Human Tissue Sampling in New Drug Research

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Human tissue samples are becoming more widely used in new drug research, and this – coupled with difficulties in sample sourcing – is driving the emergence of on-demand, virtual biobanking companies.

High quality human tissues have become the gold standard for biomedical research, and reliable access to such material is a critical resource for many companies. In addition, the rapid growth of translational research and personalised medicine has further increased demand for human biological samples. Biobanking has been identified as a key area to accelerate growth in the pharma industry, and it has been widely recognised that the old ‘blockbuster’ model is no longer an efficient way to produce new chemical entities (NCEs).

The situation was highlighted in the US FDA report, Challenge and Opportunity on the Critical Path to New Medical Products (1):

“...there is growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, more affordable, and safe medical products for patients. This is because the current medical product development path is becoming increasingly challenging, inefficient and costly. During the last several years, the number of new drug and biologic applications submitted to FDA has declined significantly...”

To address these issues, drug companies are turning to human samples as one route to fast-tracking drug discovery.

Biobanks

Biobanks and tissue suppliers have grown exponentially in response to this increasing demand for samples and there now exists a broad range of suppliers; provides from niche collections that specialise in one disease area to commercial suppliers. According to a recent report, the number of biobanks has been on the increase since the 1970s, with a growth rate of 42 per cent over the period 1990 to 1999, and a further rise in the last decade of 36 per cent. The biobanking market is estimated at $7,880 million by the business information provider, Visiongain, and looks likely to carry on expanding as researchers continue to favour human tissues and biomaterials for pharmaceutical and diagnostics research (2,3).

Prospectively sourced samples from consenting patients are much in demand for scientific research. While banked collections are an invaluable resource, it can sometimes be difficult for researchers to source the exact material required for a project. Additionally, there are still some tissues and disease areas that are very difficult to source and a lack of industry standardisation means there are inconsistencies in terms of sample quality and clinical data. For many researchers, this leads to a frustrating inability to obtain high-quality human samples and leaves them with no alternative but to design experiments around whatever tissues they can get, rather than pursuing the most promising research leads.

It is clear that no single biorepository can cover the range of samples needed for research; moreover, sample demand changes as trends change. Some biobanks operate strategic alliances to overcome this but there is currently no standardisation across the industry. These needs are driving a general trend towards harmonisation and sharing of best practice across biobanks. The International Society for Biological and Environmental Repositories (ISBER) and its European counterpart (ESBER) represent an international forum for addressing the technical, legal, ethical and managerial issues relevant to repositories of biological and environmental specimens, and are working to promote and achieve standardisation across biobanks.

The ultimate goal is a cross-functional network to allow the sharing of data, sample databases and analyses. The success of this goal is dependent on the standardisation of processes such as sample collection, storage and information management, and although some cooperative networks have now been successfully established, the ideal is still a long way off. It has been estimated that around 68 per cent of biobanks are still ‘stand-alone’ organisations and those within networks are mostly government funded (3). Increased sample demand, coupled with difficulties in sample sourcing, is driving new ways of working in the biobanking industry, and the availability of ‘on-demand’ samples is emerging.

On-Demand Samples

The majority of biobank samples are collected either as surgical excess, diagnostic remnants or post mortem tissue. While all of these sources are extremely valuable, they each have limitations. Surgical excess
and diagnostic samples come from diseased patients, often cancer donors, and the closest to a ‘normal’ fresh sample is adjacent tissue – that is, tissue obtained from the perimeter of the excised area and graded by a pathologist as within normal limits. Normal samples are essential for comparative studies as without them correlations cannot be drawn, but there is an argument that normal adjacent tissue (NAT) is not a true ‘normal’ and may carry genetic abnormalities (4). The quality of post mortem tissue will depend on the speed of collection. Furthermore, if the clinical information linked to a sample is limited, then this will limit its usefulness in a research setting.

On-demand samples are collected prospectively to fulfil a client’s needs, and the process works in reverse. The collecting site obtains the researcher’s request in advance of the collection, and works to obtain material to meet these requirements. In this way, both the tissue and clinical information can be matched to the research requirements. Samples collected on-demand can be obtained from specific donors with very specific inclusion or exclusion criteria and come with very detailed information. Working in this way maximises the value for both the donor and the researcher, but it can be difficult to set up, requiring both management and clinical contacts. Sample availability also varies according to disease area, with some disease groups better represented than others. For this reason, samples are usually only obtained through personal contact or by researchers working in a hospital or academic environment; even here, availability is dependent on in-house expertise and departmental collaboration. Samples collected in this way from consenting patients are high in demand for scientific researchers as they are of high-quality, are well annotated, and can be obtained from very specific patient groups and sub-groups. Furthermore, for some patient groups, true normal tissue can be offered by this method.

In the past, researchers considering undertaking their own prospective collection were faced with the difficult task of overseeing the whole management of locating clinical collaborators with access to suitable donors, obtaining ethical approval for the project and then overall management of the study. The practical implications and challenges of such studies were often prohibitive for the individual researcher. The new on-demand collection services are routinely offered by virtual biobanks and can overcome these difficulties.

**Virtual Biobanks**

Virtual biobanks do not store samples but provide a single point of access to a range of biospecimens using networks of ethical sources. They source tissues to client specifications – thereby streamlining the procurement of tissue to the benefit of all parties.

Real and virtual biobanks have a two-way relationship that works to the advantage of both. By offering the capability to source specific, rare samples, virtual biobanks fill a niche in the market that is not covered by large, commercial biobanks (3); they provide a valued service to the research community by taking advantage of their vast experience and knowledge to track down rare specific sample types. They can also advise on the likelihood of finding certain tissue types. Virtual biobanks are, however, still reliant on physical biobanks to provide the raw materials.

Virtual biobanks guarantee ethical sample collection and ensure that the required reviews, approvals, licences and consenting procedures are in line with both local and international regulations so that the samples can be used in commercial research. Working in this way is advantageous to both the patient and the scientist. High-quality samples are made available to the scientific community, and donors are assured that their samples will be used in the laboratory for a relevant research project and not stored long-term in a freezer. The rapid turnaround of samples means they are of the very highest quality; furthermore, the control over sample collection, handling and storage reduces variations and inconsistencies across samples.

Biobanking has a critical role to play in new drug research, and future success will depend on innovative solutions to sample provision, to help facilitate effective and productive drug discovery.

**References**

2. GBI Research Press Release, Biobank Boom Damaged by Lack of Tissue Samples, 12 July 2012