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Clinical Outsourcing Models: "Drive a Hybrid"

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Clinical Outsourcing Models: "Drive a Hybrid"



Singapore: When we think "hybrid" we think of taking the best components from often opposing approaches and forming a new optimised solution. We think hybrid car; the hybrid cloud; maybe even a political coalition? This concept of combining the features or capabilities of two approaches has long been an effective strategy - the proverbial "best of both worlds."

When it comes to clinical outsourcing the biopharma industry has traditionally viewed full-service outsourcing and functional service provision (FSP) as binary options; where sponsors would select one or the other as their outsourcing solution. Yet, as the industry continues to evolve focusing ever more on cost efficiencies, enhanced performance and reduced time to market there is a need for more flexible outsourcing solutions. Enter "the hybrid outsourcing model" that challenges this paradigm, combining the strategic focus of a full-service model with the scalability of an FSP model, with a view to building custom solutions on a sponsor-specific basis.

Know Your Options

In full-service outsourcing, a sponsor relies on a CRO to handle all (or most of) the development project; from trial start up and execution, to accumulating and analysing the data, and finally to reporting on it. In recent years, companies have taken full-service outsourcing to the next level by developing strategic partnerships with CROs, such that both parties invest in the relationship with the understanding that it will be long term and value driven.

In contrast, with FSP, the sponsor turns to a CRO to perform a key function across the sponsor's portfolio of trials. The CRO may, for instance, provide resource and expertise in project management, clinical monitoring, data management, medical affairs, or statistics across the sponsors' business. The systems and procedures employed may be either the sponsor's or the CRO's, but the sponsor typically manages the project and controls the trial technology. The CRO operates as a natural extension of the sponsor-its arms and legs, while the heart and mind reside within the sponsor organisation.

A hybrid approach- aims to harmoniously marry these approaches, to create a more flexible, highly-customised solution for the sponsor. In this model, functional outsourcing fits within a partnership. The CRO is able to deliver economies of scale as well as the expertise borne of focusing on a specific function. The sponsor is able to take advantage of the CRO's deep expertise, technology infrastructure and SOP's while enjoying a high degree of transparency, control and flexibility in the process.

Rule of thumb

Selecting the best approach can be a challenge, and should involve a CRO having a deep understanding of the sponsors' underlying development strategy and the scale of the work portfolio. These guidelines provide a useful starting point in the decision making process:

Full-service outsourcing is preferable when a sponsor:

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Has a trusted CRO partner whom they rely on to be innovative, share in the decision making process and oversee quality drivers
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Needs access to expertise, technology and leadership in any of the clinical phases
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Is looking for an outcomes-based measures of success
Functional service provision is the right choice when a sponsor:
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Wants to retain a degree of control over, and oversight into how a project is delivered
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Has access to, and wishes to retain internal expertise, systems and processes that are already in place
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Has variable workloads which require flexibility and scalability
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Is seeking improvements in quality and consistencies, while realising cost efficiencies
A hybrid outsourcing model is appropriate when a sponsor:
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Requires a lean, resource-focused solution, which may include infrastructure and process input across multiple functions and/or regions in order to optimise gains
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Is looking to for significant reductions in oversight and cost, enabling them to pursue value-added, core activities
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Need the scalability, control, transparency, and flexibility of a functional model, coupled with the expertise, innovation, and SOPs in a full-service solution; supporting their expanding pipelines and improving efficiencies of development

The Must Haves

For a hybrid model to work well it must be custom designed to meet the sponsor's unique needs. Critical to its success is a highly structured relationship guided by trust and communication. No two outsourcing solutions are exactly alike. Therefore, the CRO must remain flexible; capable of accommodating and supporting a variety of permutations in the working model. The CRO must have a proven background in FSP delivery and a solid, global infrastructure that can support the sponsor's vision and evolving development needs.