructure working towards improved health outcomes, adopting a collaborative "One Health" approach is key to successfully tackling the complex interconnected challenges affecting human, animal and environmental health (see Figure 1)[3].
According to the WHO, "One Health" is defined as "an integrated, unifying approach to balance and optimise the health of people, animals and ecosystems."[4] Recent epidemics and pandemics, notably COVID-19, have underscored the interconnectedness of human, animal, plant, and environmental health. BBMRI-ERIC firmly believes that a concerted and integrated effort across health and life science sectors is required. We also consider the "One Health" concept as essential for building a resilient global health research system capable of addressing existing and emerging health issues and for achieving successful implementation of the UN SDGs and the post-2030 development agenda. Focusing on "One Health" will also help streamline national and EU investments in research infrastructures, as aligning resources to avoid over-diversification of the European Research Area. Finally, this approach will also foster responsible and collaborative research and innovation (RRI) and accelerate green innovations needed to address current and future global challenges.

Importantly, larger political challenges, such as Russia's war against Ukraine, have also had direct consequences for research infrastructures. According to an ESFRI report, 80 % of monitored infrastructures were struggling with related higher energy prices and many were facing shortages of key materials and consumables. These challenges also call for substantial efforts in greening of infrastructures, which in the long term will also contribute to European Green Deal ambitions. BBMRI-ERIC also sees the urgency of greening its biobanks and operations to thus contribute to long-term planetary health.

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[3] While we also acknowledge the "Planetary Health" concept, which refers to the health and well-being of both human civilisation and the natural systems on which it depends, we emphasise the "One Health" approach for the purpose of this Roadmap.

[4] See: WHO definition: www.who.int/health-topics/one-health

Developing the 10-Year Roadmap

This 10-Year Roadmap provides a path based on strategic objectives and operational goals so that the ambition is realisable by our research infrastructure (Headquarters, National Nodes, biobanks, and Assembly of Members). It has been developed through an iterative process based on input from the entirety of BBMRI-ERIC and is furthermore closely linked to European initiatives and Framework Programmes[5].

Previous draft versions have been refned during the MC/AoM workshop in Milan in October 2023 and the MC/AoM workshop in Vienna in January 2024. Key aspects of the Roadmap were also shared with the European Commission, Member State ministries, and representatives of industry and partner research infrastructures during BBMRI-ERIC's 10th anniversary event in Brussels at the end of February 2024. Based on these discussions, a revised draft was prepared and then further refined by inviting the Headquarters team, representatives of MC/AoM, the BBMRI-ERIC Stakeholder Forum, in particular the Stakeholder Forum Patients and Citizens' Pillar and the SEAB to share their input through spring 2024 (see Figure 2 and Figure 3). Through this iterative transparent approach, we have produced a 10-Year Roadmap that we hope will inspire and empower the European biobanking community to realise its full potential towards "One Health".

It must be noted that this Roadmap builds on the success of BBMRI-ERIC's core domains developed during its first decade of its existence. All of these remain fundamental to the further evolution of our infrastructure over the next 10 years: the Scientific Affairs for Biobanking and Biomolecular Resources (*Biobanking Development; Ethical, Legal and Societal Issues; Information Technology; Quality Management*) and Central Services and Functions (*Public Affairs; Outreach, Education and Communications; Finance and Project Management; Central Office*). We intend that the core activity of biobanking such as the collection, processing, storage and sharing of samples/biological materials and data in a quality-asserted and FAIR manner will be strengthened via the implementation of the 10-Year Roadmap.

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[5] See, e.g.: European Commission, Directorate-General for Research and Innovation, Horizon Europe strategic plan 2025-2027, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/092911
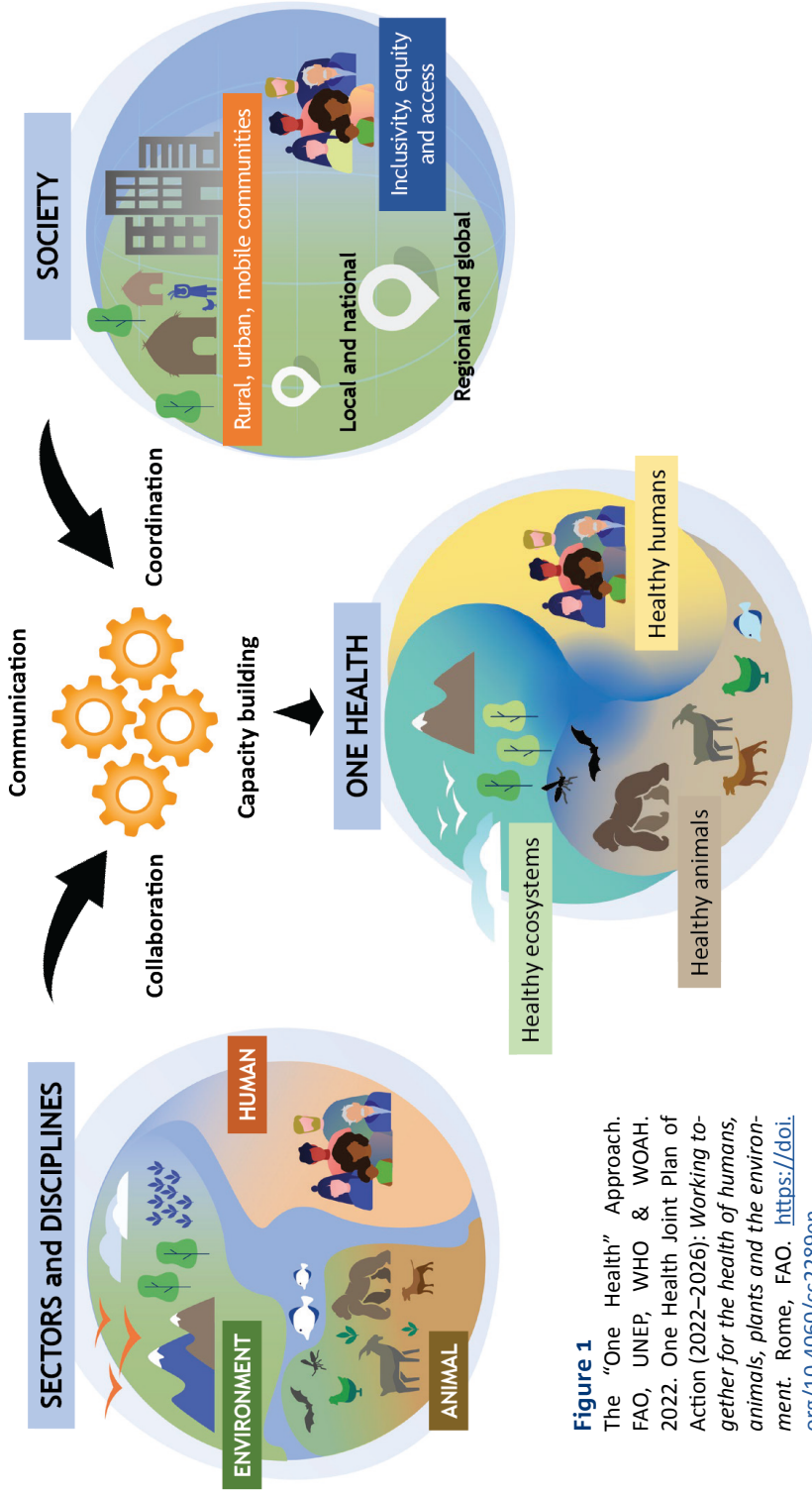
Figure 1

The "One Health" Approach. FAO, UNEP, WHO & WOAH. 2022. One Health Joint Plan of Action (2022–2026): *Working together for the health of humans, animals, plants and the environment.* Rome, FAO. https://doi.org/10.4060/cc2289en

BBMRI-ERIC
Vision Statement

"Biobanking for a Healthier World"

By unlocking the potential of biobanking and biomolecular resources, BBMRI-ERIC inspires the best research to benefit patients, the public and the planet.

BBMRI-ERIC
Mission Statement

BBMRI-ERIC enables the development of innovative technology and processes as a cross-domain network that facilitates responsible access to high quality samples, data and biomolecular resources. We achieve this through multidisciplinary expertise and service provision, scientific excellence, knowledge exchange and partnerships in health and life sciences.

"Biobanking for a Healthier World"

Vision[6]

By unlocking the potential of biobanking and biomolecular resources, BBMRI-ERIC inspires the best research to benefit patients, the public and the planet.

Mission[7]

BBMRI-ERIC enables the development of innovative technology and processes as a cross-domain network that facilitates responsible access to high quality samples, data and biomolecular resources. We achieve this through multidisciplinary expertise and service provision, scientific excellence, knowledge exchange and partnerships in health and life sciences.

Strategic Objectives

- Optimise the interconnection of human, animal, and environmental health research
- Accelerate datafication to enable trustworthy, fit-for-purpose data for high-quality research
- Foster green biobanking and Research Infrastructure operations
- Secure infrastructural scalability, sustainability and service excellence
- Strengthen the National Node and biobank community within Member States
- Educate, train & build capacity
- Strengthen stakeholder engagement and awareness
- Advance a global biobanking community

BBMRI Core Domains

Scientific Affairs
Biobanking Development; Ethical, Legal, and Societal Implications; IT; Quality Management

Central Services & Functions
Public Affairs; Outreach, Education & Communications; Finance & Project Management; Central Office

Figure 2: BBMRI-ERIC's 10-Year Roadmap overview

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[6] A "vision" typically refers to a concise and inspirational statement that outlines the long-term goals, aspirations, and desired future state of the organisation. It serves as a guiding principle to align the organisation's efforts and decisions toward a common strategic direction.

[7] A "mission" usually refers to a clear and concise statement that outlines the purpose, core values, and fundamental goals of an organisation. It serves as a guiding principle for decision-making and actions to fulfil the organisation's overall objectives.

1st Head of Dpt Workshop

Head of Dpt Alignment meeting

Process presentation to MC/AoM

Head of Dpt Alignment meeting

Process update at AoM meeting

Written/ online consultation MC

2nd Head of Dpt Workshop

Draft strategy document

Feedback at MC/AoM & f2f EvolveBBMRI kick-off meeting

3rd Head of Dpt Workshop

10th BBMRI anniversary event

Feedback by Stakeholder Pillar, SEAB & HQ

Written Feedback AoM/MC

Final Draft strategy document

Final approval at AoM

Sept 2023

Oct

Nov

Dec

Jan 2024

Feb

Mar

Apr

May

June 18 2024

Document drafting
regular alignment with HQ, MC & AoM

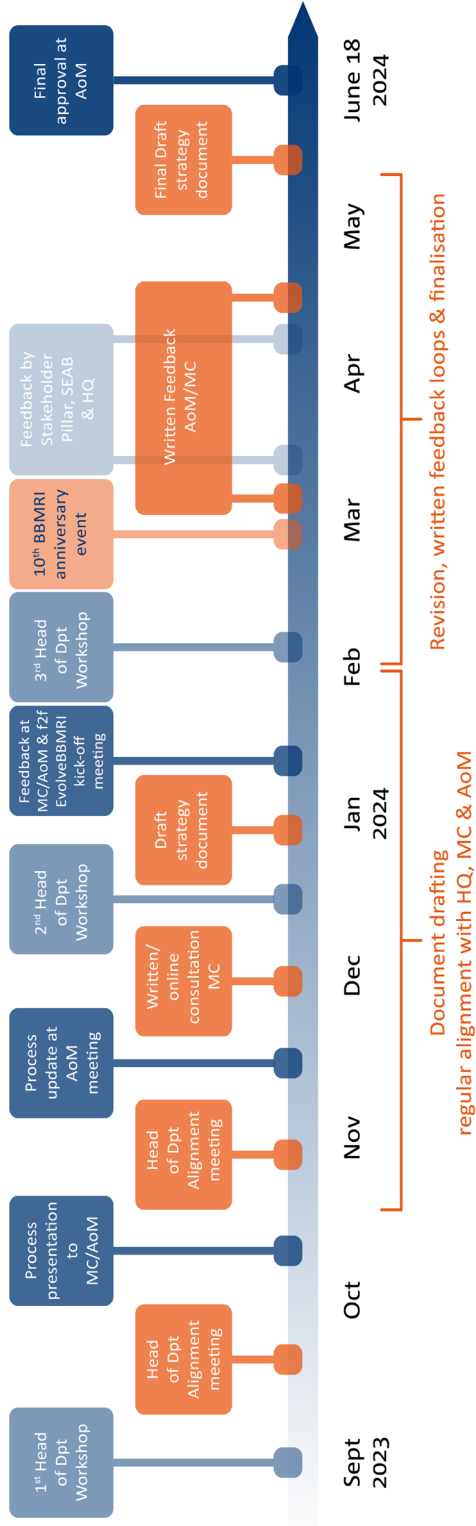Revision, written feedback loops & finalisation

Figure 3: Timeline - BBMRI-ERIC 10-Year Roadmap development process

Strategic Objectives

Operational Goals

Strategic Objective: Optimise the interconnection[8] of human, animal, and environmental health research

BBMRI-ERIC will focus on optimising the interconnection of human, animal and environmental health research by exploring opportunities based on the "One Health" paradigm. This will build on the strong expertise in, and infrastructure for, human biobanking which BBMRI-ERIC has developed so far. This will, inter alia, entail connecting to other types of biobanks and repositories, research infrastructures and initiatives with the aim of using the generic BBMRI-ERIC access pipeline for other types of data and samples, thus facilitating different aspects of research. We plan to strengthen these collaborative efforts across scientific domains, which will lead to better research for the benefit of patients and wider society. This approach will also further streamline research efforts and investments in infrastructure, ultimately saving Member State and EU resources. With the implementation of the "One Health" approach, BBMRI-ERIC also wishes to further facilitate international cooperation.

Operational Goals

Engage with different Member State ministries (e.g. Research, Education, Innovation, Health, Environment), as well as the European Commission (e.g. DG for Research and Innovation, DG Health, DG Connect) to foster understanding of biobanking and its role in encouraging cross-domain collaboration towards "One Health".

Scale up interactions and alliances with other research infrastructures and initiatives. This would involve preparation (mapping non-human biobanks/networks, a gap analysis of potential transdisciplinary collaborations) and active cooperation towards "One Health", when needed on pilot projects.

Expand viral, microbial, environmental, animal and/or plant collections into BBMRI-ERIC by linking to non-human databases/data sources and provide access through BBMRI-ERIC's IT ecosystem.

For this purpose, new IT models will be developed to describe human and non-human resources as well as synergies with existing biobanking practices for non-human samples. This includes new quality management models (e.g. ISO requirements, audit processes, Quality Labels). In addition, BBMRI-ERIC will develop discovery services beyond human data and support with on-demand services in the implementation of a service description model that includes support for discovery of non-human samples and datasets linked to "One Health".

Build on existing expertise and provide self-service and on demand guidance on ethical, legal, and societal aspects of biobanking within the complex "One Health" paradigm to enable Responsible Research and Innovation (RRI) and promote good practice within the biobanking community.

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[8] Interconnection: to explore, define and setup (automated) interfaces between existing tools and solutions for human, animal, and environmental resources. Integration may be possible if politically and strategically sought by all partners involved.

Strategic Objective: Accelerate datafication to enable trustworthy, fit-for-purpose data[9] for high-quality research

Accelerating datafication by applying FAIR-Health principles (Findable, Accessible, Interoperable, Reusable, quality-defined, with incentives for data sharing and reuse, including ELSI aspects)[10] will enable reproducible advancements in science. BBMRI-ERIC has already showcased the value of pan-European datafication of biobanks through its role in projects that include EHDS2, EUCAIM and GDI. By accelerating developments in this area, such as responding to the increasing need for on demand access in biobanking and facilitating on demand data generation (e.g. developing AI models for advanced biobanking use of biomolecular resources and streamlined access to those resources) significant contributions can be made to EU priorities in health and life sciences research. In addition, datafication will spearhead developments in semantics, interoperability, fitness-for-purpose, and legal and ethical compliance, thereby supporting our ability to respond to advanced research needs.

Operational Goals

Support and accelerate datafication at source by interconnecting data from different sources at local level into common data warehouses and include quality-defined data from patient/public (e.g. from wearables and sensors). Second, datafication at source will be supported by utilising synergies between academia and industry to accelerate local datafication on fair and transparent terms, including developing and using AI for quality-defined data mining. Datafication will be further achieved by developing and fostering implementation of incentive schemes for data producers to prepare and share fitness-for-purpose data.

Enable reproducible research through good data traceability and quality management. This involves implementing provenance for complete lineage of samples, data and other research objects (e.g. software and data processing workflows).

Ensure international interoperability, connectivity with (local, national and international) medical data ecosystems and across human and non-human registries and catalogues.

Address ethical, legal and societal aspects of datafication by monitoring the implications and providing guidance on the ever-developing ethical (e.g. trustworthy AI) and legal landscape in medicine (e.g. AI Act, EHDS, IVDR/MDR) and proactively advising on shaping policies and guidelines at national/EU level. In addition, ensure fairness by producing guidance on the implications of research innovations and technological advancements in medicine and the datafication of health.

Align and interconnect data-related services with other ESFRIs and European data spaces (e.g. EHDS (HealthData@EU), EOSC, UNCAN.eu, EUropean Federation for CAncer IMages (EUCAIM), GDI).

Expand the Federated Platform - the high-granular search and analysis core component of BBMRI's user access pipeline - by adding new data and analysis types using data retrieval, extraction and curation processes in collaboration with industry to improve data readiness in biobanks and biomolecular resources. Furthermore, develop safe mechanisms for data quality assurance in federated data analysis environments.

Enable on-demand data generation to advance biobanking that incorporates easily accessible anonymised synthetic data resources and synthetic data generation until real-world data are available in an on-demand setting. This includes developing AI/ML methods, tools for data synthesis and anonymisation and privacy risk assessment.

Ensure vendor neutrality in all collaborative efforts involving industry.

Increase capacities to host result data obtained by providing access to samples, data and biomolecular resources at the biobanks, National Nodes and/or Headquarters pending purpose and resources.

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[9] "Fit-for-purpose data" refers to data that is suitable, adequate, and appropriate for a specific intended use or purpose; it is data that meets the requirements and criteria necessary for a particular task, analysis, or decision-making process.

[10] Note: the FAIR-Health concept includes the following additional components: (1) quality aspects related to research reproducibility and meaningful reuse of the data, (2) incentives to stimulate effective enrichment of data sets and biological material collections and its reuse on all levels, and (3) privacy-respecting approaches for working with the human material and data. See also: www.ncbi.nlm.nih.gov/pmc/articles/PMC5906729

Strategic Objective: Foster green biobanking and research infrastructure operations

By investigating and promoting the most sustainable and energy-efficient setup, BBMRI-ERIC will support a low carbon future for biobanks and research infrastructure operations (National Nodes and Headquarters). Ultimately, this will also positively affect operations at the local level, including hospitals and universities. The new BBMRI-ERIC Green Incentive will drive forward clean-tech investment in line with the Green Deal concept, therefore supporting the achievement of the UN SDGs and the post-2030 development agenda. BBMRI-ERIC will foster clean-tech innovations through academia-industry co-creation and public-private-partnerships. Progress towards a low carbon future will deploy actions towards cost reduction while boosting and preserving resources, consequently ensuring financial and environmental sustainability. Finally, the biobanking community will implement greener biobanking operations with BBMRI-ERIC provision of guidelines and raised awareness of long-term benefits of green biobanking.

Operational Goals

Achieve a Green biobanking approach, incl. Green Incentive and Green Label by defining the Green Incentive criteria. This criteria includes various measures on sustainability such as energy efficiency, waste management and sustainable procurement for all biobanking practices and procedures.

Foster Greening for Biobanking Operations through first, mapping the challenges faced by biobanks and intensify engagement with industry (e.g. co-creation of tailored green solutions for biobanking practices and procedures, better reuse of consumables and good practices to save energy). Second, developing "greening" educational material and guidelines promoting sustainable storage of samples (retrospectively and/or prospectively). Third, the implementation

of better waste management practices (including e.g. recycling programmes and the reduction of single-use plastics) aligning with the principles of a circular economy. Fourth, promoting green computing to reduce the carbon footprint generated by high power consumption data storage and analysis. Finally, BBMRI-ERIC will build an exchange platform for second use/exchange of technical equipment to promote the circular economy.

Leverage funding and subsidies to support biobanks in the green transition by exploring available funding opportunities, such as government programmes, or funding from the environmental sector.

Strategic Objective: Secure infrastructural scalability, sustainability and service excellence

BBMRI-ERIC recognises the constraints faced by Member States in today's political and economic climate and we will therefore investigate additional avenues for generating sustainable income. The ambition is to successfully engage with and generate new sources of income through alliances with universities, industry and private foundations that explore collaboration models such as support for specific visionary projects, in-kind contributions, industry collaboration, public-private partnerships as well as open innovation models. In parallel, the ambition is to nurture close and high-value partnerships with associated and third countries.

Operational Goals

Explore and develop new service models to ensure the portfolio of BBMRI-ERIC's scientific core domains continue to evolve: This will be achieved by further expanding and evolving BBMRI-ERIC's current access pipeline by e.g. developing an innovation portal.

Build different partnership models with e.g. universities, hospitals, industry, and foundations for increased opportunities for cooperation, co-creation and public-private partnerships that accelerate developments, fully leverage innovations and foster implementation whilst remaining sensitive to patient and public perceptions.

Develop new membership and partnership models beyond ERIC Statutes for e.g. countries outside the EU, industry, and foundations.

Create new and novel models for data access that feature efficient user interfaces utilising interactive AI methods to enhance the discovery and accessibility of biobanking and biomolecular resources and support (on-demand) services and service chains. This would include building sustainability and cost recovery models to promote responsive behaviour, and provide interfaces to other systems (biobanks, National Nodes, EHDS, EUCAIM, etc.). The aim is to develop cohorts, services and reference databases of common interest, incorporating an expedited, low-barrier access mechanism and simplified contracting processes through BBMRI-ERIC.

Ensure biobanking adapts to and leverages innovative technological developments, e.g. home-sampling of automatable testing, single-cell or analyte-based analyses such as Circulating Tumour Cells, patient avatar models[11], integration of AI and advanced data analytics, virtual biobanks and cloud collaboration platforms.

Develop and implement risk assessment tools, including risks related to privacy, consent, or possible discrimination.

Define and build a back-up system at national and international level for hosting samples/data in cases of force majeure.

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[11] Patient avatar models are representations or simulations of patients used in health research contexts. They are created to mimic characteristics, demographics, medical history, and behaviours of patient populations.

Strategic Objective: Strengthen the National Node and biobank community within Member States

The long-term sustainability of BBMRI-ERIC depends upon the expertise of the local and national community. Active engagement and shared responsibilities across the RI will strengthen collaboration with the network, including national policymakers, delegates, National Nodes, and biobanks. Building on the expertise and already existing synergies will be crucial to facilitate knowledge exchange among the RI network and contributes to greater visibility of the overall community. The ambition is to also expand BBMRI-ERIC membership to EU countries that are not yet members to strengthen collaboration and impact.

Operational Goals

Empower National Nodes and biobanks to engage with the community and relevant stakeholders. This will be achieved by developing the role of NNs (e.g. their requirements and responsibilities, identifying champions overall/per region for the wider network) and include seeking integrative and interdisciplinary alliances that avoid duplication and foster synergies. It will also entail collaboration between NNs and biobanks to produce communication and outreach materials for consistent and strong engagement with stakeholders. Empowerment will be furthered by exploring different ways of working with relevant stakeholders (e.g. academia, industry, patients and the public).

Attract remaining EU Member States and countries associated to the Framework Programme as Members or Observers and encourage further prioritisation and additional EU funding for CEE and associated countries to develop their infrastructure and integrate into BBMRI-ERIC.

Facilitate learning, knowledge exchange and improved communication within the BBMRI-ERIC community. This will be achieved by building a digital channel for peer-to-peer learning and communication that fosters capabilities, enables staff exchange and mentoring programmes and strengthens the community that includes the BBMRI-ERIC Working Groups, Task Forces, Expert Groups and ELSI Helpdesk Network.

Maintain and expand rich partnerships between Headquarters, National Nodes and their associated biobanks for effective relationship management with experts, thus helping to understand and respond to challenges.

Support intensified Member State relations by directly engaging with relevant ministries on different levels, aiming for strengthened cooperation.

Raise awareness amongst funders (ministries, funding agencies and EC) on the long-term importance of a sustainable biobanking community, in particular the need for long-term cost-recovery solutions, the importance of biobank regulation and legislation and visibility of BBMRI-ERIC NNs within national RI networks.

Strategic Objective: Educate, train & build capacity

BBMRI-ERIC will shape education and capacity building by developing agile and future-oriented models for collaborative training and research for different target groups (e.g. researchers, data managers, project managers, biobank technicians). An overarching holistic career and training curriculum will be developed for RI staff in the field of biobanking and biomedical research. By evolving the BBMRI-ERIC Academy, BBMRI-ERIC will be established as a complementary non-university educational organisation that will empower learners to better tackle scientific and societal challenges in the field.

Operational Goals

Evolve the BBMRI-ERIC Academy to build on its success by defining target groups, developing strategic relations with key universities for the co-development of Continuing Professional Development (CPD) and academic modules tailored for respective audiences, complementary to existing EU modules as well as harmonising and furthering content via an in-house online learning platform.

Encourage capacity building through the development of a new series of education and training content by developing National Node and biobank-focused webinars to showcase and share tools and ideas in specialised topics of interest to the rest of the biobanking community.

This includes expansion of webinar and training content for each BBMRI service (e.g. IT training on core tools, ELSI dialogues, QM specialisms and capacity building in leadership and stakeholder management).

Build specific career development programmes for RI community (staff exchange and mobility, affiliations, contracts).

Evolve scientific education through e.g. a biobanking journal (potentially linking to wider context of "One Health" or "Planetary Health").

Strategic Objective: Strengthen stakeholder engagement and awareness

Increasing multisectoral engagement with stakeholders – including Member States, National Nodes, patients and the public, policymakers, industry and academia – is crucial to further develop and strengthen BBMRI-ERIC to generate further socio-economic impact and awareness among wider communities. Patient and public engagement will be achieved through cooperatively created channels. Different parts of BBMRI-ERIC – biobanks, National Nodes and HQ – are each accountable for engaging with their own stakeholders at local, national and European levels.

Operational Goals

Strengthen communication, outreach, and demonstrate impact to key stakeholders (incl. EU and national ministries, universities and hospitals, funders and foundations) through existing and new digital channels, e.g. new website with integrated community learning platform, annual Global Biobank Day for key audiences, the Europe Biobank Week (EBW) Congress and Roadshow.

Engage existing and new stakeholders through multiplatform content that profiles multidimensional perspectives (researchers, policymakers, patients and public). This focuses on further developing existing and new social media channels to engage a wider range of stakeholders, and creating simple, engaging, multimedia content. Collaboration will be explored with researchers to showcase success and impact stories. Outcomes of EU projects and how they strengthen BBMRI-ERIC core services will be clearly communicated.

Improve stakeholder engagement by continuing to strengthen the Stakeholder Forum Patients and Citizens' Pillar: The Patients and Citizens' Pillar network across Member States – locally, nationally and internationally will be further strengthened. A platform for exchange and the European web portal for patients and the public[12] will be established. Furthermore, BBMRI will act as a bridge towards EU policymakers on key topics (e.g. EHDS, cancer, rare diseases) and, together with patients and wider society, co-create policies and responses to public consultations on new legislation.

Strengthen ability to illustrate the socio-economic value of biobanking – samples, data and biomolecular resources of BBMRI-ERIC and wider biobanking community by conducting a qualitative/quantitative sweep of existing projects and deliverables to establish alignment to socio-economic measures. This will enable clarification of existing and establish new quantitative and qualitative KPIs that reflect recognised socio-economic measures and inform a programme of content within the communications strategy to demonstrate socio-economic impact.

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[12] Exact concept to be developed from dynamic consent over proactive enrolment into research projects/clinical trials to EU wide Donor Biobank ID (card).

Strategic Objective: Advance a global biobanking community

BBMRI-ERIC has the potential to play an impactful leadership role to strengthen the global biobanking community and standards, as well as advance the biobanking field in Europe and beyond. This is important as global challenges need to be dealt with at global level. With the wider expansion of ERICs, it will also be increasingly important to respond in a timely manner to political and scientific demand while navigating complex ethical and legal frameworks. In close collaboration with its community and other RIs, and by working towards a global biobanking community, BBMRI-ERIC aims to be a first mover in contributing to and shaping the global agenda. This includes, amongst others, the "One Health" approach, the UN SDGs, the EC's Gender Equality Strategy[13], sensitive health data policy, and setting of quality standards.

Operational Goals

Identify and implement different "BBMRI-ERIC Global" formats by exploring levels of membership and scale up collaborations with non-European countries when mutually beneficial. This approach will include other entities (e.g. RIs, scientific organisations), and obtaining (EU) project funding suitable for stimulating international cooperation.

Lead global standardisation initiatives by maintaining and expanding BBMRI-ERIC's strong position in ISO and supporting the development of international biobank relevant standards in the life sciences (e.g. pre-analytical, data and provenance standards) and grassroot standards (e.g. GA4GK, HL7, OHDSI). Moreover, BBMRI-ERIC's strong position on contributing to the development of ethical guidelines or consulting on governance aspects (e.g. models of consent) will be taken forward.

Consolidate BBMRI-ERIC's leadership as an opinion leader for health and life sciences RIs within the overall EU and global policy arena. BBMRI-ERIC aims to provide leadership of ERICs for key initiatives where needed, as well as continuously develop partnerships with key EU institutions and European-level initiatives (e.g. EU institutions, EOSC), and exploring broader policy engagement with OECD, G7 and UN initiatives.

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[13] See: EC (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Union of Equality: Gender Equality Strategy 2020-2025. Brussels, 5.3.2020, COM(2020) 152 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0152

Conclusion

The BBMRI-ERIC 10-Year Roadmap represents a pivotal pathway to foster ground-breaking science that benefits not only European patients, the public and economies but also ensures that the wider interdependence of environmental and health outcomes is fully recognised. Through a comprehensive approach encompassing interdisciplinary collaboration, innovation and strategic partnerships, we are poised to drive significant advancements in biobanking and biomedical research. We hope that the vision, mission, strategic objectives and operational goals set out in this document define the path for the entire BBMRI-ERIC infrastructure - biobanks, National Nodes, Member States and Headquarters.

The Roadmap places a particular emphasis on the "One Health" approach, underscoring the critical interconnection of human, animal, and environmental health research. In this regard, accelerating datafication and fostering green biobanking will be cornerstones of our work for the next decade. To achieve this, we aim to secure infrastructural scalability, sustainability and service excellence and will strengthen the National Node and biobank community within Member States. Education, training and capacity building combined with stakeholder engagement and awareness will remain high on the agenda. Finally, BBMRI-ERIC aims to advance a global biobanking community and play an impactful leadership role for the next ten years and beyond.

Throughout the implementation of this Roadmap, we recognise the importance of overcoming challenges and adapting to evolving trends in health and life science. By remaining agile and responsive to change, we will navigate obstacles with resilience and determination, ensuring the success of our collective endeavours.

As we embark on this journey, we invite all stakeholders within the BBMRI-ERIC community to join us in our mission. We are confident that the Roadmap will serve as a guiding beacon, leading BBMRI-ERIC towards greater impact and sustainability in the years ahead. Finally, with unwavering dedication and collaboration, we will realise our shared vision:

Biobanking for a
Healthier World

BBMRI-ERIC's
current National Node Directors

Assoc. Prof.
Georg Göbel
Austria, BBMRI.AT

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

Dr. Annelies
Debucquoy
Belgium, BBMRI.BE

Dir. Anne-Marie Vangsted
Denmark, BBMRI.DK

Prof. Radka Kaneva
Bulgaria, BBMRI.BG

Marco Hautalahti,
MSc MBA
Finland, BBMRI.FI

PD Dr. Sara Nußbeck
Germany, BBMRI.DE

Dimitris Thanos, PhD
Greece, BBMRI.GR

Prof. Lili Milani
Estonia, BBMRI.EE

Prof. Mária Judit Molnár
Hungary, BBMRI.HU

Dr. Christine Joye
Switzerland, BBMRI.CH

Prof.ssa
Marialuisa Lavitrano
Italy, BBMRI.IT

Dr. Carolina Stylianou
Cyprus, BBMRI.CY

Dr. Daiva Dabkevičienė
Lithuania, BBMRI.LT

Teresa Escámez Martinez
Spain, BBMRI.ES

Vita Rovīte
Latvia, BBMRI.LV

Dr. Nikolai Pace
Malta, BBMRI.MT

Dr. Anna Beskow
Sweden, BBMRI.SE

Prof. Gerrit Meijer
BBMRI.NL

Prof. Urban Bren
Slovenia, BBMRI.SI

Prof. Nine Knoers
BBMRI.NL

Dr. Fatima Qafoud
Qatar, BBMRI.QA

Prof. Kristian Hveem
Norway, BBMRI.NO

Prof. Bayram Yilmaz
Turkey, BBMRI.TR

Dr. Michał Malewicz
Poland, BBMRI.PL

Dr. Zisis Kozlakidis
IARC/WHO

Former BBMRI-ERIC National Node Directors who contributed to the Roadmap

Prof. Michael Hummel
BBMRI.DE

Dr. Eva Ortega-Paíno
BBMRI.ES

Prof. Neşe Atabey
BBMRI.TR

Prof. Kurt Zatloukal
BBMRI.AT

Prof. Andres Metspalu
BBMRI.EE

Prof. Tobias Sjöblom
BBMRI.SE

Dr. Nahla Afifi
BBMRI.QA

BBMRI-ERIC's
Scientific and Ethical Advisory Board

Prof.
Walter Ricciardi
(Chair)

Prof.
Carolyn Compton

"The activities of BBMRI-ERIC shall be periodically evaluated by an independent Scientific and Ethical Advisory Board (SEAB). The SEAB shall also advise the Assembly of Members with regard to proposals of the Director-General on the implementation of the Work Programme."

(STATUTES, ART. 16.1)

Mr.
David Byrne SC

Prof.
Jane Kaye

Prof.
Jean-Yves Blay

"The SEAB shall be composed of distinguished scientists or experts appointed in their own right, not as representatives of their respective background organisations or of Members."

(STATUTES, ART. 16.2)

Prof.
Aarno Palotie

Dr.
Eric Vermeulen

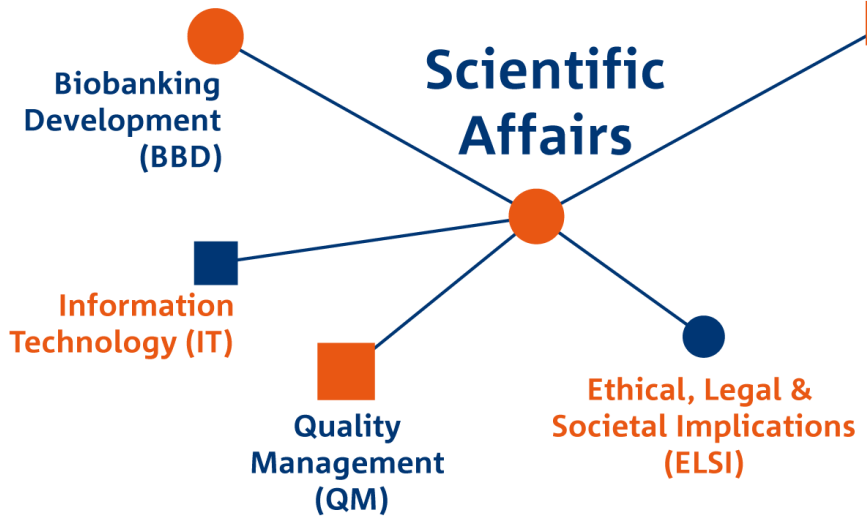# BBMRI-ERIC's Stakeholder Forum Patients and Citizens' Pillar

Patient organisations involved in biobanking topics have been onboard of BBMRI-ERIC's Stakeholder Forum from the very beginning of the infrastructure. They provide guidance to BBMRI-ERIC on strategic topics like EHDS, future of consent, EU Mission on Cancer and other. BBMRI-ERIC furthermore engages patient organisations and citizens in biobank oversight committees, research projects, ethics committees, and works together with them in outreach events.

In 2024 the Patients and Citizens' Pillar includes 20 patient organisations from 13 BBMRI-ERIC Member States and Observers and 7 EU-wide patient organisations. Having a broader membership base provides not only enriched discussions, but also a good representation of patients' interests from BBMRI-ERIC Member States and Observers. All BBMRI-ERIC Member States and Observers are invited to have patient organisations represented in the Stakeholder Forum.

Dr. Eric Vermeulen
Chair Stakeholder
Forum Patients
and Citizens' Pillar

BBMRI-ERIC's Core Operations & Services

Biobanking Development (BBD)

Scientific Affairs

Information Technology (IT)

Quality Management (QM)

Ethical, Legal & Societal Implications (ELSI)

Our Headquarters team from A-Z

Saba Abdulghani
Head of BBD

Kaya Akyüz
ELSI / Scientist

Stella Antoniou
Quality Manager

Judit Balogh
Senior Project Manager

Viridiana Beltrán Venegas
Senior Administrative Assistant

Marthe Bierens
Public Affairs Specialist

Verena Borecky-Kutej
Research Assistant / ELSI

Saša Božić-Kraljik
Administrative Assistant

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

Olivera Ciraki
Research Assistant / IT

Ilaria Colussi
Data Protection Specialist
Data Protection Officer

Niina Eklund
Data Quality Manager

Erdina Ene
Legal Expert

Alexander Fürbaß
Systems Administrator

Eva Garcia Álvarez
IT Scientist & Project Manager

Melanie Goisauf
Senior Scientist / ELSI
Lead Ethics of AI Lab

Jasjote Grewal
ELSI Services Officer
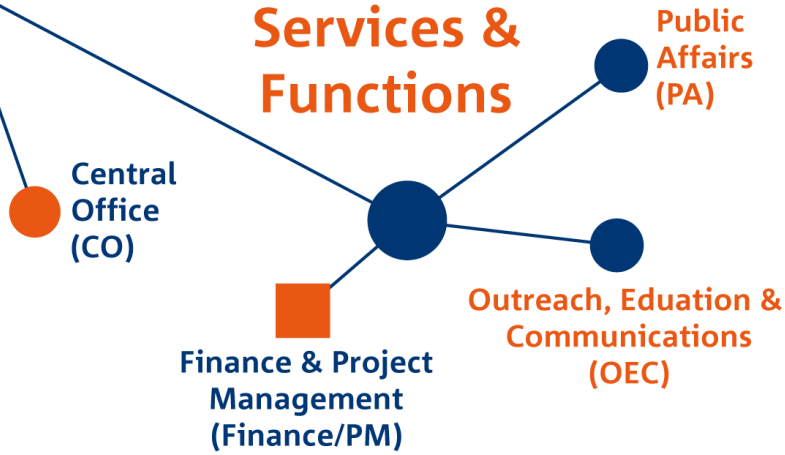
Jens K. Habermann
Director General

Barbora Halmová
Head of CO

Petr Holub
Head of IT / CIO

Central Services & Functions

Public Affairs (PA)

Central Office (CO)

Outreach, Eduation & Communications (OEC)

Finance & Project Management (Finance/PM)

Jirka Horák
Developer for WSI

Johanna Kostenzer
Senior Public Affairs Specialist

Łukasz Kozera
Senior Programme Manager

Konrad Lang
Lead Developer & Service Operator

Kurt Majcen
IT Scientist & Project Manager

Grazia Malovan
Biobanking Specialist

Mariangela Masiello
Media Relations Specialist

Michaela Th. Mayrhofer
Head of ELSI

Aurel Molina
Project Management Officer

Lana Mulabdic
Finance Officer

Heimo Müller
IT Senior Scientist

Nadja Palko
QM Representative

Manuela Pausan
Scientific Stakeholder Specialist

Jana Pavlič-Zupanc
Head of PA

Michael Prattes
Media Relations Specialist

Sára Pungor
Administrative Assistant

Ulrike Rohrer
Human Resources Specialist

Bridget Sheehan
Media Relations Specialist

Eleanor Shember
Head of OEC

Thomas Steger
Head of Finance/PM

Maike Tauchert
Quality Manager

Milos Terzic
UI Developer

Radovan Tomášik
Developer & Service Operator

Rudolf Wittner
IT Scientist

Andrea Wutte
Head of QM