The challenges of biosample access and what needs to change

By Robert Hewitt, MB BS, PhD, Biosample Hub

Introduction

Clinical samples like blood and surgically excised tissues that are surplus to diagnostic requirements may be discarded as waste, or if the patient gives informed consent, they may be used for medical research. Such biosamples are vitally important for research because they contain molecular clues in the form of biomarkers and drug targets that scientists need to devise new and improved diagnostic tests, therapies and vaccines. Without biosamples, medical research would quickly grind to a halt.

The Role of Biobanks

The collection, processing and storage of biosamples is organised by specialist hospital units called biobanks. These biobanks have two main responsibilities: firstly they protect the interests of the patient donor, which they do by ensuring informed consent for donation and maintaining the confidentiality of patient information. Secondly, they ensure the quality and reliability of samples, which they do by following standard operating procedures for collection, processing and storage. By provision of reliable samples these units support meaningful research that will lead to new and improved diagnostics and personalised treatments. In view of their key role, biobanks and the discipline of biobanking can be regarded as the foundation of personalised medicine (Hewitt, 2011).

The two main responsibilities of biobanks are underlined by a number of significant past events that shocked people out of complacency and demanded that action be taken.

The need for biobanks to protect the interests of the patient donor was highlighted in the UK by 'events in the 1990s that revealed a culture in hospitals of removing and retaining human organs and tissue without consent' which included the Alder Hey scandal. As a result a regulatory body called the Human Tissue Authority (HTA) was set up in 2005. The HTA licenses establishments that store and use human tissue for a variety of purposes including research and ensures the safe and ethical use of human tissue https://www.hta.gov.uk/about-hta.

The need for biobanks to ensure the quality of samples was underlined some years later in the USA, when researchers on a major international research initiative called The Cancer Genome Atlas (TCGA) project had unexpected difficulty in sourcing adequate numbers of high-quality, well annotated biospecimens. Nearly 99% of the 1,500 samples promised for this study were not available or did not meet requirements and nearly 30% of those submitted failed molecular quality control (Blow, 2009). As a result of these surprising findings, attention has been sharply focussed on development of evidence-based quality standards in biobanking and quality control with many biobanks obtaining certification and accreditation according to various quality assurance schemes.

The Needs of Industry

Hospital biobanks are rooted in the public sector. However, the medical research that depends on their support does not only take place in universities and research institutes in the public sector. A very important part of this research takes place in the private sector, in pharmaceutical and biotechnology companies. Unfortunately, there are signs that industry's needs for clinical samples are not served well by the public sector, and this is particularly so for small biotechnology companies.

The 2018 annual report of a UK agency called Medicines Discovery Catapult (MDC) revealed a major problem: that 80% of SMEs (small to medium sized biotechs) found accessing samples from the national health service 'unexpectedly difficult with the result that 75% imported samples from abroad'.

https://md.catapult.org.uk/resources/report-state-of-the-discovery-nation-2018/

There are a number of fairly obvious reasons why it is difficult for industry to access samples from the health service and why this difficulty impacts smaller biotech companies in particular. Firstly, hospital biobanks are generally established by academic institutions and their primary responsibility is to supply these institutions with clinical samples. Secondly, small biotechnology companies are generally much younger organisations than large pharmaceutical companies and have had less time to develop supply networks. Furthermore, unlike pharmaceutical companies, they do not have the advantage of running clinical trials with the access this provides to clinicians, patients and their samples.

What is less obvious, is the significance of the fact that 75% of SMEs in the UK apparently import samples from abroad. Does this mean that they obtain samples from hospital biobanks abroad that are for some reason more accessible to biotech companies? The answer is almost certainly not. Hospital biobanks around the world are set up for the same reasons and have the same top priority: to support academic researchers.

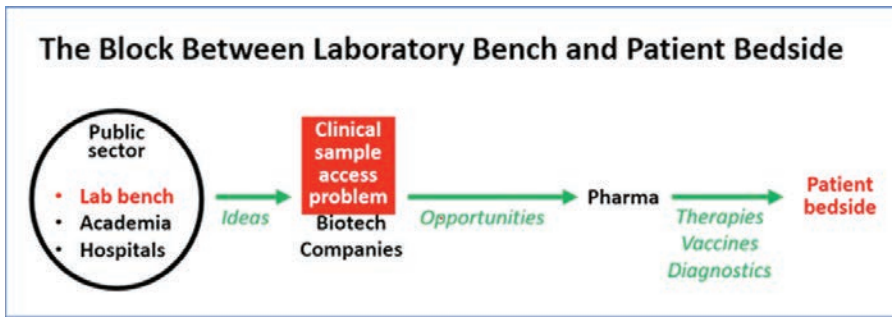
The real answer is that the majority of SMEs in the UK have little alternative but to obtain their samples from commercial brokers. These brokers have great difficulty in accessing samples from hospital biobanks in western Europe. Instead, they source predominantly from eastern Europe and parts of Asia where they often obtain samples from local brokers with ever more extensive networks.

One feature of commercial brokers is that in general they do not reveal their sources for business reasons. To do so would risk their circumvention because the requester could subsequently obtain samples direct from source, thereby eliminating the need for a middleman. So the result is that the client does not know the original source of the samples. Without knowing the source, it is hard for the client to be confident that a reliable biobank was involved in collection, processing and storage of samples. In other words, the end-user lacks reliable sample provenance information.

The Importance of Small Biotechnology Companies

Biotech companies play a key role in developing new therapeutics, diagnostics and vaccines. They are the risk-takers and innovators upon which big pharma often depends for new opportunities. They translate promising ideas generated in academia, into potential therapies, vaccines and diagnostics that can be evaluated by well-resourced pharmaceutical companies. For this reason it is vitally important that these companies should be provided with the most reliable biosamples possible and not forced to take a second best.

Biotech companies face a major clinical sample access problem and as a result there is a block between researchers at the lab bench and doctors and nurses at the patient bedside.



Practices to be encouraged

So, what should be done in response to revelations of the 2018 MDC report? How can we ensure that small biotech companies get improved access to the high-quality, reliable samples they need? This is important because all of us, as patients (past, present or future), depend on the therapeutics, diagnostics and vaccines that biotech companies make possible. The answer is that some practices need to be encouraged, while others need to be discouraged.

1. Making it easier to obtain samples from hospital biobanks

It must be made easier for biotech companies to obtain their samples direct from hospital biobanks where they are assured of reliable provenance information. To make this possible, there need to be greater incentives for hospital biobanks to provide samples to biotech companies. Biobank access committees need to be motivated to provide samples to industry. Funding agencies can play a role here by providing funding on condition that samples are provided to biotech companies. In addition, patient advocacy organisations have the potential to have a decisive influence here.

2. Further regulation

New regulations are likely to have a major impact on how biotech companies source their clinical samples. The new European regulation governing manufacture of in vitro diagnostic devices (the IVDR) provides one example. This will require biotechs in the diagnostics field to only use samples with reliable provenance information. It makes complete sense that in the future similar regulations will apply to companies in the therapeutics field as well. As patients (past, present and future) we should expect to have our diagnostics, therapies and vaccines developed and tested using the most reliable resources possible.

References

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