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BRIEF REPORT

Enhancing Cooperation Between Academic Biobanks and Biomedical Industry: Better Mutual Understanding and New Collaborative Models Are Needed

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Introduction

Academia and biomedical industries often still operate in their own ivory towers, although collaboration has long been considered desirable and important. This also applies to biobanks and the area of biobanking in general. Regardless of where biobanks are located—in an academic setting, as part of a biomedical company, or any other place—they all serve as a central source for samples and data in research, both for academic researchers and researchers in the biomedical industry. Theoretically, all researchers have the possibility of getting access to thousands or even millions of samples and their related data donated by a large number of patients and volunteers to hundreds of academic biobanks worldwide.[1] Therefore academic biobanks are pivotal research resources for drug and biomarker research and development (R&D) carried out by researchers in the biomedical industry.[2]

The different cultures, objectives, and working practices of the two different worlds—academic biobanks and researchers from industry—are possible reasons for the lack of understanding and cooperation between these stakeholders. Despite the fact that there is an obvious potential fit between academic biobanks and industry, a broad gap exists between them.[3,4] We argue that with improved mutual understanding and by changing age-old traditional working practices, both academic biobanks and researchers in the biomedical industry will benefit. This could also lead to an enhanced sustainability of academic biobanks.[5,6] In our article, we will highlight some key obstacles to this collaboration and will propose some solutions.

Research in Academia and Industry Differ

To understand the challenges of the collaboration between academic biobanks and industry, we would like to briefly outline the major differences of research in academia and industry. The strength of research in academia lies in its ability to excel in basic/translational/clinical research, while industry is more inclined to pursue applied research with an aim to translate laboratory discoveries to clinics. Both of these research activities are important and certainly complementary to achieve efficient transfer in clinical care.[7] Compared to industry research, academic research is more curiosity driven and academic researchers are more likely to work in an environment driven by research publications.[8,9]

The biomedical industry is very diverse. It includes pharmaceutical, biotech, and *in-vitro* diagnostics (IVD) companies. All these companies are more end product and more business driven,[10] and provide an all-important translational channel to bring cutting-edge laboratory research to clinics.

Beside the well-known big players, there are hundreds of small- to medium-sized companies investing heavily in research to successfully launch new products. These financial investments are mainly geared toward developing new products that have been discovered in house or that have been in-licensed either from other companies or from academic technology transfer offices. Chances for a company to get returns on large R&D financial investments are low, with very few new drug or biomarker candidates making it to clinical use.[11–13]

Most big pharmaceutical companies take over the entire development process (discovery–preclinical–phase I–to phase IV) until the launch of the final product, while the majority of drug biotech companies will out-license their new drug to a big pharma player after successful phase I or II trials. Biomarker companies will launch their new assay proposing their own laboratory platform or a bigger well-known clinical laboratory. They might also just out-license their final product to a bigger IVD company.

More than in academia, research activities in industry are heavily regulated and are bound to strictly adhere to predefined timelines and budget constraints. Industry is also concerned with having the shortest possible R&D timelines due to the limited lifespan of their intellectual property (IP) protection and the deadlines imposed by their shareholders.[13] This is one of the reasons they usually prefer to outsource

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some of their activities to private professional Clinical Research Organizations (CROs) that have a similar working attitude regarding timelines and budget rather than to academia. Importantly, to protect their investments, industry will not embark on a specific drug or biomarker R&D program if they cannot be protected by an IP patent. This means that any new drug or biomarker for which information has been released publicly through publications and/or oral presentations, before being patent protected, has very little to no chance of being considered by industry as a potential candidate for future development, even if the discovery made initially at the academic level might have a tremendous impact and be of great benefit to patients.

Industry is sometimes considered a cash cow by academia and academic biobanks rather than intellectual peers.[14] Industry is working in an area of high financial risk with a very low probability of success[15,16] supporting their R&D efforts by reinvesting profit generated by commercializing their launched products, or with funding obtained from investors. All companies have to respect their predefined R&D and financial plans, timelines, and deliverables. Research activities are conducted internally or externally, subcontracting studies to CROs or collaborating with academic teams, especially for drug clinical trials. Depending on reached milestones, a project may be stopped during the R&D process if it does not meet the predefined go/no go conditions that could impact the financial health of the company.

It is clear that the models for driving and sustaining research in industry and academia are different, even if the ultimate goal of both the stakeholders is to discover, validate, and expand clinical utility for the benefit of patients. They do not necessarily work hand-in-hand owing to their contrasting incentives and their constraints, whereby academia wants broad knowledge sharing and publications as soon as possible (before patentability) and industry wants to preserve their IP (before publishing) and bring their product to market as soon as possible. Based on these opposing attitudes, it is clear that cooperation between both of the stakeholders is difficult and initiatives to accommodate both these parties for the overall benefit of patients should be taken.

Academic Biobanks and Biobanks in Industry

The spectrum of biobanks is very variable. One of the many possible classifications is based on the user type: monouser, oligouser, or polyuser.[17] Most of the industry-run biobanks are monouser biobanks, where ''mono'' refers to the researchers within the company. Monouser academic biobanks often are managed by academic researchers on a part-time basis and these researchers do not even see themselves as biobankers. They only established the biobank to enable their own research.

In contrast, oligouser and, especially, polyuser biobanks have external end users. Since these types of biobanks are usually located within an institution that is part of a hospital or, at least, has close links to a hospital, access to patients and their samples and data is relatively easy. Hundreds of polyuser biobanks were founded with the primary objective of serving the needs of scientists for samples and data for their research, assuming that having collections for many different diseases would lead to many new discoveries and publications. This may result in academic biobanks hoarding a wealth of valuable samples and data and sharing them with external scientific stakeholders, which until recently was often not a priority for many of these biobanks.[18,19]

The discussion about sustainability of biobanks in recent years has led to more and more academic biobanks improving their administrative structure, that is, employ professionals with biobank specific skills, knowledge, and expertise. Also, there is a better-defined strategy for what kind of biospecimens and data should be collected. New, updated, and better standards, best practices, and guidelines and tools that are based on these recommendations help the biobanks to develop further. All these actions will improve the operational dimension of sustainability of academic biobanks.[5]

One of the major differences between academia and industry-based biobanks is financing. Biobanks in industry are more sustainably funded as long as their activities are part of the same activity as the company in question. Academic biobanks are exposed to a rougher wind regarding financial sustainability. Most academic biobanks are supported by public and private funding and grants. Cost recovery only plays a minor role. Funding and grants sometimes can be relatively large, but there is a high risk to a biobank if these findings and grants cannot be renewed. Academic biobankers therefore spent a significant time devoted to fundraising. On the other hand, they have greater freedom to whom they can provide the samples and data.

Since most of the academic biobankers have started their professional careers as scientists, they tend to still act as academic scientists and are in favor of a hybrid function as biobank manager as well as biobank scientist.

However, while in academic research, publishing and knowledge sharing remain the primary objectives that in turn translate into career advancement and international scientific recognition, the situation for biobankers is not so clear. There are initiatives to ensure that the contribution of biobanks to biomedical research projects is better recognized.[20,21] In the meantime and as a consequence of their hybrid functions, academic biobankers continue publishing scientific articles that are sample based and may generate some IP rights. However, filing an IP that may later generate revenue is not really a priority for, and a core competence of, academic biobankers, as demonstrated by the very low number of academic biomarker-based patents that have been forwarded for development into further clinical use. This situation results in numerous publications on new biomarkers that are only partially validated with relatively poor clinical proofs of concept leading to nonpatentable biomarkers dying on the shelves.[22]

Needs for Samples and Data by Industry

Industry-based researchers need human biospecimens for their drug or biomarker R&D programs and the quality of these samples and data must fit the purpose.[1,23,24]

For drug R&D, a small number of samples and data are needed at the discovery stage to identify new drug targets. This work is typically done internally. The discovery research groups most of the time use resources either internally if available or outside directly with an academic biobank where there are well-established connections, or through a vendor. The latter resource is more common since it is easier and faster to get samples and data from vendors with no obligation and constraints with respect to the sample

and data sources (IP sharing, publications, return of results, material transfer agreements [MTAs], etc.).

During the clinical development, biospecimens and data are collected during clinical trials with the drug candidate, either by the own research teams or through a CRO. Alternatively, for-profit biobanks and academic biobanks which provide this kind of service will act as storage infrastructure. Usually, only the sponsor of these trials will have access to these biospecimens and data due to the nature of the study and informed consent language.

For biomarker R&D, a small number of samples are needed in the discover stage to identify new potential biomarker candidates. For the screening and first clinical proof-of-concept phase only small number of samples (tissues, biofluids, and tissue microarrays) are needed. Due to the size of the organization, IVD companies usually do not have internal biobanks. As with pharmaceutical and biotech companies, the IVD research groups use resources outside either directly with an academic biobank, where there are well established connections, or through a vendor.

Analytical validation of biomarker assays is also a critical step for an IVD company before applying for approval from a registration agency. It requires a larger sample size to conduct these studies.[25] Most of the time, internal expertise will be used for the analysis. To protect the IP, open publication will not be possible. To assess the clinical validity and demonstrate clinical utility of its new biomarkers, a company will require access to hundreds or possibly thousands of clinically well-annotated samples, retrospective or prospective, and usually more than one biobank is required as a source.

In summary, pharmaceutical and biotech companies, on average, do not need so many samples as IVD companies. However, there are not as many IVD companies. Pharmaceutical and biotech companies conduct clinical trials with their candidate drugs where they are able to collect biospecimens and data that they might be able to use later again for discovery. Participating investigators in these clinical trials who enroll and monitor patients are paid fees for service. Academic biobanks that can provide samples and data will also get some fees for service. The possibility of a potential authorship in a publication has to be discussed separately.

Main Points of Disagreement Between Academic Biobanks and Industry

Timely and secure planning is a crucial factor for the industry. However, based on an in-depth survey among 36 pharma, biotech, and diagnostic companies, one of the major obstacles is the length and complexity of the administrative process for establishing contracts between industry and academic biobanks, including MTAs.[26] In another survey among almost 200 academic biobankers, about three quarters reported to need up to 4 months only for reviewing and approving an MTA (data on file). Academic biobankers must recognize the importance of speed to industry and invest in accelerating this process. Aside from this time issue, two other obstacles should be also mentioned, as discussed in the next section.

Biobank Policies That Explicitly Exclude Scientists Associated with Industry

Many biobanks have access policies that explicitly exclude investigators associated with industry, arguing that patients would not want their samples and data to be used to generate profits by for-profit organizations. However, when presenting projects led by industry to patients, is there a clear distinction between research use and commercial use? Is it clearly explained that exchange with industry is necessary since they are the entities who stand the best chance of translating new discoveries into clinics and who undertake much of the financial risks of developing a clinically useful product for the benefit of future patients?

Indeed, we believe that the intention of the altruistic patient in providing biospecimens and data is to enable the best possible research to be undertaken, irrespective of who the researcher will be, as long as his samples and data are used for high-quality research. Patients deliberately donate their tissues for the greater good. They are not seeking to help only themselves—or one or two others—they want to give all scientists, public and private, the resources needed to move medical research forward.[19,27,28] Too often investigators consider the collection as their own, preventing others from having access to it. Most of the time, when patients sign an informed consent for donating samples, the donation is not for limited use by only one investigator.

Biobank Policies That Require Their Representatives Be Co-Authors of Publications and/or Share IP Rights

Some biobanks believe that exchange with industry will allow them to get more publications as a metric of success. We have discussed earlier that this is not always possible for industry, depending on the status of the filing of the IP by the company, which might be compromised by early publications. When possible, industry might agree to include academic biobankers as co-authors, but there is a competition with the clinicians. If there is not much opportunity for publication, there is even less opportunity for biobanks that require the sharing of IP rights to consider themselves as co-inventors because they give access to the patient-donated biospecimens, most of the time without any real scientific input to the invention.

Because of these above-described bottlenecks, most of industry is encouraged to obtain their samples and data from vendors, even if for some of them the quality and traceability of samples and data and the respect of ethical and regulatory requirements might be questionable. Some companies will also buy human biospecimen from website catalogues, or by being registered on various emerging market platforms. It is, for industry, by far much easier and faster to use vendors than to work with academic biobanks.

On the other hand, industry and their purchasing/procurement departments must understand that human samples and data are not commodities or simple laboratory reagents, and if they want to gain access to the precious samples collected by academic biobanks, they will have to accept some of their requirements, including the establishment of an MTA between end users and biospecimen collecting sites, hoping that this contractual process on both sides can be done much more quickly than today, disclosing the main objectives of their study, and also proposing a co-authorship or an acknowledgement in case of publication.[29,30] On their side, if not able to establish a genuine collaboration with industry, academic biobanks should become more open to receiving cost recovery fees for services for providing biospecimens, which might help them to sustain their operations or their own in-house R&D projects.[31]

As initially mentioned, collaboration between academic biobanks and industry is desirable and important. Two of the authors of this article, who are academic biobankers (P.H. and M.H.R.), have summarized some important topics when working with biomedical industry (Table 1).

Changing Practices and New Models of Cooperation Between Industry and Academic Biobanks Are Needed

The existing models of cooperation between industry and academic biobanks are clearly not optimal. Considering the increasing importance of samples and data from discovery to a commercialized end product, several changes must be implemented, and efforts must be made by both parties to first relieve respective mistrust. There is a need for mutual understanding of industry and academic cultures and a requirement to establish a good basis for future collaboration.

In that respect, education of all stakeholders is important: patients, academic biobanks, and industry, including their legal and procurement teams.

(1) Patients must be more clearly informed about the importance of industry in the drug and biomarker development process, explaining the difference between commercial and research use by industry.[32,33]

(2) Industry must recognize that human samples and data cannot be considered a commodity and that biobanking is a scientific activity dealing with human beings. Respecting requirements from academic biobanks is important.

Table 1. Lessons Learned and Personal View from Academic Biobankers When Working with Biomedical Industry

Paul Hofman	*Michael Roehrl*
Cooperating with industry presents some advantages:	
• To find a use for already collected specimen since too many collections are indeed underused by many biobanks • To realize what are the industry-scientific biospecimen needs: this exercise will lead to better design future biospecimen collections in my biobank and therefore will minimize underuse of retrospective biospecimen collections • To respect ethical commitments that investigators have placed with patients who donated their clinical samples to advance biomedical research • To actively participate to translation of basic scientific discoveries to clinically applicable research for the benefit of future patients: from bench to beside • To generate funding: an income that could be very significant to support laboratory staff and equipment, and sustain in-house R&D programs • Getting opportunities for co-authored publications related to joint projects with pharma scientists: if the IP status allows the pharma or diagnostic company to do so (this is not always possible). For example, in 2018–2019, nine publications of the BB-0033-00025 biobank were made in collaboration with researchers from the industry • Recognition of the investigator's scientific expertise by becoming consultant or being invited to conferences or scientific advisory boards from different pharma and biotech companies	• Access to clinical trial questions and early involvement of pathology in the design of first-in-man therapeutic trials • Ability to influence and shape the design of new molecularly driven basket trials • Developing best practices for mutually beneficial R&D arrangements between academia and pharma/biotech • Joint funding of research projects that would otherwise be difficult to fund • Developing a tech transfer platform in academia that allows for rapid evaluation of new technologies and instrumentation in an academic setting and comparison of various new technologies before clinical use • Enhancing the quality of research by collaborations between academia and industry, and higher-impact articles that are practice changing • Adding immense value for the pharma/biotech partner that cannot be obtained by the classic CRO model
By choosing to work with pharma, it was necessary to:	
• Understand that industry is a key partner in the translational process • Accept that for patent-filing reasons, in most cases, there is no immediate opportunity to a direct return in joint publications • Setting up an administrative process that should be short and efficient (short turnaround time is mandatory for getting signed contract) • Be reactive and service oriented • Potentially have a partnership with a CRO that streamlines interactions with industry (commercial, contractual, logistical, etc.)	• Understand the differences between academic and industry workflows and processes • Differences in views on IP protection, regulatory requirements, and contractual paperwork • Accept sometimes slow contract negotiation process and many steps that need completion before projects can commence • Develop a deep understanding of the mutual needs and goals to develop projects with maximum mutual benefit • Develop close relationships with legal teams on both academic and corporate sides to accelerate projects and contractual agreements • Structure my center such that it is viewed as an attractive partner for pharma/biotech that is proactively contacted by companies who would like to collaborate

CRO, Clinical Research Organization; IP, intellectual property; R&D, research and development.

(3) Biobanks' access policies should be more flexible and, as research infrastructures, they must accept to serve the entire research community, considering scientists from industry as intellectual peers and as essential for developing new products for the benefit of future patients.

(4) Participation of a biobank and its scientists in R&D projects should be officially recognized as a scientific contribution, whether it lead to a publication or not.[21] Existing performance indicators should be more broadly used and new ones developed to demonstrate the scientific value of a biobank and generate credits for the academic career of the biobank scientists.[34]

(5) Biobanks should focus on the disease areas where their expertise excels[31,35] and clearly monitor the utilization rate.

(6) Biobanks and their scientists should stop working in silos. This would prevent having many biobanks collecting the same types of biospecimens, each also having their own in-house research projects competing with others.

(7) To achieve complementarities and synergies between scientists from academia and industry working on the same subject, innovative concepts of collaboration that would address both parties' needs should be implemented, such as consortia of specialized biobanks.[36]

(8) And last, but not least, both parties should have a strong focus on the quality of the samples and data they provide and use, respectively. Since biomedical research is so complex, the fitness for intended purpose should be the guidance for the involved parties.

Biobanking standards and best practices are critical to ensure that biospecimens are fit for purpose and that the results of studies using samples and data from biobanks are meaningful and reproducible. Also important is to ensure traceability. Biobanks should be able to trace forward their samples and data, that is, a biobank should know where its samples and data will be used. At the same time, researchers in industry should be able to trace them back, that is, they should know where the samples and data from patients were collected.

The recently published ISO 20387: 2018 Biobanking–General requirements for biobanking covers all these important aspects: samples and data that are fit for an intended purpose as well as traceability. Implementing ISO 20387 could facilitate cooperation, foster exchange, and assist in the harmonization of practices among academic biobanks and researchers in industry.

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