Collaboration is Essential for Successful Clinical Trial Outsourcing

PEER REVIEWED

By 2020, close to three-quarters of clinical trials may be performed by professional contract research organisations (CROs). The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), a 2015 Swiss NGO of pharmaceutical companies among others, defined a CRO as a person or organisation contracted by the sponsor to perform one or more of its trial duties and functions.

CROs have already proven successful for pharmaceutical companies carrying out clinical trials, but could freelance scientists add to their expertise as the clinical trial service market grows?

Dublin-based Research and Markets predicts that the global clinical trial service market will surpass $64 billion by 2020, up from $38.4 billion at present. This represents a compound annual growth rate (CAGR) of nine per cent between 2015 and 2020. On top of this, there is also a general agreement that clinical trials have become increasingly complicated.

The current global environment is also forcing drug companies to come up with better drugs that are developed at lower cost and, as a result, a new model of virtually integrated drug development has evolved.

At present, the developed countries still dominate the global clinical trial market. Today, major CROs in the developed countries that have sufficiently large facilities, global capacity, networked investigators, patient databases and effective recruiting tools, are being more frequently approached by drug companies for partnership collaboration.

The global clinical trial service market is also split between the developed countries and the emerging markets. Among the emerging countries, Asia has become a prominent location for clinical trials.

This geographic spread poses specific recruitment challenges for CROs and pharmaceutical companies alike, as qualified staff need to be sourced from a wider geographical area than before. This challenge is added to by the variety of skillsets present among scientists. Businesses may find it difficult to find someone with the expertise they require, sometimes due to geographical barriers and budget constraints. In a niche field, there may be no one in the local area with the required skill set for the task at hand and if the project is short, the company will be unable to hire someone to fulfil the requirements.

Collaborating with Freelancers in Clinical Trials

Whereas a CRO is usually an independent company that offers an objective assessment of a new drug in the clinical setting, freelancers can enter the research process at pretty much any stage. Because these specialists partnering with many companies throughout their career, they will typically offer broad experience and an impressive skillset.

This wider skillset is appealing to pharmaceutical companies, which has led to more opportunity for scientists and science, technology, engineering and maths (STEM) specialists who are willing to step away from education and pursue a freelance career.

Scientific organisations in particular see the advantage of using freelancers to fill critical project requirements, and scientists are adapting to the change in career that freelancing offers and many more are continuing to enter this line of work.

Science is becoming increasingly interdisciplinary, with researchers often needing to borrow skills from other disciplines. Hiring freelancers makes this process much easier for pharmaceutical companies, as they are able to source individuals with the exact skills that they require. These freelancers can then collaborate with the laboratory's own staff, cascading their knowledge and picking up new skills themselves.

Also, smaller companies rarely have access to generous funding, so may miss out on hiring specialists whose expertise they need only on a project-by-project basis. Opting to use the services of a freelance scientist gives these businesses access to overseas contract workers without the cost associated with hiring a permanent worker. A skilled freelancer can even perform some tasks, such as data analysis or report writing, remotely reducing the geographic limitations on accessing skills.

"The skills required in a laboratory can vary throughout the year," explains Leah Shifra Price, a freelance biostatistician for Kolabtree. "For example, a clinical researcher might need the help of an expert statistician to verify the results of a clinical trial. In another project, a bioinformatician might reach out to a data analyst for help understanding DNA sequencing.

"On other occasions, they may need help meeting various regulatory requirements when working on the development of a new drug or medical device. Consulting an experienced freelance specialist when putting together a proposal for FDA or MHRA approval can help improve the scientist's chances of successfully bringing their product to market. Luckily, there are a number of PhDs, postdocs, researchers and experts in these fields that are available for freelance work.

"One of the key assets that freelancers offer is that they are usually fully conversant with the standards required by Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Good Manufacturing Practice (GMP), because of their vast experience," concluded Shifra Price.

Good Clinical Practice

Prospective freelancers should have a first degree or higher, or have relevant experience; for example, several years in a clinical setting. They should also be familiar with Good Clinical Practice (GCP), an international quality standard for conducting clinical trials by ICH, an international body that defines a set of standards, which governments can then draft into regulations for clinical trials involving human subjects.

GCP enforces tight guidelines on ethical aspects of a clinical study. High standards are required in terms of comprehensive documentation for the clinical protocol, record keeping, training, and facilities, including computers and software. Quality assurance and inspections ensure that these standards are achieved. GCP aims to ensure that the studies are scientifically authentic and that the clinical properties of the investigational product are properly documented. It's fair to say that these tight guidelines can pose a real challenge to the clinical research process, particularly if certain organisations are unclear about specific regulations.

GCP guidelines include standards on how clinical trials should be conducted, define the roles and responsibilities of institutional review boards, clinical research investigators, clinical trial sponsors, and monitors. In the pharmaceutical industry, monitors are often called clinical research associates (CRAs).

Even if compliance with these guidelines can slow down clinical trials, this is not a reason to abandon the research process. If you recruit a freelance specialist to consult with on your trials, they can rise to this challenge and ensure that your research is fully compliant.

Good Laboratory Practice

Good Laboratory Practice (GLP) is a set of principles intended to assure the quality and integrity of non-clinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies.

The term GLP is most commonly associated with the pharmaceutical industry and the required non-clinical animal testing that must be performed prior to approval of new drug products. However, GLP applies to many other non-pharmaceutical agents such as colour additives, food additives, food contamination limits, food packaging, and medical devices. This is a vital stage of the process; however, it can also be a challenge to collaborate with the various trial partners that are involved in the research.

The actual regulations in the United States can be found in 21CFR58 and for the European Union via the Organization for

Economic Co-operation and Development (OECD). However, too often the GLP regulations are applied when they should not be used, creating confusion, extra work, and additional costs.

GLP is a quality management system, not a scientific management system. Or, in other words, GLP defines a set of quality standards for study conduct, data collection, and results reporting. GLP does not define scientific standards. Freelancers will not only be familiar with GLP and what it takes to ensure the integrity of your trials, but they can also offer the necessary insight to solve any collaboration issues. They may already be working with different trial partners, for example as part of universities and other research areas and will offer a fresh perspective that can help overcome this challenge to your research.

Good Manufacturing Practice

Good Manufacturing Practice (GMP) describes the minimum standard that a medicine manufacturer must meet in its production processes. GMP consists of the practices required in order to conform to the guidelines recommended by agencies that control the authorisation and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices.

These guidelines provide minimum requirements that a manufacturer must meet to ensure that its products are consistently high in quality, from batch to batch, for their intended use. The rules that govern each industry may differ significantly; however, the main purpose of GMP is always to prevent harm from occurring to the end user.

Additional tenets include ensuring the end product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented, that personnel are well trained, and the product has been checked for quality more than just at the end phase. GMP is typically ensured through the effective use of a quality management system (QMS).

The US Food and Drug Administration (FDA) regulates the quality of pharmaceuticals very carefully. The main regulatory standard for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (CGMPs) regulation for human pharmaceuticals.

Consumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective. Most people, however, are not aware of CGMPs, or how the FDA assures that drug manufacturing processes meet these basic objectives. The FDA has announced a number of regulatory actions taken against drug manufacturers based on the lack of CGMPs.

Adherence to the CGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. It is important to note that CGMPs are minimum requirements. Many pharmaceutical manufacturers are already implementing comprehensive, modern quality systems and risk management approaches that exceed these minimum standards.

A consumer usually cannot detect through smell, touch, or sight, that a drug product is safe or if it will work. While CGMPs require testing, testing alone is not adequate to ensure quality. In most instances testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets), so that most of the batch can be used for patients rather than destroyed by testing.

Therefore, it is important that drugs are manufactured under conditions and practices required by the CGMP regulations to assure that quality is built into the design and manufacturing process at every step. Facilities that are in good condition, equipment that is properly maintained and calibrated, employees who are qualified and fully trained, and processes that are reliable and reproducible, are a few examples of how CGMP requirements help to assure the safety and efficacy of drug products.

Managing Freelancers

The benefits of hiring freelancers are clear, but there are a few things that pharmaceutical companies should bear in mind when following this business model. A freelancer may not always be available as per the suggested timeline. To avoid any delays caused by only having access to a handful of known freelancers, laboratory managers should build a pool of talent that can be accessed when needed.

As long as laboratory managers have the means of reaching freelancers, the process of hiring them is often much quicker than hiring a full-time member of staff. The interview process is much more streamlined, often consisting of a quick call or meeting to ensure that they are suitable for the position. Freelancers don't have notice periods, so are often available to start sooner.

However, pharmaceutical companies need to be aware that, despite having extensive experience, freelancers still require training. If they're working on-site, it's important to familiarise them with the relevant safety procedures and working conditions. For example, if certain areas are hazardous and therefore out of bounds.

There are many ways to keep in touch with freelancers when they aren't on site, including Skype. When they are on-site, it's important to help freelancers feel integrated into the team. Providing them with the relevant training is the first step to achieving this and placing them alongside permanent members of staff will also help them pick up good habits.

With CROs expected to perform almost 72 per cent of clinical trials by 2020, more businesses are understanding the benefits of outsourcing research, including unifying clinical systems and streamlining trial processes. Meanwhile, companies are also turning to freelance scientists and STEM specialists because of their broad skillset and understanding of guidelines including GCP and GMP. It's essential that companies collaborate with different trial partners, particularly when it comes to complying with GLP, and this is again something that freelancers can help with.

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