About Vantage Partners

Vantage Partners, LLC is a global strategy and management consulting firm that specializes in helping companies achieve breakthrough business results by transforming the way they negotiate and manage relationships with key business partners, as well as by enhancing internal collaboration across functions and business units.

Sourcing & Supply Chain Management Consulting and Training

Through our sourcing and supply chain management practice, we lead supply chain transformation initiatives, support development of category strategies, help implement supplier relationship management programs, advise on high-stakes supplier negotiations, and provide a range of training solutions to executives and professionals who need to work effectively with third party suppliers.

Work in Life Sciences Focused on Clinical Research Outsourcing

We have worked extensively with large and mid-sized pharmaceutical and biotech companies over the past 15 years on the development and implementation of clinical research outsourcing strategies, and to improve collaboration with CROs and other providers of clinical development services.

© 2013 by Vantage Partners, LLC. All rights reserved.
Executive Summary

About the study

- Survey of CRO executives, as well as directors of Business Development, Clinical Operations, Data Management, Regulatory Affairs, etc., and project managers (comprising 88 individual respondents).
- Survey of Sponsor executives, as well as directors and managers from functions such as Clinical Operations, Clinical Outsourcing, Data Management, and Supply Chain (comprising 81 individual respondents).
- Interviews were conducted with more than 20 individuals representing a cross-section of roles, across both CROs and pharmaceutical Sponsors, including multiple geographic regions, and comparing a mix of high and low performers (in terms of self-reported partnership success).

The use of CROs, and Sponsor-CRO partnerships are on the rise

- The use of clinical research organizations (CROs) as outsourcing providers for clinical development work has risen sharply. Sponsors frequently cite the following pressures as reasons for shifting clinical trial work to CROs: enabling increased focus on core competencies, a need to augment staff due to downsizing, increased trial volume, a need to control costs, and increased safety requirements.¹

- Over the past several years, an increasing number of companies have entered into more strategic partnerships with a small number of CROs and/or other providers of specific services such as data management or central labs. In some cases, such arrangements are partnerships in name only. In other cases, Sponsors and CROs (and/or other service providers) have implemented formal governance structures to improve strategic and operational integration, and enable more efficient and effective issue resolution; have invested in joint training and common systems on the back of long-term commitments to continue working together; and, more recently, have begun to move away from pay-for-activity and toward pay-for-performance arrangements. These more mature manifestations of partnership have been effective in other industries and outsourcing contexts, and we believe they can deliver significant benefits to all parties involved in the drug development process.²

Outcomes (to-date) of the shift toward partnerships between Sponsors and CROs

- Closer, more collaborative relationships have the potential to save both Sponsors and CROs time and money, as well as deliver other benefits such as increased patient safety, improved regulatory compliance, and enhanced quality of trial data. The means by which such benefits are achieved include:
  - Enabling early engagement between Sponsor and CRO in protocol design and study planning
  - Reducing transaction costs associated with the need for RFP development, bid submission, and evaluation at the start of every clinical study
  - Increasing willingness to invest in joint training, improved systems, after-action analysis of clinical studies, and in general, to work together to jointly drive continuous improvement of the clinical development process
  - Enabling both Sponsors and CROs to build up tacit knowledge about how to work together effectively

Though there is evidence that CROs can reduce costs, speed time to market, and even enhance quality, Sponsors still report mixed results. Sponsors report that 70% of trials conducted with CROs end up requiring more time and/or resources than originally anticipated. This perception exists even at Sponsors engaged in strategic partnerships with CROs. Additionally, 29% of Sponsors indicate they are unsure of whether CROs are more or less cost effective than conducting trials in-house.

Many Sponsors lack the requisite information and/or tools to effectively compare the true total costs of clinical trials conducted in-house versus those that are outsourced. The lack of objective, usefully analyzed data allows various biases to warp perceptions of the relative costs and benefits of outsourced clinical development.

<table>
<thead>
<tr>
<th>Ad hoc trial contracts</th>
<th>Preferred agreement</th>
<th>Strategic partnership</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td>25%</td>
<td>25%</td>
</tr>
</tbody>
</table>

A strategic partnership with CROs is correlated with Sponsors reporting that outsourced trials are faster and more cost effective.
The frustration is not limited to the Sponsor side. CROs report performing significant amounts of out-of-scope work for little or no additional compensation. Many CROs perceive that the root cause behind over-budget and over-time trials is not the ability of CROs to effectively execute the trial, but rather, the additional work required by scope and protocol changes (many of them avoidable).

**Barriers to reducing costs and improving quality and efficiency**

Sponsors that want to significantly improve the performance of their outsourced trials (in terms of patient safety, data quality, cost, and speed) need to fundamentally alter the nature of their relationships with CROs. It is not enough to simply change the contract from ad hoc to preferred supplier or to name the relationship a “strategic partnership.” Sponsors and CROs face significant barriers to improving the results of their work together, including:

- Failure by Sponsors to involve CROs early or deeply enough in trial and protocol design and planning
- Lack of ability by Sponsors and CROs staff to work collaboratively as partners
- Failure by Sponsors to provide CROs sufficient visibility into their development pipelines
- Lack of standardization of protocols, procedures, tools, data formats, etc.
- Lack of investment in software tools to enable communication, management, and automation of activities
- Tendency at Sponsors to micro-manage CROs
- Lack of alignment between Sponsor expectations and CRO capabilities
Executive Summary

Top reported barriers to maximizing the efficiency and total value delivered through the outsourcing of clinical trials

The “average across all responses” line is an average (across all noted barriers) of the percentage of study respondents who noted a barrier as “significant” (across both CROs and Sponsors).

The further a bar extends to the right of this line, the more respondents noted the specific barrier as significant relative to all the barriers surveyed. Conversely, the further a bar extends to the left of the dotted average-response line, the fewer respondents noted the specific barrier as significant.
# Executive Summary

## Characteristics of least successful Sponsor–CRO partnerships

- Both sides have unclear and unrealistic expectations of one another
- A mindset of “You work for us / we work for you” prevails
- CROs have limited visibility into Sponsor development plans and timelines
- Lack of clarity and alignment around policies and procedures; lack of clearly defined and differentiated roles and responsibilities
- Work is either micromanaged by Sponsors or “thrown over the fence” to CROs
- Problems are often not addressed until they metastasize; finger-pointing and defensiveness are common

## Characteristics of most successful Sponsor–CRO partnerships

- Differences (in priorities, business models, etc.) are acknowledged and jointly managed
- A mindset of “We are all colleagues” prevails
- Sponsors provide a high degree of transparency to CROs regarding development pipeline and plans, enabling more efficient resource deployment and management by CROs
- Processes, policies, and procedures are clearly defined and well-integrated; individuals from both companies work together seamlessly, as if part of the same organization
- Roles and responsibilities for execution and oversight are clearly distinguished
- Potential problems are spotted and addressed early; both sides explore root causes and develop potential solutions together

## Best practices for successful Sponsor-CRO partnerships

- Overcoming these barriers requires Sponsors and CROs to sit down together to make significant changes in the ways both organizations work. Doing this requires:
  - Active and disciplined management of outsourced trial scope and budget
  - Formal processes to facilitate the identification and implementation of innovation opportunities
  - Re-designed processes that enable greater transparency
  - Joint, multi-level governance
  - Performance management supported by a two-way, balanced scorecard
  - Substantial investment in systematic change management

## Sponsors with the lowest incidence of delayed and/or over budget trials (top quartile) are...

- Twice as likely to have a formal process for monitoring trial progress against contracted budget and scope
- Four times more likely to report their CROs delivered innovation

...when compared to Sponsors with the highest incidence of delayed and/or over budget trials (bottom quartile)

## Sponsors that report that trials conducted with CROs are faster and more cost effective than those done in-house are...

- 30% more likely to provide CROs with a high degree of visibility into their development pipelines and future plans
- Four times more likely to employ two-way, balanced scorecards

...when compared to Sponsors that report that trials conducted with CROs are slower and/or more expensive than those done in-house
In the study, we provide examples of each of the processes and tools recommended above. Having these in place, however, is not sufficient. Collaboration is ultimately about the interactions that happen between individuals at Sponsors and CROs on a daily basis. While there is some overlap between the skills Sponsor staff need to manage studies in-house or through ad hoc CRO engagements and the above skills (which Sponsor staff need to realize the most value from a CRO partnership), there are also substantial differences. It is helpful to separate the required skills into two categories:

1. **Analytical skills** which can be developed through a variety of mechanisms, including lecture, reading, and computer-based training

2. **Behavioral skills** which generally require experiential learning vehicles and extensive reinforcement to ensure the skills are used even in high stakes, high stress situations (because developing these skills involves unfreezing strongly held beliefs and unconscious assumptions, introducing new ideas, then “refreezing” to make the new behaviors part of the individual’s repertoire)

Not surprisingly, developing these skills requires a significant investment of time and resources. Individuals need time to absorb new information, become accustomed to new procedures and responsibilities, and to try out new patterns of behavior. The most successful training and development programs span several months and incorporate multiple modes of learning: classroom training, online workshops or tutorials, intact team workshops, and consistent feedback and reinforcement from senior management.

### Illustrative skills needed for Sponsor staff in oversight roles

- **Analytical**
  - Report interpretation
  - Timeline planning / enrollment modeling and management
  - Budget planning and management
  - Risk identification and management
  - Audit analysis and corrective action planning

- **Behavioral**
  - Risk and issue management
  - Problem solving
  - Project management, in an outsourced context
  - Influence and alignment building
  - Communication and feedback
  - Emotional intelligence
  - Dealing with ambiguity
  - Conflicts management
  - Relationship management

To request a fully copy of the study, please visit [www.vantagepartners.com](http://www.vantagepartners.com) or call us at +1 888 547 8852