WHAT ARE THE KEY FACTORS FOR THE SUCCESS OF BBMRI-ERIC?

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The general aim of the breakout sessions during the 1st Scientific Retreat was to identify 3-5 key factors that are considered indicators for the success of BBMRI-ERIC by National Node Directors and their Representatives respectively. This White Paper represents the results and concensus reached among the Members of the Management Committee representing the scientific biobanking community of their respective Member States and National Nodes:

Article 3 of the statutes defines that BBMRI-ERIC shall establish, operate and develop a pan-European distributed research infrastructure of *biobanks* and *biomolecular resources* in order to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research. BBMRI-ERIC shall implement its Work Programme as adopted by the Assembly of Members. Moreover, in its mission statement, BBMRI-ERIC commits to increase efficacy and excellence of European bio-medical research by facilitating access to quality-defined human health/disease-relevant biological resourced through:

- the inclusion of associated data in an efficient and ethically and legally compliant manner,
- by reducing the fragmentation of the bio-medical research landscape through harmonisation of procedures, implementation of common standards and fostering high-level collaboration and
- by capacity building in countries with less developed biobanking communities thereby contributing to Europe's cohesion policy and strengthening the ERA.

Today's knowledge on human diseases as well as available diagnostic assays and drugs essentially rely on systematic investigation of human biological samples from healthy populations or diseased individuals, and by correlating molecular disease phenotypes with information on genetic makeup, life style, therapeutic interventions and diseases outcomes. Biobanks contain collections of a variety of human biological samples, such as blood, cells, tissues, and DNA, as well as associated information on the sample and the sample donor and biomolecular resources. As such, they provide a well-defined framework enabling medical research in a quality-controlled and ethically and legally

compliant manner. Biobanks are typically established in the context of prospective cohort studies involving individuals of a healthy population or as clinical biobanks established within health care containing samples and data from patients with certain diseases or disease groups.

Hence, it is considered of the highest importance to both recognise and emphasise that running a Pan-European Research Infrastructure is something quite different than running a research project. Within the legal entity of BBMRI-ERIC, the HQ is to be considered as the central co-ordination and support office. Overall, BBMRI-ERIC is complementary to the National Node infrastructures established by the Member States. Furthermore many highlighted the importance to integrate the National Nodes via the BBMRI-ERIC Headquarter (HQ) based on a spirit of mutual trust.

Any decision can only be made and be effective after a thorough exchange of views and needs of sample/data providers and users. Hence, any decision taken must reflect the Pan-European scope of BBMRI-ERIC and should add value to the national infrastructures by co-ordination, co-operation, harmonisation, or standardisation as well as by making use of and sharing the limited resources available throughout Europe and its Member States to everyone's benefit.

Moreover it was seen of utmost importance to consider what would be seen as the first indication of success of BBMRI-ERIC to the outside world. All agreed that getting fair access to samples with a high quality that is fit-for-purpose would consitute this important element. This should be reached with an updated and newly structured BBMRI-ERIC Catalogue of biobanks, therewith creating a gateway to it. Also, there was agreement that dedicated frameworks for prospective and retrospective sample collections are required.

With new ISO standards on the way we will have new tools to better describe the pre-analytical phase for many samples. But Europe has key function to be intermediate to transfer this also to other parts of the world. Many also pointed out the importance to better work on the integration for healtcare and BBMRI-ERIC needs to show what is the impact on society that it recognises as a value. Using pilot projects for testing solutions, BBMRI-ERIC should soon be able to show concrete results, which would not be possible without the infrastructure as the added value of BBMRI-ERIC has to be made visibile. BBMRI-ERIC should stand for high quality samples and data (credible source).

Hence, the key factors for BBMRI-ERIC's success are:

- Fair access to both samples and data (fit-for-purpose) enabled;
- A new BBMRI-ERIC Catalogue (including well-anonated samples and quality criateria) provided;
- An operational Research Infrastructure for the benefit of all its Member States which focuses on the particular stenghts and knowledge capacities of the individual National Nodes established.

In a spirit of mutual trust and collaboration for a truly Pan-European endeavour, BBMRI-ERIC henceforth intensifies the collaboration with other BMS RIs and biobanking initiatives stronger integrates the bibanking community and National Nodes on all levels and commits to a both bottom-up and top-down process therewith allowing to obtain both the political support and the support from the scientific communities.