Role of Academic Biobanks in Public-Private Partnerships in the European Biobanking and BioMolecular Resources Research Infrastructure Community

Hämäläinen, Iiro

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The role of Biobanks in Public-Private Partnerships and the BBMRI Expert Centres

Iiro Hämäläinen[1,2], Outi Törnwall[3], Birgit Simell[1,2], Kurt Zatloukal[4], Markus Perola[2,1] and Gert-Jan B van Ommen[5].

1. University of Helsinki, Institute for Molecular Medicine, Finland (FIMM) and Diabetes and Obesity Research Program
2. Department of Public Health Solutions, National Institute for Health and Welfare, Helsinki, Finland
3. Biobanking and Biomolecular Resources Research Infrastructure-European Research Infrastructure Consortium (BBMRI-ERIC), Graz, Austria
4. Institute of Pathology, Medical University of Graz, Graz, Austria
5. Department of Human Genetics, Leiden University Medical Center, Leiden, The Netherlands

Correspondence:

Name: Iiro Hämäläinen

Address: Haartmaninkatu 8, Biomedicum 1, 00290 Helsinki, Finland

E-mail: iiro.hamalainen@helsinki.fi

Telephone: +358407437006

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Abstract

Public-private partnerships (PPP) are an efficient means to advance scientific discoveries and boosting the medical innovations needed to improve precision medicine. The increasing number and novel nature of such collaborations is keeping the biomedical field in a constant flux. Here we report the views on PPP of 20 key players in the European biobanking community. The results indicate that PPP have become a reality in biomedical research collaboration and are also constantly yielding further collaborations and benefits. The interviewed academic representants broadly show interest for their institution to initiate or partner with BBMRI Expert Centres, a specific type of PPP, established by BBMRI (the European Biobanking and BioMolecular Resources Research Infrastructure) to facilitate access to samples and data and to improve data interoperability and reproducibility.

Introduction

PPP are multi-stakeholder institutional arrangements between actors of the public and private sector[1, 2]. They generate benefits for both sides: access to the other parties' resources or expertise, joint scale advantages, outsourcing part of the work to the other party, and increasing the efficiency of product development.

PPP have an increasingly recognized role in advancing medical science through combining efforts and sharing risks between academic teams and companies (e.g., technology providers, biotech, diagnostic companies and manufacturers, pharmaceutical industry). In designing new drugs and treatments, the basic research is

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typically done by academic researchers, while the private sector then takes care of the development. Combining these allows sharing of core competencies and knowledge between both parties, replacing the classical model of R&D, where the basic academic research is performed in isolation, incidentally followed by a licensing procedure after which the actual drug development is conducted in-house in the private arena[2, 3].

Biobanks, most often publicly funded, offer a wide range of biospecimens with associated clinical and lifestyle information, omics profiles, and/or imaging data ('deep-phenotypes'). This broad and deep combination of samples and associated data is a powerful asset of the public sector, in its scale unique to biobanks and cohorts and invaluable in drug discovery and development process. Thus far, the downstream analytics are often done in the private sector to ensure standardized conditions and protect Intellectual Property (IP). Arguably, much can be gained by integrating this segmented process, increasing technological aptitude in basic research and reducing entrepreneurial risk in development. The inclusion of biobanks and cohorts in PPP greatly strengthens theirs scope, and it also increases financial sustainability for academic institutions, biobanks and cohorts.. The greater operational efficiency of this integration will lead to savings and reduction of time-to-market, benefiting patients and society.

On the other hand, while academic researchers mostly aim to serve the common good by addressing medical problems not-for-profit, generating scientific publications, the private sector is more typically profit-driven. Thus, the goals of PPP parties are not automatically aligned and timely negotiations are required to find common interests and to maximize use of resources. The different objectives may raise ethical issues related to the privacy and ownership (control) of samples and data. Striking a proper

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balance between individual privacy and the public right to medical progress[4,5] will remain a central issue for the future of PPP in health research.

BBMRI-LPC (Biobanking and BioMolecular Resources Research Infrastructure – Large Prospective Cohorts) was an FP7 EU project active from 2013 to 2017 aiming to provide facilitated access to large European cohorts. BBMRI-LPC united large study sets of the European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) and the International Agency for Research on Cancer (IARC), thus constituting a biobank network of a globally unique scale and integration. BBMRI-LPC has assisted the European health field by providing transnational access to biobanks and by promoting new and existing Public-Private Partnerships (PPP). This strengthens the European Research Area in translating science to better treatments and enhances the return of investments by the European tax payers.

The BBMRI Expert Centre model

In an earlier paper we outlined the BBMRI Expert Centre concept, as a specific type of PPP linking the public and the private sector[6] (Fig. 1). Briefly, such a Centre functions by performing the primary analyses of quality-defined biological samples under internationally standardized conditions, in order to improve interoperability and reproducibility of research data, which can be jointly used by the public and private partners. Furthermore, this highly standardized transformation of biological material into data offers new opportunities for data sharing and integrated data analysis, which becomes increasingly important in the context of open science and open innovation. This goal builds on four major pillars:

- to provide access to quality-defined samples which comply with international standards;
- to perform sample analyses under highly standardized conditions as a basis for reliable and reproducible data on human diseases;
- to provide high-quality information from biological samples to industry for product development[7];
- to provide access to quality-defined and reliable data to the international scientific community, reducing transnational sample shipment and reanalysis..

The BBMRI Expert Centre concept is flexible: it can be a consortium or bilateral collaboration, transnational, national or regional, and can have a general scope or a specialized focus (Fig. 1). To maximize discovery involving (multi)national public funds, the generated data and resulting insights should become public as soon as possible. However, to properly function at the public-private interface, a limited period of

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confidentiality is allowed, e.g. for allowing IP protection. This does not preclude parallel engagement of Expert Centre parties in confidential research, but then transparent, market-conform arrangements should apply to the use of the facilities.

For Expert Centres to gain BBMRI approval, and thus to distinguish themselves from many other Expert Centre activities, they must comply with the following criteria[7]:

- use of common standards and reference materials;
- participation in proficiency testing/ring trials;
- publication of general SOPs for sample pre-analytics, analysis and data generation;
- implementation of common quality management systems
- certification where applicable (e.g., ISO)
- periodic external audits according to the BBMRI-ERIC quality system. transparent confidentiality and IP rules;
- ethical and legal compliance;

This concept has been adopted by BBMRI-ERIC (BBMRI-European Research Infrastructure Consortium), and two approved BBMRI Expert Centres are described below.

To assess the public-private collaborations in the European biobanking field in more detail, we here interviewed BBMRI-LPC participants about their current PPP activities and their thoughts about the BBMRI Expert Centre model

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Materials and Methods

In total 25 key individuals involved in the BBMRI-LPC-related biobanks and academic centers were contacted, all representing different institutions, and 20 agreed to be interviewed for the study, representing institutions from 10 European countries (Table 1). Two declined due to time constraints and 3 did not respond. 16 people were interviewed by a semi-structured telephone interview and 4 answered in a written form. Two of them answered together and are considered in the results as a single answer. The interview questionnaire (Table 2) was developed jointly by University of Helsinki-Institute for Molecular Medicine Finland (UH-FIMM) and Leiden University Medical Center (LUMC). The interviews were conducted between September 2015 and September 2017 by the same institutions.

Results

While most of the interviewees were supportive of either establishing or becoming a partner in a BBMRI Expert Centre (Table 2), several needed more information on the concept, its requirements and their potential role. Eg one of the interviewees said:

> *"…in my experience for the management of many institutions like mine and all these in our country have faced multiple initiatives for these collaborative efforts. And for many of these managers it's hard to tell whether this is an important or immature initiative and this makes me a little hesitant to make another level of complexity on top of simply participating BBMRI as it is."*

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Almost every interviewee stated that they already collaborated with many partners including companies, both nationally and internationally (Table 2 and TEXT INSERT PANEL). These collaborations were usually described as research/scientific collaborations (Table 3) and had been mostly initiated through official national and international programs. The collaborations with companies were mainly with diagnostic, pharmaceutical or IT industry and usually involved only one or a few companies at a time. The most popular types of collaboration were specified to be joint discovery, precompetitive research or biomarker development , but there were many other activities mentioned multiple times, like vendor-customer, imaging, software development, creation of protocols, training and joint research programs (Table 3).

Almost every interviewee reported that their collaborations, mainly with IT and big pharma companies, had led to additional benefits or new joint alliances (Table 2) and several reported that they were negotiating new ones. The interviewees had also met challenges with establishing collaborations and were hoping for possible solutions to increase the collaboration. One interviewee said:

> *Industry tends to rather work with a small amount of people than with larger consortia. If you really want to make these connections, it isn't easy if you present yourself as a consortium with many collaborators. We should highlight this problem and point out that many common disease academic consortia have been very successful, and that now the time has come for industry to also move into 'consortium mode'. Especially for less common diseases this is the only way forward.*

Only a few of the interviewees' collaborations were confidential (Table 2) at the moment of the interview. Even then several companies were already mentioned and in later interviews many of the restrictions had fallen away (Table 4).

As key impact areas the interviewees mentioned improving access of industry to public biobanks, improving reproducibility of research data, and enabling open science and open innovation.

Six interviewees stated that their biobank/academic center already worked like a BBMRI Expert Centre and might officially become one. Two interviewees specified their organizations' interest to function as a national Expert Centre, offering a wide variety of Expert Centre-like services.

A few more hesitant interviewees had concerns of increased bureaucracy (n=2) and/or questioned the benefits compared to their present setup (n=2).

Discussion

The main objective of the present study was to examine the types of collaboration between the public and private sector in the European biobanking field. We find that significant national and international collaborations have already emerged, both amongst biobanks and cohorts, and between biobanks and industrial partners, in many European countries. There is great interest towards extending PPP collaborations. The steeply rising cost to generate or access high-quality, large-scale clinical samples and deep-phenotype data has caused a crisis in time and money spent for R&D, while ever fewer new drugs are produced[8]. To accelerate translational research and increase the supply of the clinical samples and pertaining data, it is critical that biobanks achieve

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sustainability, for which engaging in PPPs is a valuable route[9]. There is a strong need to assess already operational PPP models, widely share insights and best practices, and generate new formats.

The fact that several interviewees were as yet unable to talk about some of their current and future public-private collaborations suggests that more of these exist than presently known. These may well be reported more openly once the capabilities, impacts and benefits of operational BBMRI-ERIC Expert Centres have become more concrete, and results from the first round of audits of established Expert Centres will become available.

In a more general perspective, all across Europe, the economy is on the rebound and local and regional public-private collaborations are being established. Some examples of this are:

1. In 2016-2017, two BBMRI-ERIC Expert Centres were officially approved: CBmed in Austria and ATMA in Italy. CBmed is an Austrian funded competence center, bringing together experts from the public and private fields of pharmaceutical, diagnostic, medical-technology and IT industry, and with a strong network in the field of Biobanking including Biobank Graz.

2. ATMA-EC is a non-profit organisation with a public-private partnership model, established under BBMRI.it and providing access to biological samples and data and medical and scientific expertise related to archive tissue samples and their analysis (hub IRCCS-CRO in Aviano, Italy), medical imaging and laboratory medicine (hub IRCCS-SDN in Napoli, Italy). Both CBmed and ATMA perform not-for-profit public-private research for identification and validation of biomarkers, and to conduct translational

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research under strict and transparent quality conditions, to help bring products to clinical practice.

3. BBMRI-LPC partners Zatloukal (BBMRI-LPC participant and part of the CBMed Expert Centre) and Landegren (BBMRI-LPC participant and part of the prospective SciLifeLab Expert Centre) participated in the IMI project OncoTrack, a public-private project led by Hans Lehrach (MPI, Berlin) and David Henderson (Bayer). Different types of samples from colorectal cancer patients in Austrian and German biobanks were being analysed at series of European centres with advanced expertise in a broad range of molecular analyses, with the aim to build in silico disease models to better predict therapeutic responses to potential therapeutic agents.

4. Several public-private collaborations are also established by BBMRI-NL cohorts. An early study led by Boomsma (Dutch Twin Registry) and the late David Cox of Pfizer studied the heredity of microbiome in monozygotic twins (manuscript in preparation). A second one, led by Wijmenga (Lifelines, BBMRI-LPC partner), involved 5 food companies (Nestle, Danone, Friesland Campina, Christian Hansen and Kellogg), integrating genome, transcriptome and methylome data of GoNL/BBMRI-NL and microbiome and intrinsic and exogenous factors of Lifelines. They found amongst others that blood lipid levels are partly explained by the gut microbiome (Fu et al., Circ res 2015), the genome (Bonder et al., Nat Genet 2016), and the role of diet and medication on gut microbiome (Zhernakova et al., Science 2016). In particular the effect of proton pump inhibitors has ignited a discussion on the 'over-the-counter' availability of proton pump inhibitors. The genetics x microbiome studies in turn led to a large consortium between many biobanks (MiBioGen) to increase the power to detect genetic variants contributing to microbial composition and hence disease susceptibility, proof of which

has been shown for IBD (Imhann et al., Gut 2016). Based on these results a much larger public-private enterprise has started between Lifelines and Novogene to sequence 10K metagenomes and to correlate the information with all phenotypes in the biobank.

5. GRC, the Genomic Research Consortium, is an international public-private consortium established by a number of major Pharma and Biotech companies (including GSK, Merck, Jansen, Takeda, BMS), a number of key Biobanks, some of which are BBMRI-LPC partners (NTNU/HUNT, Norway; EGCUT, Estonia, Biobank-UK, Karolinska, SE and Decode), and several international IT companies (WuxiNextcode, Genomics plc and Farr). GRC's mission is to "accelerate the genetic evaluation of clinically important outcomes to enhance the productivity of translational research for drug development". Following a successful proof of feasibility, it is currently in its expansion phase. Its aim after a development phase, is "to make its research capabilities available to member companies, bio-banking partners, and academic researchers pursuing non-commercial research endeavors". This is fully in line with the precompetitive nature of the BBMRI-ERIC Expert Centre model.

6. FinnGen is a second international large-scale genomics public-private partnership research project led by UH/FIMM (the Institute for Molecular Medicine Finland) the current BBMRI-LPC coordinator, and also involves THL, a BBMRI-LPC partner, and several pharma companies. FinnGen includes all nine Finnish academic biobanks and their background organizations, such as THL, universities and university hospital districts. The consortium includes seven big pharma companies Abbvie, Astra Zeneca, Biogen, Celgene, Genentech, Merck and Pfizer. The pharma parties and Business Finland, the Finnish funding agency for research and technology development, are

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funding the project by 59 m€. The project aims to enrich the Finnish biobank resources by new DNA samples and GWAS genotyping. During six years the FinnGen project aims to perform PheWas analyses to 500 000 study participants with the aim to initiate and enrich drug discovery programs.

In conclusion, after initial delays due to external economic circumstances, with the economy on the rebound, many public-private collaborations are being initiated Europe- and worldwide. This offers excellent perspectives for PPP-based innovation, with significant funding participation of the pharma industry and national and international funding bodies. One should be aware however, that it may take a few years before the recently initiated large PPP interactions will fully bear fruit, and continued funding – also for infrastructural maintenance – from public and private sources, including the European Commission's H2020 and national programmes, NGOs as well as from industry, is essential for maximal translational benefits of innovation.

Conflicts of interest

The authors report no conflicts of interests.

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List of figure legends

Figure 1: Expert Centres as new 'highways' for transnational research. In addition to public-private partnerships, the Expert Centre model can be used in public-private collaborations to provide efficient and secure access to samples and data between the collaborative parties (modified from van Ommen et al. 2015).

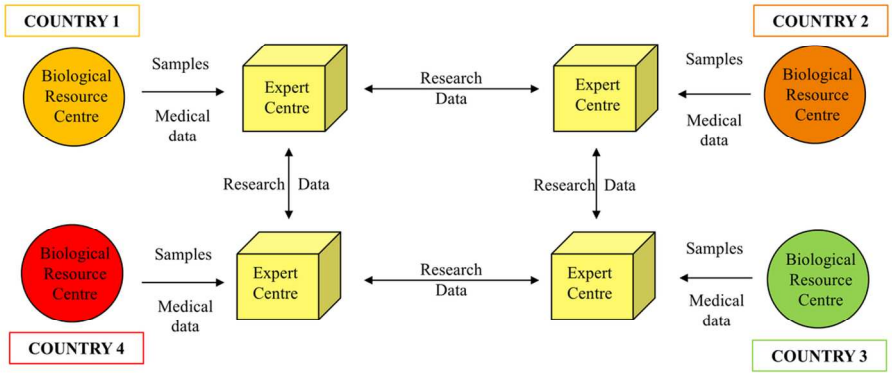
Table 1: The list of the interviewees and their institutions/networks.

Table 2: The questionnaire and the simplified and compiled results of the interviews for the inventory of PPP-based activities in BBMRI-LPC-related biobanks and centers.

Table 3: Types of public-private collaboration in BBMRI-LPC-related biobanks and centers.

Table 4: **Industry collaborations specifically mentioned. Additional companies were indicated but not named and referred to as "and other pharma/diagnostic/technology companies".**

Text insert (panel): Other biobank context aspects mentioned



Expert Centres as new 'highways' for transnational research. In addition to public-private partnerships, the Expert Centre model can be used in public-private collaborations to provide efficient and secure access to samples and data between the collaborative parties (modified from van Ommen et al. 2015).

114x52mm (300 x 300 DPI)

Interviewee	Institution/Network
Boomsma, Dorret	VU University Medical Center, Amsterdam, NL
Dagher, Georges	• INSERM, (past Nat Coord Biobanques), Paris FR • University of Milano Bicocca, IT
Goldberg, Marcel	• Population-based Epidemiological Cohorts Unit, UMS 11 INSERM, FR • Paris Descartes University, FR
Gut, Ivo	CNAG, Barcelona, ES
Hummel, Michael	Central Biomaterial Bank Charité, Berlin DE
Hveem, Kristian	K G Jebsen Center for Genetic Epidemiology, Department of Public Health and Nursing, NTNU, Trondheim, NO
Jalanko, Anu	THL-Biobank, FI
Landegren, Ulf	Uppsala University, SE
Lavitrano, Marialuisa	• BBMRI.it • UniMiB, Milan IT
Meijer, Gerrit	NKI Netherlands Cancer Institute, Amsterdam, NL
Metspalu, Andres	The Institute of Genomics, Estonian Genome Center, Tartu, EE
Palotie, Aarno	Institute for Molecular Medicine, Helsinki, FI
Pedersen, Nancy	Karolinska Institutet, Stockholm, SE
Slagboom, Eline	Leiden University Medical Center, NL
Solesvik, Ove	• Lifandis / HUNT Biobank, NTNU, Trondheim, NO • Currently: Aleap Health Incubator, Oslo, NO
Sundström, Johan	Epihealth Cohort, SE
van Duijn, Cornelia	Erasmus Medical Center, Rotterdam, NL
Wichmann, Eric (Retired)	• Institute of Medical Informatics, Biometry and Epidemiology, Ludwig Maximillians University, Munich, DE • Helmholtz Center Munich, Institute of Epidemiology, DE • Institute of Medical Statistics and Epidemiology, Technical University Munich, DE • Joint Biobank Germany, DE
Zatloukal, Kurt	Institute of Pathology, Medical University of Graz, AT
Zins, Marie	• Population-based Epidemiological Cohorts Unit, UMS 11 INSERM, FR • Paris Descartes University, FR

Table 1. The list of the interviewees and their institutions/networks.

Question	Yes	No	Not sure
1. Do You collaborate with other biobanks?			
- Nationally	**19**	**0**	**1**
- Internationally	**17**	**3**	**0**
2. Do You collaborate jointly or bilaterally with companies?	**20**	**0**	**0**
3. Has the collaboration with companies led to additional benefits and new/continuous collaboration?	**18**	**0**	**2**
4. Are you currently negotiating with any companies for future endeavors?	**17**	**1**	**2**
5. Do you expect your biobank to increase its collaborations in the coming year?	**10**	**0**	**10***
6. Do you wish to join or become a BBMRI Expert Centre in the future?	**14**	**3**	**3**
7. Do you have interactions/ collaborations that you are not licensed to discuss in this interview?	**6**	**10**	**4**

*For details of "other aspects", see TEXT INSERT PANEL

Table 2: The questionnaire and the simplified and compiled results of the interviews for the inventory of PPP-based activities in BBMRI-LPC-related biobanks and centers.

TEXT INSERT (PANEL).

Other biobank context aspects mentioned

" The biobank for the cohort is still under construction, so we are currently more focused on operational aspects."

"We are well on the way, so we'll mainly be consolidating and trying to benefit as much as possible from the recent infrastructures as a basic marketplace common environment."

"This kind of collaboration is definitely going to be a necessary feature in the future of large prospective cohorts. The interest towards public-private partnerships is on the rise. We're actively making our biobanks information more easily accessible, so private parties can better see what would be of potential value for them."

"We are focusing on this national network, a public company that would have all the national main biobanks and owners, to have a joint consortium but also a joint industry interphase."

"I think our cohort is doing the same amount of collaboration with industry than in a formal Expert Centre because we're already doing that on an intense level. We want to make sure that we don't just do the research the companies have already done or will do."

"The biobanks develop from sample into a knowledge infrastructure. So we're mainly focusing how we can better exchange data and knowledge. So we move from the classical sample issue more to the result."

"It's time for the biobanks to work more in collaboration with the two major stakeholders, on one side the patients and citizens and on the other side industries. Industry is still not confident towards public biobanks and we should help changing that."

Type of collaboration	Times mentioned
Research Collaboration	13
Joint discovery	9
Biomarkers	9
Imaging	6
Software (development)	6
Test runs/protocols/methods	6
Vendor-customer	5
QA/QC	4
Other mentioned	Training (n), ELSI-services (m)

Table 3: Types of public-private collaboration in BBMRI-LPC-related biobanks and centers.

Times mentioned	Name of the company
4	Pfizer
3	Biogen, Merck
2	Astra Zeneca, Eisai, Philips
1	ASSOBIOTEC, BC Platforms, Bracco, Decode, Dompé, Esaote, Felix, Ferrer, GBS Leiden, GenAlice, GRC, Johnson Pharmaceuticals, Lilly, Marck Kgaa, MBH House, Millennium Pharma, Nestle, Novartis, Olink Bioscience, Piramal Healthcare, Regeneron, Roche, Rutgers repository, Somalogic, Stella, Synlab, Unilever

Table 4: Industry collaborations specifically mentioned. Additional companies were indicated but not named and referred to as "and other pharma/diagnostic/technology companies".