

INSIDE OUTSOURCING

A Guide to Pharma's Newest Core Competency

Pharma Outsourcing Comes of Age

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OFFSHORING:
A BENCHMARK SURVEY

THE RIGHT WAY
TO OUTSOURCE
PHASE IV

PROCESS DEVELOPMENT:
BALANCING SPEED AND QUALITY

THE CRO CROP

by HAROLD E. GLASS, PHD, AND
DANIEL P. BEAUDRY, MBA

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THE CRO CROP

Pharmas want a CRO that has similar values and a convincing project plan. So how do they choose the cream of the crop? Both sides speak in a recent survey.

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The pharmaceutical industry makes widespread use of CROs and, most likely, this trend will increase in the coming years. But little empirical research exists on why and how pharmaceutical companies select CROs. Overall, sponsor companies and CROs have a fairly consistent view of the criteria used to select CROs, but there are some notable differences.

The University of the Sciences in Philadelphia (USP) and TTC, a drug development data company, are conducting a multi-year research program on the factors associated with improved speed and cost effectiveness in clinical studies. Since outsourcing to CROs represents an integral part in developing drugs, USP and TTC will also analyze how CROs are selected and used in clinical trials. Part of this CRO analysis involved a Web-based survey of sponsor pharmaceutical companies and CROs to learn:

- ▶ Current and expected use of outsourcing
- ▶ Specific outsourcing processes and techniques such as project budgeting, CRO selection, study management, bid grids, and cost overruns management
- ▶ Perceptions of how CROs and sponsor companies interact in the areas of business development, CRO selection, and project management
- ▶ Training needs for industry

professional to improve CRO selection and CRO project oversight.

Previous studies have reported that industry professionals involved in outsourced clinical studies expect the overall level of outsourcing to continue to grow. In addition, quality and timelines of a CRO's work dominate as the basic selection criteria. This paper accepts that previous work quality is a central criterion for selection and focuses on other issues that might be involved in the CRO selection. Set within the anticipated continued growth of CRO usage, this paper examines these additional key criteria that individuals working in drug development use to select CROs, highlighting differences between the selection criteria that sponsor companies emphasize and how CROs think sponsor companies decide.

Pharmaceutical company participants indicate that approximately 64 percent of all post Phase I studies involve the use of CROs for one or more parts of the study. However, when measured by pharmaceutical company size, there are very large differences in current outsourcing practices. For example, within the 20 largest pharmaceutical companies, 52 percent of all post Phase I studies use CROs, a number that jumps to 88 percent for smaller companies. These smaller pharmaceutical companies often do not have the permanent in-house staff to conduct all aspects of a



clinical trial, especially when the trial involves many sites and multiple countries. The smaller companies may, for any number of reasons, also lack the employee headcount or expertise to carry out clinical trials.

The use of CROs in clinical trials, while already extensive, will most likely to continue to grow. Both sponsor company and CRO participants anticipate increased outsourcing in the next five years. Very few drug industry professionals see a decrease in CRO use.

While many industry professionals expect the use of outsourcing to increase, only one-quarter of people from pharmaceutical companies think that their company is better than competing companies in selecting CROs, with no significant differences when measured by the size of the companies involved. That is, large companies are no more likely to think they are especially good at CRO selection than are small companies. And there is a general agreement between the reasons pharmaceutical companies cite for selecting an outsourcing organization, and how CROs think pharmaceutical

companies select them. There are some striking differences in the individual decision criteria.

TOP FIVE CRUCIAL CRITERIA

We tested 17 criteria that arose from our literature review and preliminary interviews with industry professionals, and five of these items were deemed to be especially crucial in the selection of CROs. The five criteria are team chemistry, CRO experience, project execution plan, problem solving processes, and other.

► **Team Chemistry**

Both sponsor company and CRO respondents think that the sponsor wants to know above all else that it could work with the CRO. More than any other single selection criterion, sponsor companies stressed the importance of a good relationship between the two company teams. These teams must work closely with each other for an extended period of time, often on projects involving multiple countries and large sums of money. The sponsor company needs to know that both its team and the CRO's team share the same values,

**PERCENT WHO INDICATED A CRITERION WAS VERY IMPORTANT
IN THE DECISION TO SELECT A CRO (N = 398)**

	TOTAL
Your team's general sense that you can work with this CRO	63
The project management team to be devoted to the study	62
The CRO's recent experience in the same indication	61
A CRO's overall experience in the study's therapeutic area	57
The backgrounds of the project team members	51 (*)
The project execution plan presented by the CRO in the bidding process, including such items as resources and site selection	48 (***)
A clear process exists within the CRO to present project problems to the appropriate senior CRO management	43 (*)
The CRO's geographic reach/presence	42
The CRO is a preferred, or qualified, provider	39
CRO staff turnover	38 (*)
The CRO's SOPs	33
Project references	25
The CRO's willingness to accept penalty clauses for poor performance	23
Superior technologies, e.g., site performance tracking	21 (**)
Lowest price	18 (***)
CRO invoicing/billing processes	11
One of the 20 largest CROs	8
* p= .05 ** p=.01 *** p=.001	

work ethics, and general approaches. CROs also clearly understand the need sponsors place on teams that work well together.

The CRO's project management team contributes significantly to the overall positive sponsor-CRO relationship. Yet sponsors were far more likely than CROs to stress the importance of the project management team as a CRO selection criterion. While 68 percent of the pharmaceutical company participants stressed this criterion in their selection process, only 51 percent of the CRO respondents thought sponsor companies valued this as very important.

► **CRO Experience**

Sponsor companies as well as CROs placed great weight on a CRO's relevant experience, both in the same indication as the study and in the CRO's overall experience in the appropriate therapeutic area. Sponsor companies and CROs differed somewhat on the weight of the importance of a project member's background. While only 45 percent of the pharmaceutical company participants considered this very important, 62 percent of the CRO respondents considered it very important to sponsor company decision makers. Sponsor companies seem more interested in the overall

cohesiveness of the CRO team members than their vitae. As one pharmaceutical company project manager put it: "CVs can take you only so far. You want to know that the CRO's team fits with the way you want things done and the way you want to work."

▶ **Project Execution Plan**

Another essential criterion raised by more than a third of the study's R&D professionals was the project execution plan. But no other single criterion carried a greater difference between sponsor company and CRO responses. Fifty-nine percent of pharmaceutical company professionals considered the execution plan as fundamental in hiring a CRO; only 28 percent of respondents from CROs placed the same importance on the execution plan.

In their responses to this criterion, the pharmaceutical company decision makers appear to be

emphasizing a level of project specificity that many of the CROs may not

appreciate. Far more than the CRO project team's background, pharmaceutical companies want to see a convincing project execution plan, including such concrete items as resources and site selection. According to one pharmaceutical company outsourcing professional: "Every CRO claims to be customer oriented, responsive, and so forth. Exactly how a CRO proposes to carry out a project...now that can be convincing—or not."

▶ **Problem Solving Processes**

Sponsor companies are also more

likely to value the internal processes CROs use to make appropriate senior CRO managers aware of project problems. Forty-seven percent of the pharmaceutical company participants considered this capability to be essential in selecting a CRO. In contrast, only 34 percent of the CRO respondents thought it was essential for sponsor companies.

▶ **Other Criteria**

A smaller number of respondents, from both sponsor companies and CROs, considered the CRO's role as a preferred provider and the CRO's geographic scope to be very important. CRO staff turnover was somewhat more critical to the sponsor companies than many CROs thought was the case.

Of the remaining criteria, one in particular merits its own discussion: the role of the lowest bidder. Sponsor companies and CROs differ in how

"Fifty-nine percent of pharmaceutical company professionals consider the execution plan as fundamental in hiring a CRO."

they view the role of the lowest price. According to an experienced business development manager from a major CRO: "Pharmaceutical companies rarely say price is important. But we know that it really is." Yet in this study a mere 7 percent of the sponsor company respondents considered the lowest price as decisive in selecting a CRO. In contrast, 38 percent of the CROs felt price was a fundamental selection measure for sponsor companies.

EUROPE VS. AMERICA

The greatest differences across the

dimensions are associated with a respondent's geographic location. The components of the CRO selection criteria are important to both Europeans and Americans. However, Europeans and Americans do differ on three of the dimensions. For example, Europeans are far less interested than others in the details and mechanics of identifying and resolving issues and, ultimately, in CRO's willingness to accept accountability. Americans are more likely to consider execution specifics and CRO capabilities important. They want to see the details of the project plan and project management team devoted to the study. They are more interested in a preferred provider relationship with a larger CRO having geographic reach.

While Americans stress the mechanics of the sponsor-CRO relationship, Europeans tend to emphasize more intangibles. These differences by a respondent's geographic location remain significant even when we use ANOVA to control for the possible influence of other variables, such as company size and whether a person works for a CRO or sponsor company.

SUMMARY

Sponsor companies and CROs have a generally similar view of how important each of these dimensions is in selecting a CRO. One dimension CROs and sponsor companies differ on quite



clearly is the specifics of project execution. Not surprisingly, CROs think considerations such as price play a larger role in the sponsor company's decision making than sponsor companies state is the situation. Less expectedly, CROs may not appreciate the value that sponsor companies place on presenting a convincing execution plan. People in larger organizations are especially likely to emphasize a CRO's size and relationship with the sponsor company. However, more than company size or whether a person comes from a CRO or sponsor, a respondent's geographic location is often a key to the relative importance of the decision criteria in CRO selection.

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