Virtual Clinical Organization: The New Clinical Development Operating Model

Executive Summary

Clinical development executives are facing more pressure than ever to reduce costs while maintaining quality and improving operational efficiency. As a result, clinical development organizations are rethinking their operating models. Mergers and acquisitions, outsourcing, downsizing and strategic alliances have become the new normal.

As the industry continues to evolve, one thing has become clear: The new clinical development operating model will be a partnership-driven one. Partners can provide the global capabilities, a flexible resource pool and the supporting technology needed to run large global trials and manage a widely diversified product portfolio. While some clinical trial sponsors have tried to limit the number of partners they work with, most research continues to require a large number of specialized skills.

Achieving alignment of strategic and operational goals with partners continues to be among the greatest challenges that sponsors face. To achieve tighter alignment, sponsors need to understand where clinical operations are heading and establish partnerships to help them achieve their objectives. This means embracing a clinical operating model that we call a virtual clinical organization (VCO). A VCO is a network of clinical partners who are:

- Committed to a common set of strategic and operational business objectives.

- Supported by integrated business processes and technologies that enable real-time collaboration.

- Capable of providing consistent performance, regardless of time zone, location, department or company affiliation.

This paper will discuss the critical success factors for creating a VCO and how this emerging model differs from traditional vendor or preferred partner relationships.

Evolution of Clinical Research Partnerships

Vendors have always played a critical role in clinical trials; however, the nature of the relationship between the sponsor and outsourcer is evolving from one with an operational focus to a long-term, strategic focus. Sponsors that are able to align their strategic objectives with those of their partners will experience the greatest improvements in timelines, cost and operational efficiency.

Evolution of Clinical Development Partnerships

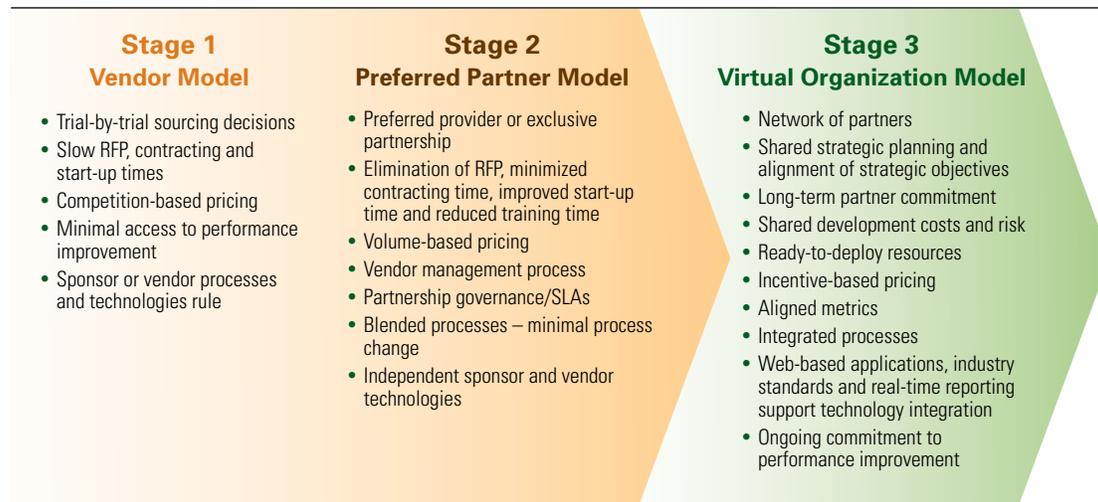| Stage 1 Vendor Model	Stage 2 Preferred Partner Model	Stage 3 Virtual Organization Model
• Trial-by-trial sourcing decisions • Slow RFP, contracting and start-up times • Competition-based pricing • Minimal access to performance improvement • Sponsor or vendor processes and technologies rule	• Preferred provider or exclusive partnership • Elimination of RFP, minimized contracting time, improved start-up time and reduced training time • Volume-based pricing • Vendor management process • Partnership governance/SLAs • Blended processes – minimal process change • Independent sponsor and vendor technologies	• Network of partners • Shared strategic planning and alignment of strategic objectives • Long-term partner commitment • Shared development costs and risk • Ready-to-deploy resources • Incentive-based pricing • Aligned metrics • Integrated processes • Web-based applications, industry standards and real-time reporting support technology integration • Ongoing commitment to performance improvement

Figure 1

Partnerships have evolved in three stages (see Figure 1).

Stage 1: Trial-By-Trial

Until recently, vendor partners were selected on a trial-by-trial basis. Each study team had the ability to choose its vendors through an RFP process. Trial-by-trial outsourcing, however, resulted in a significant vendor management challenge. With so many vendors, it was difficult for sponsors to manage vendor performance. In an effort to control quality, many sponsors forced vendors to utilize their standard operating procedures (SOPs) and technologies (e.g., clinical trial management systems, electronic data capture and integrated voice response systems). This created longer training times, reduced study team flexibility to adopt new processes and technologies and increased project risk. Sponsors also realized that the RFP and vendor-contracting processes were creating unnecessary delays in study start-up. Many smaller pharmaceutical and biotech companies continue to use this partnership model.

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Stage 2: Preferred Partners

In recent years, pressure to improve quality while minimizing cost and reducing study timelines has led many large pharmaceutical companies to establish preferred vendor relationships and exclusive partnerships. Most preferred partnerships have improved pricing and reduced study start-up timelines. Many sponsors also successfully developed their vendor management capabilities and were able to hold their partners accountable for performance against specific operational measures.

Stage 3: Virtual Clinical Organization

Building a VCO requires the sponsor and its network of partners to completely align strategic and operational objectives. This requires a new level of cooperation, investment and shared risk. For sponsors, this means taking a lead role in facilitating process and technology change across partner ranks to achieve optimal performance against timelines, cost and quality objectives. For functional service providers, clinical research organizations and other vendors, this means finding an appropriate balance between standardization in their own organizations (which provides economies of scale) and providing partners with customized solutions that meet their needs. Sponsors also need to think differently about how they select their partners and begin evaluating potential partners based on how well-aligned their business strategy is with their strategic objectives. Figure 2 (next page) provides examples of how traditional vendor selection criteria are expected to change under the new VCO model.

Changing Vendor Selection Criteria

Trial Management & Monitoring Functional Service Providers	Data Management Functional Service Providers	Technology Partners	Site Partners/ Centers of Therapeutic Excellence	Labs/Clinical Testing Partners
Traditional Selection Criteria				
• Therapeutic expertise • Capacity/Number of available resources • Project management capabilities • Quality and compliance	• Per page pricing • Database build and lock timelines • Quality of data cleaning • Project management capabilities • Data reporting capabilities • Data quality and compliance	• Industry knowledge • Customer service • Project management • Breadth of service offerings, spanning development, maintenance and support	• Key opinion leader status • Trial experience • Access to patients/ recruitment success • Compliance • Development timelines	• Ability to perform specific tests • Site lab preference • Global reach • Expertise in specific testing areas
Additional VCO Selection Criteria				
• Willingness to invest in global therapeutic expertise • Technology investments and infrastructure • Site start-up, country start-up and monitoring timeline commitments • Willingness to change current business processes	• Technology investments and infrastructure • Ability to support new automation and data capture tools • Customer service and site support • Data cleaning and data availability timeline commitments • Ability to fully adopt industry and sponsor data standards	• Willingness to include sponsor feedback in product development • Investment in product development	• Site growth plans • Facility development • Physician and trial staff hiring plans • Site standard operating procedure development	• Customer service and site support • Breadth of expertise • Global logistics • Timely access to data • Willingness to coordinate lab kits and specimens for specialty labs • Willingness to advise on protocol patient procedures

Source: IDC

Figure 2

Creating a Virtual Clinical Organization Through Strategic and Operational Alignment

The VCO addresses many of the hurdles that plague traditional partnerships – misaligned goals, lack of shared investment and competing priorities. Integrating a partner into your VCO requires the following :

- **Integrated strategic planning:** Sponsors need to include partners in their strategic planning process to ensure that the partner truly understands the challenges the sponsor faces. This will help the partner think strategically about how it can help address the sponsor's most pressing business problems. Each year, the VCO should set realistic performance improvement objectives and commit resources to ensuring that these objectives are met. Finally, each organization must also have a financial commitment to the partnership so that the partners succeed or fail together. Strategic plans must be backed by investments and incentive-based rewards.

- **Effective governance with aligned metrics and rewards:** Senior leaders from both organizations should be part of a governance structure. The purpose of the governing body is to ensure the strategic goals of the partnership will be achieved and that investments in the partnership are continuously monitored. The governance body should also have an operational focus, reviewing operational performance against agreed upon goals and ensuring that performance continues to improve. The governance team should be responsible for identifying the process and technology improvement initiatives the partners believe could have the greatest impact. Pricing should be directly linked to outcomes, and both partners should be held accountable for their performance

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against a clear set of shared metrics. An effective governance structure can help ensure that partners build a "ready-to-deploy" resource pool. Partners that allow the VCO to be managed like an independent business unit are best positioned to achieve shared VCO objectives.

- **Integrated clinical trial processes and technology:** Sponsors must work with their partners to develop integrated business processes that optimize the process rather than the needs of either party. Activities

should be performed in the most efficient way, and responsibilities should be divided in a way that drives operational efficiencies and improvements in timelines, as well as provides dramatic cost reductions without sacrificing quality. Integrated processes must be supported by integrated technologies that help all partners communicate throughout the network. Effective tools include study portals and executive dashboards, which can provide real-time insights and timely data to support decision making. Data exchange

Case Study: Enabling the Virtual Clinical Organization

Client: A top-10 pharmaceutical organization with established partnerships with separate vendors for data management and site management, as well as long-term strategic relationships with three therapeutic centers of excellence.

Strategic Objective: Improve and simplify site operations.

Operational Goal: Reduce site start-up timelines by 50%.

Approach:

- **Evaluate current cause of delays:** We assisted the client in analyzing the causes of start-up delays. Representatives from the vendor partners and therapeutic centers of excellence provided significant insight into the problem, identifying the main causes of delay in getting a site started. Some of the main causes of delays included: delays in training the site monitor; difficulties completing and tracking site training; getting the drug to the site in time for initiation; and scheduling the site initiation visit with the site.
- **Develop integrated business processes:** We worked with this client and its vendor partners to develop a new site start-up process that streamlines these activities by changing roles and responsibilities, improving communication between the

parties involved and making training completion reports available to site personnel.

- **Develop a performance management process:** We facilitated discussions between the sponsor and the vendors, which led to an agreement on both operational and strategic metrics that would indicate progress against the site start-up timeline reduction objective.
- **Update client's clinical data repository (CDR):** We then worked with the sponsor and its vendors to identify the data needed in the CDR to support the integrated business processes and performance metrics. For each data point contained in multiple systems, a source system was defined, and processes were defined to ensure that key individuals would be notified if critical information changed. Metadata and master data was defined across sponsor and vendor systems, and data required for reporting was defined.
- **Build collaboration tools:** We also worked with the client to build a portal that provides all players in the site start-up process with a simple way to communicate and track communications, access documents and use a dashboard to see progress against agreed-upon metrics.

Outcome: This client reduced average site start-up time – from final protocol to site initiation visit – from four months to six weeks.

between partners needs to be near-real-time. Developing an integrated information architecture helps the sponsor monitor the partner's performance and can help build trust between companies. This will reduce the need for process redundancy (i.e., individuals in two organizations performing the same tasks in order to check accuracy).

Whether building on an existing partnership or selecting a new partner, it is critical that all partners understand the commitment needed to build a VCO. Ultimately, success depends on the willingness of all partners in the network to align their strategic and operational goals and fully integrate their business processes, people and platforms.

About the Author

Nancy Fuller is a Senior Manager in Cognizant Business Consulting's Life Sciences Practice. She has over 20 years of experience in the life sciences and consulting industries, leading business process and technology change initiatives. She has worked for clinical trial sponsor organizations, clinical research organizations (CROs) and several leading consulting organizations. Nancy holds a master's degree in Human Resources and Business Administration from the Krannert School of Management at Purdue University and a Bachelor of Science in Business from Miami University of Ohio. She is a certified Project Management Professional (PMP). Nancy can be reached at Nancy.Fuller@cognizant.com.

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