Infrastructure: Delivering on the Promise of Biobanking

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Erik Steinfelder

Abstract

Researchers are constantly looking for high-quality samples and associated data stored under the right conditions. Hence, for many it is still difficult to find the right biobanks and to gain access to the collections. This puts the sustainability of individual biobanks at risk. At the same time, the samples and associated data are crucial for biomedical research not only for the development of new drugs and new treatments but also to support developments in prevention. In order to drive research and generally promote innovation as efficiently and effectively as possible, the European Commission has responded with an initiative called Research Infrastructures. Research infrastructures cover many scientific topics such as translational medicine, social sciences and marine biology to advance knowledge and technology. This chapter lists some services that can help biobanks find solutions to their problems in the daily work process.

Keywords

Initiatives · European Commission · Research infrastructure · Services · BBMRI-ERIC · ADOPT project

Researchers are constantly looking for high-quality samples and associated data that are stored under the right conditions [1]. However, for many it is still difficult to find the right biobanks and get access to the collections. In daily routine the complex legal and ethical frameworks in combination with different procedures are creating such hurdles that currently less than 5% of the stored samples in Europe are actually used [2]. Hence, sustainability of individual biobanks runs into mischief. At the

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E. Steinfelder (✉)
Thermo Fisher Scientific, Eindhoven, Netherlands
e-mail: erik.steinfelder@thermofisher.com

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same time, the samples and associated data are crucial for biomedical research not only for the development of new drugs and new treatments but also to support developments in prevention. This would be impossible without biobanking.

To drive research and foster innovation as efficient and effective as possible in general the European Commission responded with an initiative called Research Infrastructures [3]. Research Infrastructures cover many scientific topics like translational medicine, social sciences and marine biology to advance knowledge and technology. In these new research ecosystems, involving many different countries, researchers have shared access to a variety of services that can support their journey to find solutions for problems that society faces today.

BBMRI-ERIC

On December 3, 2013, a Research Infrastructure, with the special legal status of an ERIC (European Research Infrastructure Consortium), dedicated to biobanking started and was named BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure-ERIC) [4]. Founding member countries were Austria, Belgium, Estonia, Germany, Greece, France, Italy, Malta, Netherlands and Sweden. Observer countries were Norway, Poland, Swiss and Turkey.

Building a biobank community, currently connecting over 500 biobanks, and having a joined approach on quality, IT and ELSI were the cornerstones of the activities of BBMRI-ERIC. Since the participating member states also created an infrastructure on a national level (“BBMRI.xx program”), a distributed European approach was possible creating an overarching structure with common goals but also flexibility to address country-specific challenges.

Knowledge Hub of BBMRI-ERIC

The quality activities in the so-called knowledge hub brought together over 100 biobank quality experts who can be consulted for questions and guidance in international standards that are relevant for biobanking and biomedical research. An instrumental contribution was delivered to the creation of the new ISO 20387 biobank standard, launched in October 2018 [5]. The same group of experts continued educating the wider audience on compliance, the advantages, challenges and opportunities when looking at the details of quality. Biobanks can also assess their own internal processes via the BBMRI-ERIC Self-Assessment Survey or peer-reviewed style audits on request [6].

ELSI Group of BBMRI-ERIC

The ELSI group was instrumental in creating the self-service knowledge base and federated ELSI helpdesk, where support on topics like access policy and MTA/DTA (material transfer agreement/data transfer agreement) can be given via a network of experts. In response to the launch of the EU General Data Protection Regulation (GDPR) on May 2018 an initiative for a code of conduct on Health Research started, providing guidance to researchers and administrative staff, reducing unnecessary fear related to compliance and enhancing data sharing [7].

IT Group of BBMRI-ERIC

Samples without associated data have little to no value for the majority of researchers, and therefore IT-related services were on the program from day 1. Several tools were launched to support researchers in finding material, also enabling effective communication between the parties involved. Services for newly established biobanks or biobanks lacking sufficient IT systems are also offered, and in the near future, data harmonization services are planned. BBMRI-ERIC leads the development of provenance information standard in the ISO Working Group TC 276 in order to allow computer-based assessment of the quality of samples and data.

Sample Directory of BBMRI-ERIC

Improving access is a key indicator to measure the success of BBMRI-ERIC in general where the described services should enable this on a more detailed level to the various stakeholders. The Directory, for example, a catalogue containing collections from biobanks all over Europe, creates the possibility to simply browse biobanks by name or search sample collections according to different criteria such as kind of material, diagnosis, country, etc. [8]. Since it allows researchers to check if there are samples matching their criteria, the Directory is a very powerful tool, especially if someone is in the early stage of writing a project proposal or developing a research project. There are great collections and in Europe, over 100 million samples are stored but as mentioned hardly 5% are used on average. Monitoring the number of visits, requests or samples or cooperation and successful matches on a monthly basis is a good indicator to see if access is really increasing.

The ADOPT Project and Beyond

Executing on the improving access strategy and achieving the desired goals require funding and resources. Research and Innovation Actions (RIA) were activities within Horizon 2020 that aimed for establishing new knowledge and/or to explore the feasibility of new or improved technologies, services or solutions, supported with in most cases 100% funding of the activities. A Research Infrastructure could apply for this type of grant and BBMRI-ERIC was successful with the ADOPT proposal (implementAtion anD OPeration of the gateway for healTh into BBMRI-ERIC). The ADOPT project started in 2015 and aimed at boosting accelerating the implementation of BBMRI-ERIC and its services [9]. Aware of the challenges in getting access and sharing data across Europe and the desire from the funders to increase the actual use of the collections, a dedicated task was created to map the challenges to be overcome and develop a blue print on how to share data sets from patients across Europe, who were in this specific case diagnosed with colorectal cancer (CRC). To achieve this, a common data model was defined, a data protection policy written, the recruitment process defined and how participating biobanks could be reimbursed. During a period of 30 months, the project was executed and delivered an impressive result; in the end, 25 biobanks from 12 different European countries were able to bring 10,480 cases together [10, 11].

Important learning point is the need of expertise on the ethical and legal side that both have to work constructively with IT to create the needed contracts. An important aspect that shouldn't be underestimated when respecting both national legislation and university policies. A major other learning point in the project was the discussion around reimbursement. There was funding to support the biobanks that delivered the datasets, but in hindsight, this was far from being enough to compensate the real costs involved.

Overall benefit to the wider community is that the models that were developed are now publicly available and can be used for projects and consortia that do want to access pan European datasets. For an individual university to have the bandwidth to achieve something similar is close to impossible and is a waste of valuable resources to reinvent the wheel all the time in every biobank for every contract or sample sharing activity. Projecting this information to, for instance, Ukraine, where colorectal cancer in 2020 is the third cause of cancer death for both men and women, it can significantly advance the research and re-use of data, which is another important aspect of the fact why we are biobanking [12].

Biobanks have a variety of stakeholders, (researchers, clinicians, policymakers, funders, patients, regulatory bodies, industry) that have power, legitimate interest and are willing to take action. If you want to have maximum impact speaking in one voice with a clear mandate, this is the only way forward. Within an individual institution, you can negotiate and focus on specific items relevant for you, but if this is too much of a difference, you can end up with many different contracts and in daily practice this is not workable. This also was a learning point in the described CRC cohort. Within a research institution (RI), you can try to work out consensus and with that agreement you can go to other negotiations, and this is working bi-directional. For policymakers or patient organizations, for instance, it is also more efficient and creates more impact if they can discuss with a network organization or infrastructure versus several separate universities.

When resources and funding are scarce, you have to do it right. This is certainly an obligation to the patients whom you are taking into account. You are actually using their material and data to really foster research and drive innovation. In recent discussions around the GDPR implementation experiences, it was clear that it sometimes creates so many hurdles to actually use the samples in other institutions that they are simply not willing to cooperate or share, afraid of the legal consequences. Research Infrastructures can address this to the right policymakers and have a strong united voice.

Joint Forces of Research Infrastructures

The wish from ESFRI (European Strategy Forum on Research Infrastructures) and BBMRI to actually start measuring KPI's (key performance indicators) should also give more transparency of the results that have been made or where a change in strategy is needed to gain more impact. By doing, this on a national level you can also see where additional help is needed. An extra step that is currently made to have more impact is the fact that in some countries different medical RI's joint forces; Health RI in the Netherlands and AMRI (Alliance of Medical Research Infrastructures) as an initiative on a European scale; here BBMRI-ERIC, EATRIS-ERIC (European Advanced Translational Research Infrastructure in Medicine-ERIC) and ECRIN-ERIC (European Clinical Research Infrastructure Network-ERIC) are joining forces to tackle pressing issues in medicine development for the benefit of the patients. Increasing the visibility and getting access to the stored samples is key, not only in the countries that were there from the beginning, but maybe even more for those biobanks in LMICs (Low- and Middle-Income Countries).

In quite some Western European countries, a strong network of scientists and departments in academic centres already exists and via H2020 scientific excellence was achieved. But how does this work for Eastern Europe that in some cases is still building and not ready for excellence? Another good example where a research infrastructure can help: learn from the ones that have done it already, but also learn from their mistakes. Transparency can help drive research forward and deliver on the promises that biobanks have already for quite some time. Bulgaria joined BBMRI-ERIC in 2019 and Lithuania in 2020, which shows interest from Eastern Europe and connections with the biobank community. In response, one of the activities of BBMRI-ERIC is to develop a strategy for National Nodes to use European Structural and Investment Funds and other capability building opportunities, also supported by Latvia, Poland, Lithuania and Estonia.

Increasing access of samples cannot be achieved without investing in the visibility of the biobank community and the collections that are available for research. Communication is key: What can you do as individual biobank in promoting your own collection? There are of course the networks between universities in one country and beyond and this is happening already within consortia. However, outreach activities only show that average researchers simply are not aware of the availability of catalogues or sample collections in the medium and small size academic institutes. Visibility might even be more important for those that are in LMICs. They manage in many cases unique collections that are of high interest to other academic institutes and biotech companies. Initiatives like B3Africa, the ESBB Africa Working group, and the BBMRI-ERIC ADOPT internationalization project task in the Middle East and Latin America all can help support multiple biobanks in one communication campaign to reach a wider audience.

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