4. Biosample Needs of Different Industry Players

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This article examines three different actors in industry that require biosamples including:

- **Large pharmaceutical companies**
- **Large *in vitro* diagnostics companies**
- **Small and medium enterprises (SMEs) in healthcare biotechnology**

The article describes the major differences that exist between these different actors, and points to the particular difficulties that SMEs experience in obtaining biosamples for their vital research.

Large Pharmaceutical Companies

Examples of **large pharmaceutical companies** include: Johnson & Johnson, Roche, Pfizer, Novartis, Bayer, GlaxoSmithKline, Merck & Co, Sanofi, AbbVie, Abbott, Eli Lilly & Co, Amgen, Bristol-Myers Squibb, Gilead Sciences, AstraZeneca, Boehringer Ingelheim, Merck Group, Novo Nordisk, Allergan plc, Takeda Pharmaceutical, Celgene, and Biogen.

The pharmaceutical industry builds upon scientific discoveries and pre-clinical research to develop new drugs. It requires biosamples for early-stage drug discovery when this is conducted in-house. It also requires biosamples during the course of its clinical trials in order to measure the effectiveness of new drug candidates or profile potential side effects (**Mackenzie, 2014**).

Pharmaceutical companies have historically performed the majority of their drug discovery research in-house and only collaborated at the stage of clinical trials. However, this practice is changing as Pharma is increasingly trying to cut costs and improve efficiency by outsourcing the earliest phases of drug discovery to academic labs and SMEs (**Ledford, 2011**; **Lawlor & Scarpa, 2017**).

Pharmaceutical companies have access to biosamples from their own clinical trials and many of them have developed their own in-house biobanks. Unfortunately, regulatory and ethical issues (eg. constraints due to the specificity of informed consent) considerably limit the use of biospecimens that have been collected during past clinical trials (**Lindpaintner, 2011**).

Pharmaceutical companies have the budgets to obtain biosamples from commercial providers, or to outsource collection to clinical research organisations (CROs). They may also obtain biosamples from academic biobanks, sometimes through supply agreements or in the setting of a research collaboration. However, there are many problems to be overcome for such Pharma-Academia partnerships to succeed:

- Difficulties in locating and accessing suitable biospecimen and data collections.
- Long timelines for establishing contractual agreements with academia.
- Unacceptable requirements in terms of publications and IP sharing.

A survey by one commercial provider of biosamples, found that requests from pharmaceutical companies tend to be broad and are typically for large numbers of samples. Increasingly, the requests require very detailed clinical information about the donor (**Mackenzie, 2014**).

Large *In Vitro* Diagnostics Companies

Examples of **large *in vitro* diagnostics companies** include: Roche Diagnostics, Abbott Diagnostics, Siemens, Thermo Fisher Scientific, Becton Dickinson, Sysmex, bioMérieux, and Ortho Clinical Diagnostics.

In vitro diagnostics companies must obtain biosamples both for their biomarker discovery and biomarker validation work. They have a very significant demand for biosamples, particularly for the clinical validation of biomarkers, when large sample numbers are required.

Unlike pharmaceutical companies, they do not have direct access to biosamples from clinical trials. They may obtain biosamples from academic biobanks or alternatively from commercial sources. They may also obtain samples through partnership with pharmaceutical companies. For the development of companion diagnostics, the majority of pharmaceutical companies need to partner with one or more *in vitro* diagnostic companies. Some pharma companies have brought diagnostics under their own roof through **mergers and**

acquisitions (eg. acquisition of Ventana by Roche), but most partner with external companies as well.

SMEs In Healthcare Biotechnology (a European/UK perspective)

According to European Union definitions, the category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover (or revenue) not exceeding EUR 50 million.

There are SMEs in 3 main biotechnology categories: healthcare, industrial and agricultural. This section only relates to SMEs in healthcare biotechnology. To provide some examples, here are the winners and runners-up in the healthcare category of **EuropaBio's** 'Most Innovative Biotech SME Awards' for 2017 and 2018:

- **NovaBiotics** is a UK company focused on the design and development of first-in-class anti-infectives for difficult-to-treat, medically unmet diseases.
- **Nightingale Health** is a Finnish company with a proprietary blood analysis platform that can improve risk prediction of, among others, cardiovascular diseases and diabetes.
- **Genoscience Pharma** is a French company in the product development phase with their therapy against cancer stem cells.
- **Medicortex Finland** is a Finnish company currently focusing on developing a diagnostic kit for the detection of traumatic brain injury.
- **CHAIN Biotechnology** is a UK company focused on the development and commercialisation of microbial technology for the production and delivery of biotherapeutics to the gut.

SMEs like these use biosamples for development of new drugs and diagnostics. They incubate emerging research projects to a more commercial position and subsequently sell or out-license the resulting products (**Mackenzie, 2014**).

The importance of SMEs for the pharmaceutical research field is widely recognised. According to the European **Innovative Medicines Initiative (IMI)**:

SMEs are key players in the European pharmaceutical research and development landscape, and we strongly encourage their participation in our projects.

According to Chris Molloy, CEO of the UK Medicines Discovery Catapult:

Biotechnology SMEs are key to UK plc's future and a vital link in the supply chain of new medicines.

However, a number of problems need to be overcome if these SMEs are to achieve their full potential. The UK Medicines Discovery Catapult and Bioindustry Association stated in their 2018 **State of the Discovery Nation** report, that according to their recent studies:

... over 80% of SMEs surveyed agreed that access to biosamples is hugely important for commercial development

... as many as 80% found accessing UK samples unexpectedly difficult with the result that 75% imported samples from abroad.

One of the main 'action points' in the **State of the Discovery Nation** was to improve sample and data access for all translational scientists:

We will overcome a major barrier for SMEs by developing interfaces providing straightforward, well-governed access to real world sample and patient data,working in partnership with the NHS, MRC, national biobanks and data holders, technology transfer offices and Health Data Research UK (HDR UK).

Recognising and highlighting the biosample needs of SMEs in the UK has been a major step forwards. Now we need effective solutions to help overcome this highly significant problem.

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Disclaimer: the author of this article works independently and any views expressed are his own.

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