



Functional CRO Networks: An Emerging Alternative to Global CROs

Introduction

According to data published by the Office of the Inspector General (OIG) in the US, more than 50% of patients were recruited from foreign sites, including emerging clinical trial destinations like India, China, Latin America, and CEE countries. Therefore, it is no exaggeration to say that the pharma companies that can manage global clinical trials most efficiently will be the most successful. Large global CROs are viewed as the natural choice for conducting global trials due to their geographical reach and scale of operation.

The CRO market is highly consolidated. Nonetheless, consolidation is expected to increase in the next 4-5 years as large global CROs expand their geographical reach and service portfolios by acquiring niche and local CROs in different regions. This consolidation is expected to increase the bargaining power of global CROs. As a result, pharma companies are searching for alternatives to large global CROs, such as a network of regional CROs. Pharma companies are also questioning whether global CROs can act fast enough in this environment, which demands speed (longer patent protection) and cost effectiveness (reduced R&D spending).

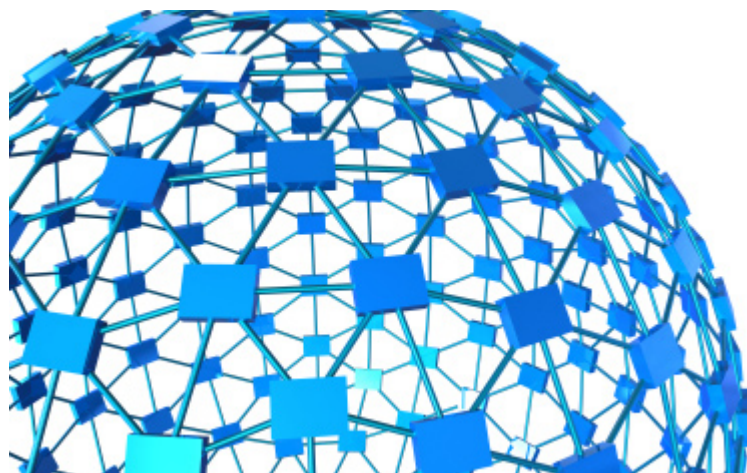
Global CROs vs. Regional CROs

Global Trial Management Competency		
Parameters	Global CRO	Regional CRO
Single Point Contact	5	1
Access to Opinion Leaders	1	5
Speed/Flexibility	1	5
Recruitment Rate	2	5
Speedy Regulatory Approval	3	5
Compliance with Local Requirements	1	5
Site Management	2	5
Experience	2	5
Low Bureaucracy	5	1
Centralized Vendor Management	5	1
Staff Turnover	2	5
Overheads	5	3
Financial Stability	5	3
Geographical Reach	5	2
IT Infrastructure	5	2

Note: 1: Very Low Advantage | 2: Low Advantage | 3: Moderate Advantage | 4: High Advantage | 5: Very High Advantage

Functional CRO Network

The advantages offered by regional CROs are offset by factors like their lack of geographical reach and central vendor management capabilities. As a result, functional CRO networks (i.e. networks made up of local/regional CROs specializing in various functional areas in different regions) have emerged.



How Functional CRO Networks Operate

Most of these networks (Harte Group, QED, Clinterra, Research Point, PSN, and Health Decisions) have a formal operations manual. The operations manual ensures all franchisees work to the same standard regardless of location. It is a step-by-step guide on how to run the network. The operations manual covers all roles, duties, and responsibilities of the network that make up the business system, from the initial RFI/RFP process to undertaking clinical trial monitoring assignments. Each section covers a specific element of the business and provides details on the policies, procedures, and methods to be used. With this manual in place, networks can define common quality standards across the entire organization and guarantee consistent high quality service. In addition, they have a clearly defined set of global SOPs, which are followed if adherence to sponsor SOPs is not requested.

The Harte Group selects and manages a core group of vendors who best fit the study or program needs. Following review of the client program or protocol, it evaluates, selects, and presents the best team approach for the opportunity. Additionally, The Harte Group manages vendor activities, including protocol development and clinical study reports, to minimize rework and complete projects on time and on budget.

If a provider does not perform as stipulated, the rules of the network allow for a new provider to be used in place of the original. This practice gives suppliers the incentive to perform and provides peace of mind for sponsors.

For the Netherlands-based CRO network, Pharmaceutical Service Network (PSN), potential members are required to be owner-driven (they cannot be a part of a larger company). Prospective members should have existed for at least three years. They should be willing to disclose their financial statements, and their financial health has to be excellent. In addition, potential members have to possess knowledge of their local market's regulations, have a solid grasp of the culture, and be willing to share potentially proprietary information with other members of the network.

Pricing Policy

Member CROs of PSN do not have uniform pricing policies across the globe but do ensure their prices are in the same ballpark and do not conflict with general national pricing rules. Sponsors are not obliged to use other PSN members. PSN is working on a template for a unified contract that could be used by all member CROs for any clinical trial.

What Value Can a Functional CRO Network Provide Large Global CROs?

1. Functional CRO networks provide global reach without loss of local knowledge. Resources are located on the ground in each country, meaning that local requirements, intricacies, processes, logistics, and language are all thoroughly understood.
2. The functional CRO networks model reduces overheads as it leverages the infrastructure and resources of already well-established local franchisees and partners. Larger, full service global CROs often provide a less cost effective solution. Furthermore, the overheads associated with a traditional CRO can result in escalated project management and administrative costs.
3. This structure allows resources to be ramped up quickly to meet the specific needs of sponsors. Whether a large global project team or local resource is required on a fully Integrated or standalone basis, this model can provide resources tailored to individual project requirements. Its lean reporting structure not only ensures total accountability but also clear transparency at the senior management level, which facilitates effective resource planning and alignment.

4. A single fixed price contract that covers all FSPs a sponsor needs during a trial can radically simplify the process of identifying and hiring several suppliers.
5. Functional CRO networks have faster turnaround times than global CROs. Their knowledge of local requirements results in shorter set up times.



“Many of the talented, experienced staff which rests in these companies has worked in sponsor or CRO settings previously. They are artisans who wish to practice their chosen craft, and enjoy the companies who employ them. Thus, turnover percentages are very small. These people are not just starting out in the industry. They have not been anesthetized inside the well-padded walls of large corporate bureaucracies. They have not lost the verve of their early years. Indeed, they continue to love clinical trials. They just might not want to spend all their waking hours wading through five or six layers of management. In essence, the smaller FSPs are entrepreneurial refugees from large CROs and sponsor firms. If they're working for Harte, they might have twenty years of experience, not two.”

Michael Harte,
Founder & President of the Harte Group

Conclusion

As large global CROs increase their market share from 60% to 75% in the next 4-5 years, R&D sourcing organizations will be presented with new opportunities to engage with functional CRO networks. Through these networks, organizations can source clinical trial services faster and more cost effectively.

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