

**VIS**

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PAPER

**BBMRI-ERIC's vision is to further build and strengthen value-added sustainable biobanking for all stakeholders, enabling academia and industry to make new treatments possible.**

BBMRI-ERIC, the Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium is a unique infrastructure with 20 Member States and one International Organisation having joined forces in establishing one of the largest health Research Infrastructures in Europe today. It is the mission of BBMRI-ERIC to establish, operate and develop a pan-European distributed research infrastructure of Biobanks and Bio-molecular Resources to promote the access to resources as well as facilities and to support high-quality biomolecular and medical research.

In line with our mission, this vision paper sets our strategic objectives for the years ahead and provides a guide to design our tactical actions. To ensure sustainability of BBMRI-ERIC, it is necessary to set a clear plan of action, which can be used by Member States, funders and possible partners as a reliable path for the development of the organisation. This approach is in line with the recommendations from the ESFRI Forum, and, more generally, it is a best practice to guarantee the smooth, transparent and progressive development of BBMRI-ERIC.

<sup>1</sup> ESFRI Scripta Volume II: Long Term Sustainability of Research Infrastructures, available here: <http://www.esfri.eu/esfri-news/esfri-scripta-volume-ii-long-term-sustainability-research-infrastructures-report-now>

## YESTERDAY'S ACHIEVEMENTS

From gene therapies to biomarkers, from rheumatoid arthritis to the latest cancer therapy, from basic research to clinical decision-making right into the hospital, everyone on the research-care continuum relies on human samples stored in biobanks. Pathologists, patients, clinicians, researchers, industry: all need a reliable way to store, access and analyse samples. Biobanking is where science meets treatment and the time is now to become systematically interwoven with other branches of biomedical research and treatment.

Research Infrastructures (RIs) like BBMRI-ERIC were specifically created to give order to disconnected scientific communities in key areas for the development of future research. ERICs provide researchers with reliable platforms to interact, by consolidating the collaboration among national research infrastructures. To do that, each ERIC focusses on a specific, narrow field, to strengthen the infrastructures and scientific community around it, and to make the ERIC itself a reliable and competent partner. RIs offer unique research services to users from different countries, attract young people to science, and help to shape scientific communities.

The results with BBMRI-ERIC are outstanding: it has created the largest biorepository on the globe, with more than 100 million samples. It's brought together the largest network of biobanks in Europe and in the world. BBMRI-ERIC has been determinant in finalising the establishment of an ISO standard that will finally help harmonise the way biobanks operate and in developing quality services to help biobanks expand further, via provided support on ethical, legal and societal issues to biobanks across the continent. In brief, BBMRI-ERIC and its Nodes have created a solid European biobanking community.

## TODAY'S OPPORTUNITIES

Currently, the larger international research trends show a call for integration, collaboration and sharing (SOURCE). Both fundamental research as well as personalised medicine research are multidisciplinary and can potentially have a real impact on making new treatments possible. This requires a solid understanding of the other forces in play, such as the needs of our partners and stakeholders. Visiting National Nodes, attending conferences and workshops, and providing a thorough market analysis yielded the following observations that will influence the strategy for the years ahead:

> The Member States and the European Commission are open to discussing the reform and consolidation of Research Infrastructures, where there is also a clear message to focus on the real added value and deliver on made commitments.

> In many cases biobanks still believe that researchers (from academia and industry) will instinctively connect with them when looking for high-quality samples and associated data. However, researchers often rely on alternatives to biobanks—mainly since sample collections hosted by biobanks are not well known, it is not easy to find the right sample in them, and, even if the sample is findable, it is often difficult to gain access to it.

On top of that, some researchers have a strong desire to just build up their own collections of specific material, hence creating duplication and confusion.

> The European Union launched various initiatives that require a closer cooperation among the health ERICs, and between them and the stakeholders:

- The European Open Science Cloud (EOSC) is the most important

European initiative on research data. EOSC helps BBMRI-ERIC to maximise the safe and secure sharing of data for research purposes.

- The next Framework Programme (FP9) potentially launches several missions (SOURCE) – one of which will focus completely on the fight against cancer. It requires a high degree of openness, collaboration and interconnection with the other stakeholders that play a role in cancer research. BBMRI-ERIC's Directory can provide the FP9 cancer mission a key competitive advantage in comparison to other national and international "wars against cancer" and poses a significant opportunity.

- The European Reference Networks (ERNs) created 24 virtual hospitals, specialised in 24 different rare disease families, bringing together most European centres of excellence in the research and treatment of rare disease. For the moment, the ERNs are focused only on treatment, but the European Commission's strategy foresees the set-up of a research component of the ERNs in the near future. This has the potential to bring together the largest cohort of rare disease patients to date.

> Major industry players are restructuring and organising their setup to be better partners, cover the majority of the needs and become less fragmented (SOURCE). On top of that, important regulatory updates will bring new opportunities for BBMRI-ERIC and the National Nodes to collaborate with industry.

> The ISO standard TC 276 on biotechnologies will be launched in late

2018. BBMRI-ERIC was a protagonist in the production of the standard, which will shape the development of existing and new biobanks.

> As of 2022, the new regulation for medical devices and in vitro diagnostics will enter into force, binding industry to new requirements to market their products. BBMRI-ERIC can provide important services to ensure patients' safety and security, while supporting industry in bringing new compliant products to the market.

> Academia and hospitals are launching new initiatives where research disciplines are brought together to have more impact and better use of technology and knowledge. The line between research and treatment is becoming less strict.

> Patients and consumers' organisations are sometimes lost in the landscape of different ERICs and other research initiatives. They aim for impact and are less interested in speaking to the individual parts of the chain.

> Several countries understood the need for a coordinated approach to health research infrastructures and personalised medicine and have already started working in a closer and coordinated way (Finland, Netherlands, Luxembourg, etc).

> Sustainability of high-potential demonstrators, tools and/or new services developed in H2020 projects can be further increased once integrated in an RI like BBMRI-ERIC.

## TOMORROW'S ACTIONS

BBMRI-ERIC has been instrumental in defining what a modern, high-quality European biobank looks like, with supporting services developed in the recent years. These services have now matured and can accelerate the pathway from laboratory discoveries to diagnostics and treatments. This requires integration in the real-life practice of academic and industry researchers, to ensure that they become stepping stones on the path toward new treatments. In addition, it is crucial to operate towards a service-oriented total workflow model, serving the needs of all our stakeholders (incl. clinical, rare disease and, for example, paediatric communities).

## **UNDERSTANDING WHO WE ARE WORKING FOR – OUR STAKEHOLDERS (SEEING)**

A service-oriented biobank must know who its stakeholders are and what they need. To provide better services to our stakeholders and build partnerships, we need to understand their needs and requirements in greater detail. A strong start has been made with the Stakeholder Forum, and its added value is already proven. Expanding the Stakeholder Forum is now instrumental in achieving the next steps: becoming our pool for first-hand information exchange directly with our stakeholders.

## **SHARING THE NEW MESSAGE: MARKETING A NEW VALUE PROPOSITION (STARTING)**

Making new treatments possible is the ultimate goal of BBMRI-ERIC and its stakeholders, and it is also the new message that will be communicated widely and consistently. In the traditional marketing approach, the end user is asked to share requirements for a specific product or service need in order to determine which solution fits best; the end user is capable of making a selection based on fulfilment of these requirements on a technical level, i.e. the needed 'ticket to ride'. BBMRI-ERIC has already developed a robust set of services but can be even more proactive to match them in a more targeted way for potential new users and significantly grow the userbase.

For example, the launch of the new ISO standard TC 276 in late 2018 will provide BBMRI-ERIC a significant opportunity to promote its Quality Services, crucial for the development of personalised medicine solutions, medical devices and diagnostics.

There are many possible BBMRI-ERIC partners (research organisations, industry) looking for experts who can guide them towards the right answers to their biobanking needs. The objective of the BBMRI-ERIC marketing strategy will be to turn this known unknown into a competitive advantage for our network.

## **INTENSIFY AND EXPAND COALITION (SUSTAINING)**

BBMRI-ERIC assets and services are key to the development of personalised medicine solutions, but they cannot solve the personalised medicine riddle on their own. This means that our services must be seamlessly integrated with other, complementary services by expanding the number of formal collaborations with BBMRI-ERIC and deepening the level of cooperation. The renewed, deeper collaboration will involve other RIs, research organisations and industry, and will have a specific scope and clear rights and duties.

Of particular importance will be the collaboration with our direct peers, the other health RIs. Consolidating a joint value offer would create an unprecedented total workflow powerhouse for personalised medicine research that can have a real impact. Increasing our collaboration with other RIs will decrease isolation and fragmentation of efforts. Most importantly, such renewed alliance will increase the impact of the activities significantly and minimise waste of precious resources.

Another key partnership shall be developed with the community around the European Reference Networks. The research component of the ERNs must integrate BBMRI-ERIC services and biobanks, to avoid duplication and ensure the samples collected within the

ERNs are preserved at the highest standard. To sustain the growth and structural change of BBMRI-ERIC, the organisation must keep and increase its high standards of employment, seek talent and implement measures to retain it.

Last but not least we need to intensify the cooperation with the large population-based cohorts of Europe containing samples and reliable phenotype and epidemiological information. They are critical when the population impact of identified genetic variants or joint effects of genes and environment/lifestyle is being evaluated. Such analyses in large prospective cohorts are necessary before any translational use of the genome or other '-omics' information in early diagnosis, or prediction of disease progress, mortality or response to treatment. For this, coordination of European biobanks and better availability of their samples/data for the research community are imperative.

## DIGITAL SCIENCE (SUSTAINING)

Data is the pivot around which BBMRI-ERIC and all its stakeholders work. Patients and consumers provide data, BBMRI-ERIC and its biobanks store it, and our stakeholders analyse it. With the advent of the big data era, the pivot shifted unmistakably from the sample to the data (originated by the analysis of the samples). A key driver for the success of biobanks and the wider workflow will be a more digital science approach. Recognising this is key to building a new BBMRI-ERIC approach to research collaborations.

In the next 5 years BBMRI-ERIC must build on its CS IT service to develop demonstrators and integrate biobanking in the electronic record evolution that is happening in Europe. We can be one of the drivers for the healthcare research community, but BBMRI-ERIC will require more expertise in sample storage and data management. Ensuring that the vast amount of annotated data is linked in a robust manner requires a complex system of integrated solutions and partners: BBMRI-ERIC can bring these together and act as the main driver.

Data is not all about technology: BBMRI-ERIC established itself as a leader in the field of data protection and ELSI issues related to health data. The full development of the Code of Conduct will consolidate our leadership role, but more resources must be devoted to “walk the talk” and create the European health data sharing space ensured by the GDPR and the Code.

## IN CONCLUSION

BBMRI-ERIC has the passion, skills and services to exceed expectations in building and strengthening value-added, sustainable biobanking. In the years ahead BBMRI-ERIC will be part of a total workflow for health research and personalised medicine, where biobanks are the key drivers in enabling academia and industry to make new treatments possible.

# INCREASING THE VISIBILITY OF BIOBANKS AND SAMPLE COLLECTIONS



# **ACTION PLAN**

## VISION PAPER 2019 – 2021

BBMRI-ERIC has the passion, skills and services to exceed expectations in building and strengthening value-added, sustainable biobanking. In the years ahead, BBMRI-ERIC will be part of a total workflow for health research and personalised medicine, where biobanks are the key drivers in enabling academia and industry to make new treatments possible.

These actions will be executed in the following years:

### WP19 **SAMPLE ACCESS**

- Create market intelligence to match service offering with stakeholders
- Expand and intensify Stakeholder Forum with Industry pillar
- Split between real services for sample access and project-driven research
- Increase outreach activities via dedicated campaigns on various services
- Publish Code of Conduct for Life Sciences
- Mobilize partner network, explore potential collaboration areas
- Finalize development pipeline tool into real services (e.g. Directory, Negotiator, pre-Audit, etc.)
- Monitor progress and drive growth of access numbers

### WP20 **CONSOLIDATION**

- Link services approach where possible with other medical RIs to prevent duplication and increase effectiveness
- Execute collaboration with partners, use Global Biobank Week as driving force
- Start building value proposition towards total workflow approach using demonstrators
- Scientific research focus on digital science
- Expand Stakeholder Forum with Regulatory Bodies
- Develop model to host sustainable project deliverables
- Monitor progress and further grow potential user base of services

### WP21 **TOTAL WORKFLOW APPROACH**

- Drive utilisation of samples supported by digital science focus
- Improve visibility by leveraging total workflow value proposition into scientific successes
- Centralise outreach activities on demonstrators in making new treatments possible
- Mobilise commitment from partners and all stakeholders

**MAKING**  
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