

An Injection of Innovation to Outsourcing: Is the CRO Franchise a New Remedy?

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The evolving biopharmaceutical market and the challenges facing it are key influencing factors for development within the CRO industry, continuing to transform more traditional outsourcing models. Increasingly, CROs need to further evolve to meet the requirements of their biopharmaceutical sponsors for new ways to reduce costs and more effectively expedite the R&D process without loss of quality.

Proposed solutions to help address these challenges have included shifting clinical trials to emerging regions, strategic or functional alignment between sponsor and service provider and “off shoring” of services, such as data management. Of course, these can all be very effective if implemented successfully, however they are not necessarily suitable or feasible for every biopharmaceutical sponsor.

As traditional models are being challenged a focus on cost effective, high quality global outsourcing has never been more pertinent. As a result, reassessment of the strategies employed by CROs and a shift to more innovative models for delivery of clinical services will help to define the appearance and structure of CROs in the future.

Similarly to how innovation drives the R&D process, the biopharmaceutical industry can also leverage the advantages of novel CRO business models with an impetus on timely delivery, cost effectiveness and improved quality.

Whilst the highly regulated and risk-averse nature of the biopharmaceutical industry has led to a more cautious approach to embracing new methods, the adoption of models from other industries is nothing new. For example, successful case studies of pharmaceutical companies off shoring clinical data management to vendors with expertise in implementing such a model, but with limited previous clinical trial experience, are well known.

The underlying need for biopharmaceutical sponsors to reduce costs without detriment

to quality, loss of experience or geographic reach calls for more innovative outsourcing strategies. One such strategy is the application of the franchise model to the CRO industry, which has been pioneered by QED Clinical Services Ltd; whereby a core CRO like QED (as franchisor) can leverage the local expertise and resource of established CRO partners (franchisees) under the same brand umbrella.

Whilst QED is the world's first franchise CRO, the idea of franchising itself is relatively elementary and is a concept that has been in practice since the 1800's. It is a model that has been successfully implemented in many other industries. Some of the most prominent franchise models can be found within the fast food service industry, with one particular iconic chain proving the most successful in the application of the model. Perhaps drawing parallels between the healthcare and fast food industries are not commonplace however the fundamental principles of franchising are no different. Quality conformity, reliability, uniformity, leveraging the expertise of teams at a local level and established brand awareness are all part of the power of franchising.

Like any large global CRO organisation, the franchise model can offer biopharmaceutical sponsors the same built-in economies of scale. However unlike traditionally structured organisations that have had to acquire or organically grow to offer coverage of new territories, there aren't the same associated overheads which allow a franchise organisation to offer a highly competitively priced service.

Franchising is also one of the only means available to grow and acquire expertise on a local level, without the need to give up control in the process.

After the quality processes, working practices and brand have been carefully designed and properly executed, the central CRO franchisor is able to expand rapidly across countries and continents using the capital and resources of their franchisees,

making the model highly flexible and scalable. This allows the CRO to offer a tailored geographic footprint which matches a sponsor's specific needs.

Quality is further driven by the franchisees increased motivation to operate their businesses successfully because they have a direct stake in the operation. The franchisor retains control over the way in which the services are marketed and delivered, and controls the quality and standards of the business. A win-win situation in terms of securing the commitment of the local CRO and quality consistency for the sponsor.

Effective due diligence and auditing of potential franchisee companies is the kingpin to the model and must include assessment of quality systems in place, resource capacity and experience, financial stability, and “chemistry” / culture fit to ensure success.

Working with associate or third party CROs is nothing new within the industry and in many cases even established large global CROs utilise the services of partner or local CROs to extend their geographical coverage. However the degree of transparency and quality consistency can often be questionable. The franchise model implements the framework to address this.

All indications point towards continued growth in market share for global CROs. However, as the market pressures continue to increase global CROs will also need to look to new ways to reduce costs, in order to remain competitive and attractive to their biopharmaceutical sponsors as they attempt to address the impact of increasing R&D costs and pricing constraints.

