

The State of Clinical Outsourcing

Results from the Avoca 2007 Industry Survey

Clinical research today is all about partnerships in which companies, often sponsors and service providers, work together to complete a fundamentally dynamic, frequently complex, and often high-stakes task.

When was the last time your company did a clinical trial completely on its own, with no input from external partners or vendors? Chances are that your answer to this is, “I can’t remember.” Clinical research today is all about partnerships in which companies, often sponsors and service providers, work together to complete a fundamentally dynamic, frequently complex, and often high-stakes task. The management of such partnerships can be difficult logistically, but is further complicated by the companies’ different goals, constraints, and levels of understanding about each other.

Recognizing the critical importance of partnerships to the success of clinical research, The Avoca Group conducts a “State of the Industry” survey each year to examine trends in the relationships between clinical research sponsors and the providers of clinical research services. Representatives from scores of companies on each side of the sponsor-supplier relationship are invited to participate.

In 2007, Avoca explored general trends in clinical outsourcing. Because change orders represent a formal amendment to the contract between a sponsor and a vendor that changes the scope of work and cost, Avoca posed questions about the procedures for and impact of change orders and the existence, nature, and impact of client feedback programs within clinical service provider companies. This article summarizes the findings of this survey.

Methodology

Two survey instruments were created: one for clinical research sponsors and another for contract research organizations (CROs) and other providers of clinical research services. The survey instruments were comprised of yes/no questions, agreement-rating statements, and free text response areas. For agreement-rating statements, respondents were to read each statement and rate their levels of agreement on a five-point scale as follows: “5” for strong agreement with the statement, “4” for general agreement, “3” for neutrality, “2” for general disagreement, and “1” for strong disagreement.

Surveys were conducted using a web-based platform. Sixty-one sponsor surveys from 50 companies and 48 service provider surveys from 29 companies were completed.

Respondents

Of the sponsor surveys, 67% of respondents were employed by pharmaceutical companies, 27% by biotechnology companies, 2% by device companies, and 5% by other sponsor companies. Thirty-four percent of sponsor respondents reported that they were employed by “top 10” companies in the industry. With respect to their positions, 55% were middle management personnel; 22% were executives; 18% were project managers; and 5% held other positions.

Of the clinical service provider respondents surveyed, 85% were employed by CROs, 4% by central laboratories, and 11% by other service providers. Seventy-two percent reported that their companies were in the “top 10” in their industry. Clinical service provider respondents were largely company executives, with 55% in executive management roles and 32% in middle management roles.

Relationships between Sponsors and Clinical Service Providers

Overall satisfaction with relationships in the industry was found largely to be good, though somewhat better from the CRO/clinical service provider side than from the sponsor side. When asked about their satisfaction with CROs, 61% of sponsor representatives provided favorable ratings (scores of 4 or 5), while 15% provided negative ratings (scores of 1 or 2) (Figure 1). When asked about their relationships with sponsors, 75% of the clinical service providers surveyed provided favorable satisfaction ratings, and 4% provided negative ratings (Figure 2).

These results varied by size of company for both sponsors and service providers, though the direction of the trend differed. “Top 10” sponsor companies were slightly more likely to be satisfied with their relationships with CROs than were smaller sponsor companies (65% versus 61%), and were less likely to be dissatisfied (10% versus 18%). In contrast, 73% of “top 10”

Figure 1 Sponsor Responses to Question: “In general, how satisfied are you with the work that has been done for you by CROs?”

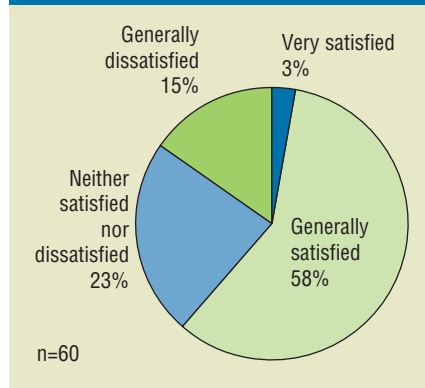


Figure 2 CRO Responses to Question: “In general, how satisfied are you with your relationships with your pharmaceutical and biotechnology company customers?”

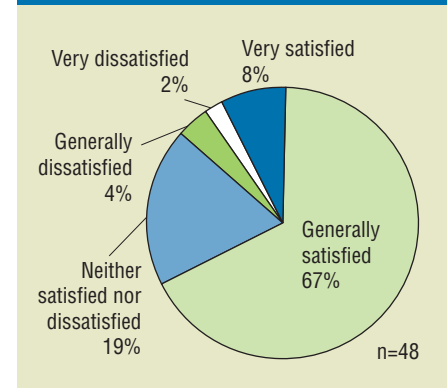
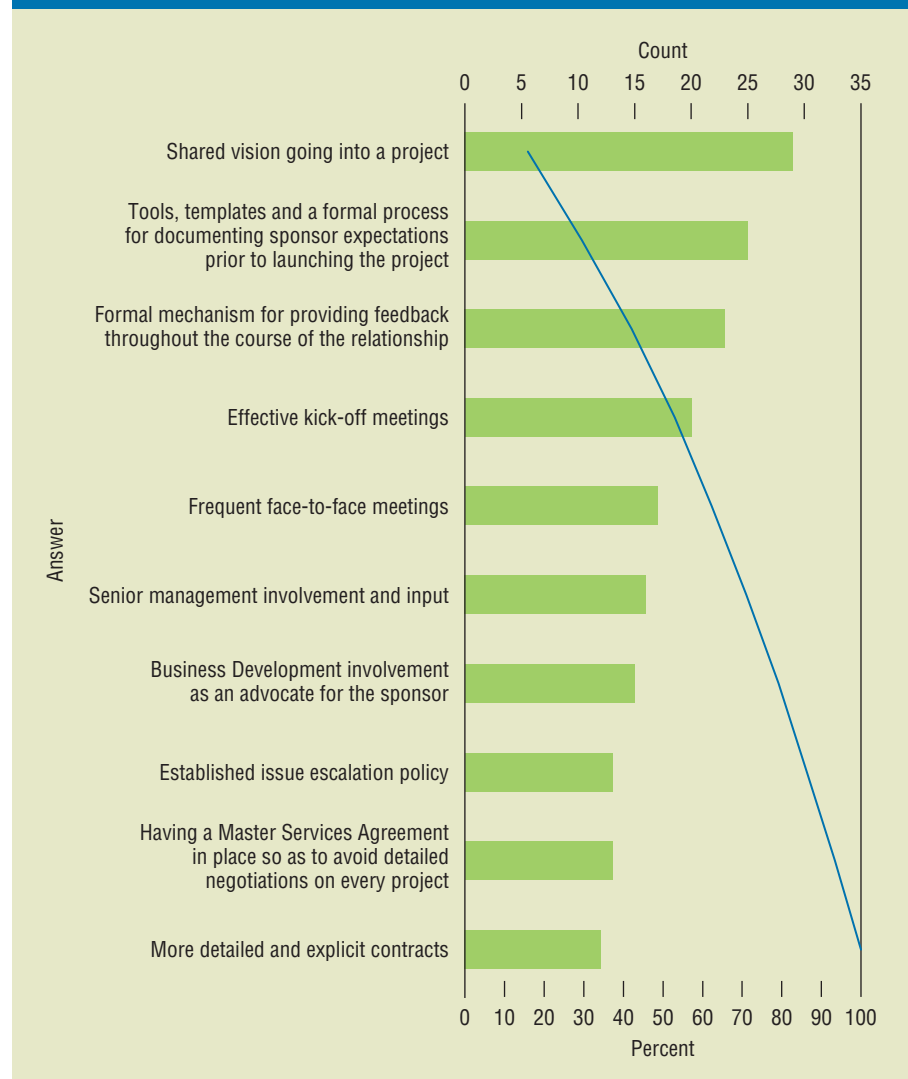


Figure 3 Sponsor Responses to Statement: “Name the top three factors that can most positively influence your relationship with your CRO on an outsourced project.”



service providers rated their satisfaction with sponsor relationships a 4 or better, whereas 85% of respondents from smaller service providers provided such ratings. Six percent of “top 10” service provider respondents, and none of the smaller company service provider respondents, rated their satisfaction level less than a 3.

The leading contributors to good sponsor/service provider relationships were seen similarly from the two sides of the relationship, and focused on shared vision and expectations, collaboration, and high-quality feedback. Factors felt by sponsors to contribute most to the success of sponsor-CRO relationships are depicted in Figure 3;

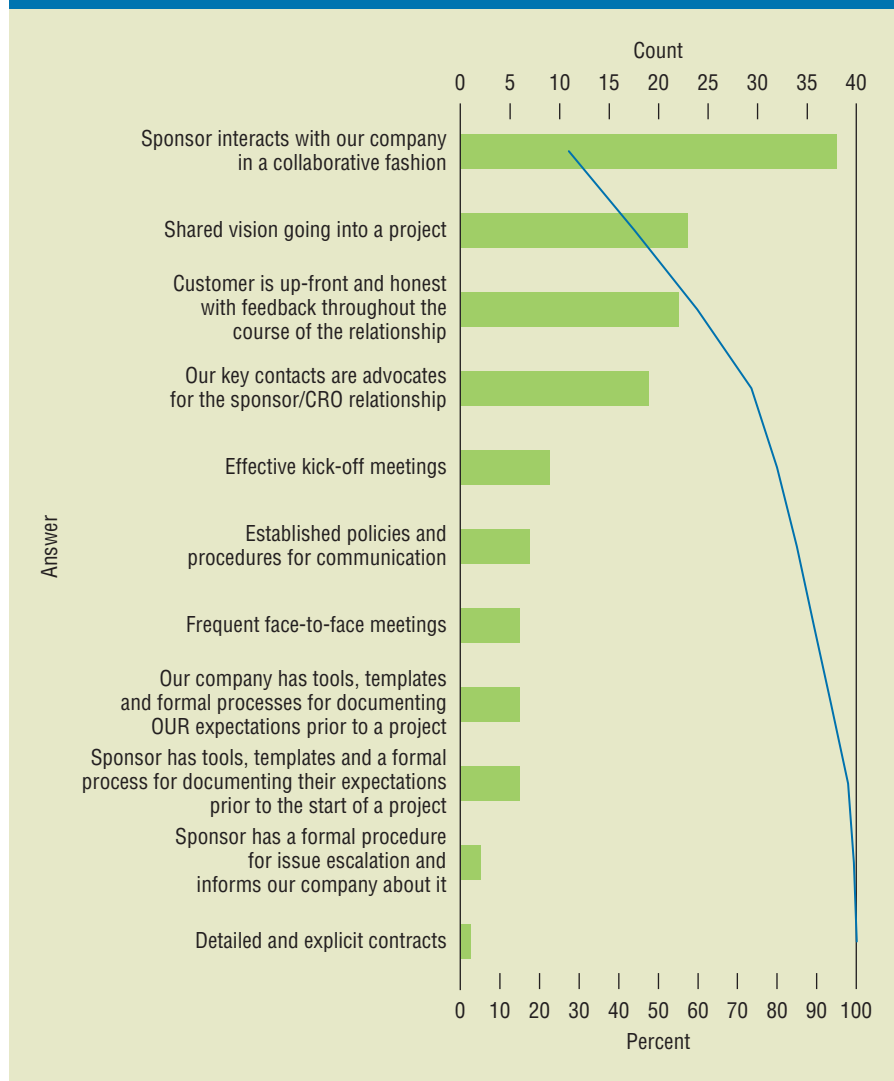
the results for service provider respondents are provided in Figure 4.

Likewise, both sponsor and clinical service provider respondents saw sources of conflict similarly and most commonly cited mismatched or ill-defined expectations as problems, and, in the case of sponsors, failure of CROs to be upfront about problems. Most (89%) of the sponsor company respondents felt that failure of clinical service providers to be upfront about problems was a significant issue (Figure 5). The other two most strongly endorsed statements related to conflicts in expectations: 88% of respondents agreed that mismatched expectations between sponsors and service providers were

the source of significant conflict, and 66% agreed that lack of defined expectations by sponsors was a significant issue for CROs. Issues of communication, “bait and switch” of personnel, and responsiveness were problems for some, and most complaints in these areas came from respondents working at smaller, biotechnology sponsor companies.

Ninety percent of service provider respondents agreed that mismatched expectations were a significant problem (Figure 6). Half (50%) felt that sponsors do not define their expectations sufficiently at the beginning of projects, and only 10% disagreed with this statement. Other strongly endorsed statements among service provider respondents related to changing demands through the course of studies and sponsor micromanagement. Lack of trust, lack of respect, and failure to include the service provider as part of the team were also, but less commonly, cited by CRO respondents as issues.

Figure 4 CRO Responses to Statement: “Name the top three factors that can most positively influence your relationship with sponsor company customers.”



Change Orders

Sponsors (66%) and clinical service providers (57%) agreed, in general, that change orders were damaging to their relationships. This result was consistent across different sizes and types of companies and was not significantly impacted by whether or not a formal change order process was employed. Interestingly, 62% of sponsor respondents felt that the responsibility for change orders was shared, and only 30% felt that sponsors were primarily responsible; however, 54% of clinical service provider respondents felt that the responsibility was primarily on the part of sponsors, and only 43% felt that responsibility was shared (Figures 7 and 8).

When asked about reasons for change orders, many responses reflected a certain level of exasperation with the partners’ failure to anticipate the needs of the project adequately, or in some cases honestly (Figures 9 and 10). Many sponsor respondents reported feeling that CROs underestimate the amount of work it takes to com-

Figure 5 Distribution of Sponsor Agreement Ratings Regarding Sources of Conflict

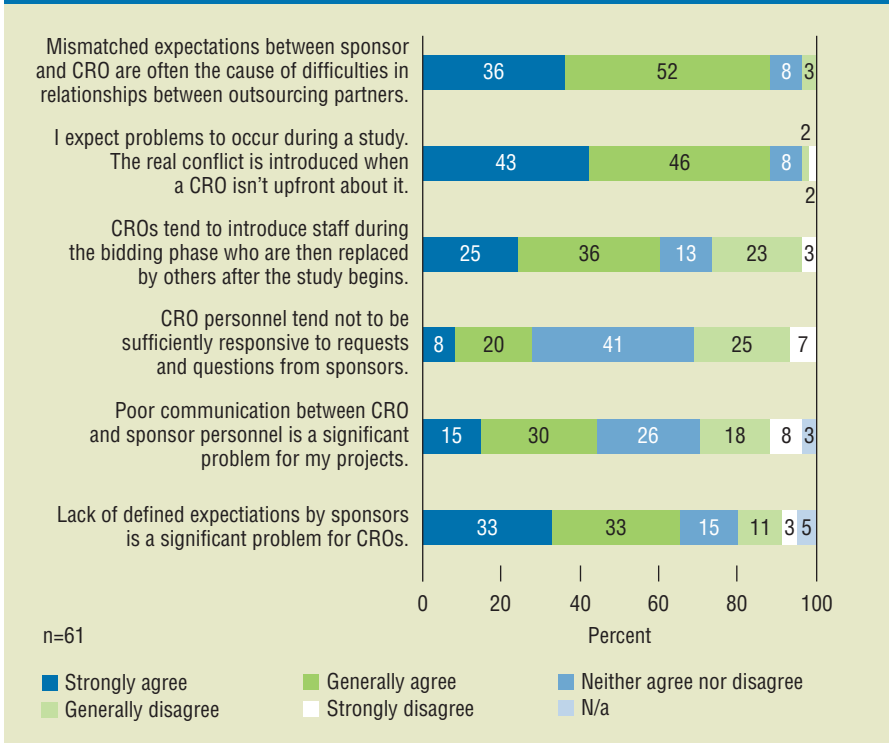


Figure 6 Distribution of CRO Agreement Ratings Regarding Sources of Conflict

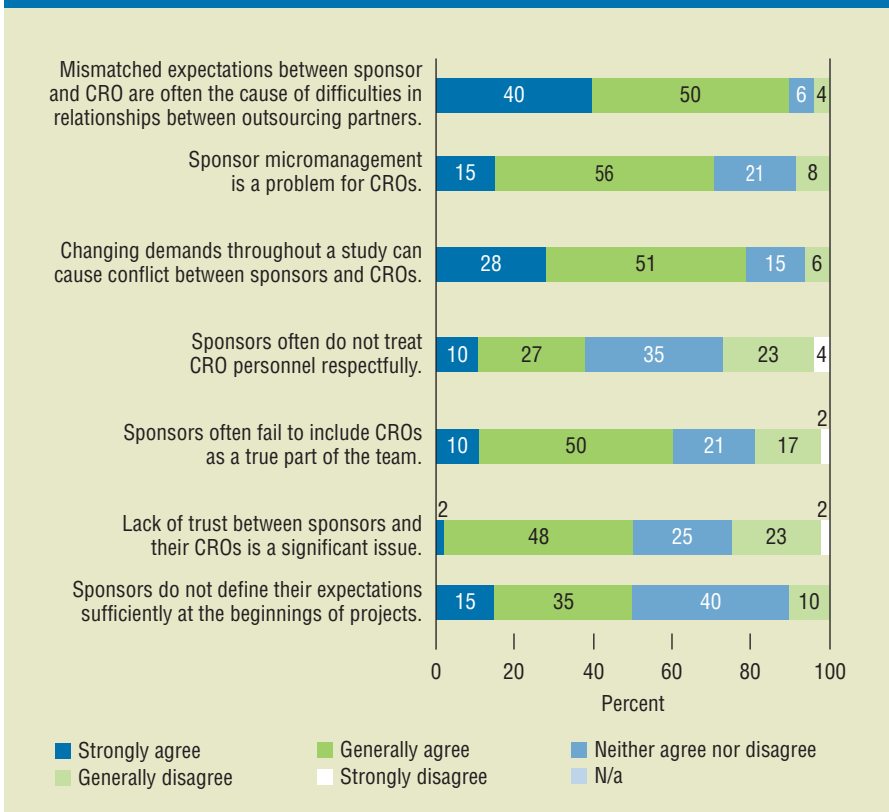
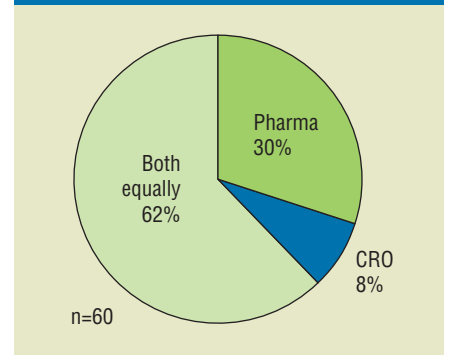


Figure 7 Sponsor Responses to Question: "In the past few projects on which you have worked, do you believe that change orders most often resulted from actions by your company or the CRO company?"



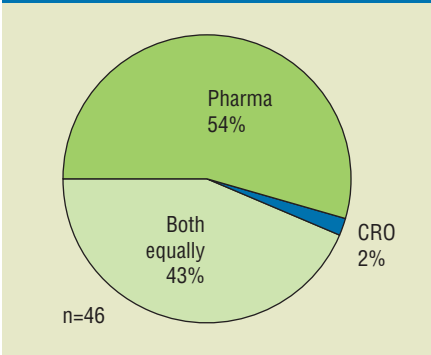
plete a project when preparing their bids, and almost a quarter felt that CROs do this intentionally in order to secure business (Figure 9). CRO respondents, in contrast, reported feeling that sponsor respondents required more from their providers than was anticipated or communicated during the contract negotiation phase (Figure 10).

The vast majority of respondents felt that more could be done by their partners to systematically reduce the occurrence of change orders. Although sponsor respondents largely held themselves at least partially accountable for the occurrence of change orders, 95% nevertheless felt that clinical service providers could do more, particularly during the bidding and contract negotiation phases, to minimize the occurrence of change orders (Figure 11).

Among the 78% of clinical service provider company respondents who felt that sponsors could do something more to reduce the incidence of change orders, specific suggestions included "openly communicate both before and during the project" (28 respondents), "be realistic about costs" (20 respondents), and "provide complete information at the beginning of the contract process" (16 respondents).

Despite the widespread recognition that things could be done to reduce the

Figure 8 CRO Responses to Question: “In the past few projects on which you’ve worked, do you believe that change orders most often resulted from actions by the sponsor company or your company?”



incidence of change orders, surprisingly few respondents reported the use of formal change order processes toward this end. Among sponsors, only 57% of respondents (54% of companies) stated that their own companies had taken the measure of instituting a formal process for the handling of change orders; among clinical service providers, only 60% of respondents indicated that their sponsor companies had shared formal change order processes with them. There was a trend whereby those who employed formal change order processes reported a negative impact of change orders less often than those who had no formal process (56% versus 65%).

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Figure 9 Sponsor Responses to Question: “In your experience, what are the top three reasons that you experience change orders?”

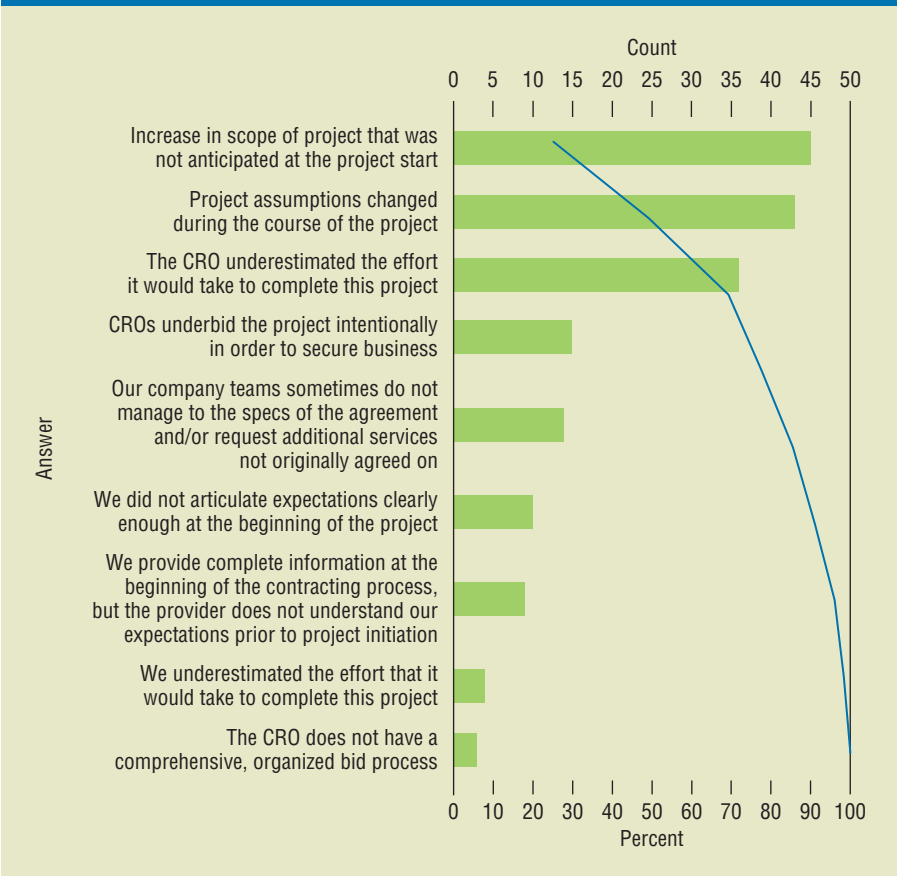


Figure 10 CRO Responses to Question: “In your experience, what are the top three reasons change orders are needed?”

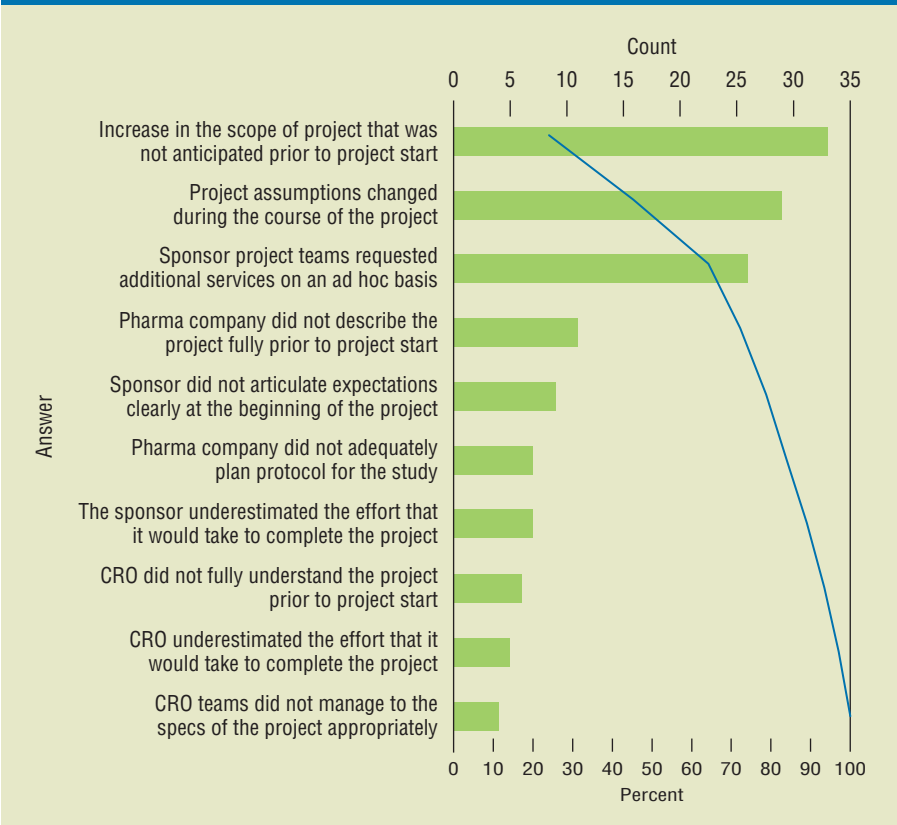
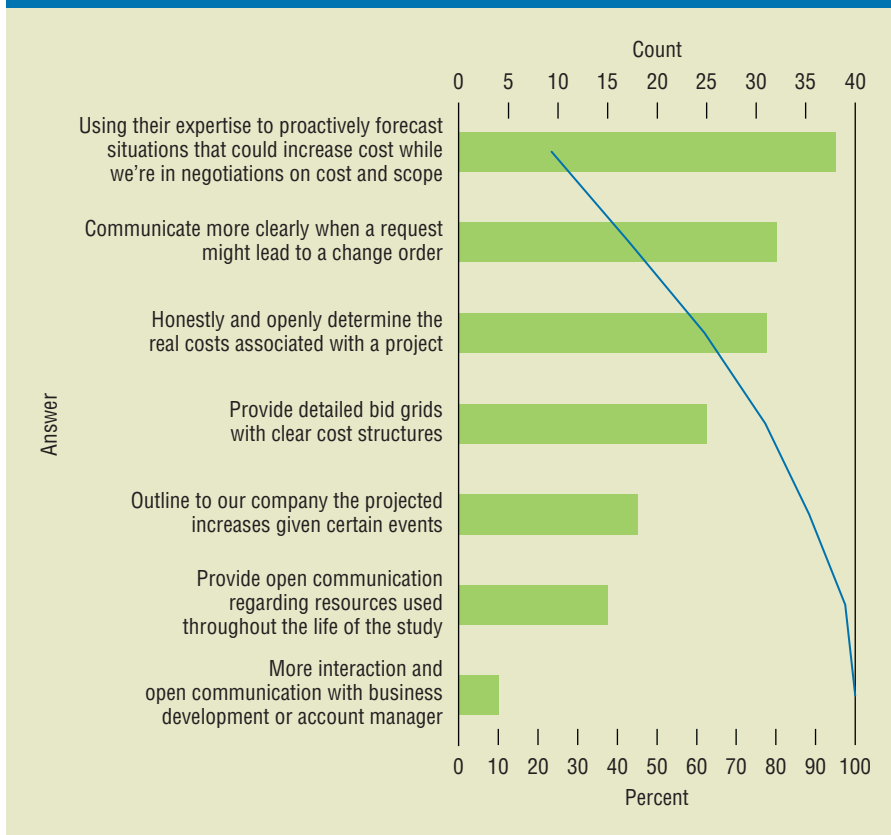


Figure 11 Sponsor Responses to Question: “How can CROs minimize the occurrence of change orders?”



Client Feedback Programs

Some of the most interesting results of the survey related to the collection of and response to client feedback. Interestingly, 90% of clinical service provider respondents reported that their companies consistently sought feedback from their clients, but only 49% of sponsor respondents reported that their service providers did this. The latter figure was somewhat higher among respondents from “top 10” sponsor companies (60%) than among those from smaller companies (46%), but both cases fell far short of the numbers reported by the service providers.

Part of the discrepancy might rest in the definition of “consistently seeking feedback.” Both sponsors and clinical service providers most often reported the use of relatively informal methods of feedback collection, including inter-company meetings and inquiries by business development representatives (Table 1); the use of more

formal, systematic collection methods such as surveys was reported relatively infrequently, particularly by sponsors. In fact, 90% of service provider respondents reported systematically collecting

feedback, but only 53% of service provider companies stated that their companies had formal client feedback programs. More informal feedback collection methods may not be perceived by some sponsors as genuine attempts to solicit customer feedback.

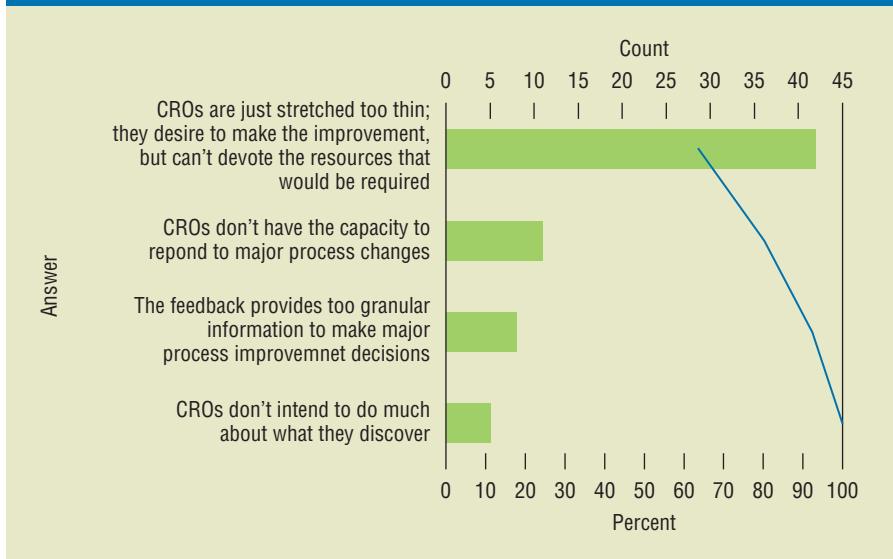
The perception by sponsors that CROs fail to adequately manage customer feedback is also reflected in the fact that only 54% of sponsor company respondents reported feeling that their CROs take appropriate action in response to feedback. The vast majority of respondents felt that CROs simply lack the resources to respond to feedback with improvements; others felt that feedback was collected in too general of a manner to provide useful information, and a small number felt that CROs solicit feedback without any sincere intention to use it (Figure 12).

The sentiment that CROs could do more to effectively collect and respond to client feedback was also reflected in the fact that the great majority of sponsor respondents did not feel that CROs were among the leading industries with respect to their relationship management and customer feedback programs (Figure 13). Despite this perceived weakness, or perhaps because of it, sponsors had very positive opinions about the idea of formal CRO client feedback programs: 52% strongly

Table 1 Methods Used by Clinical Service Providers to Solicit Customer Feedback (among respondents reporting systematic feedback collection only)

Response	Percentage of sponsors reporting (n)	Percentage of service providers reporting (n)
Discussions at lessons-learned meetings	58% (18)	57% (25)
Business development/account executive person checks on progress	55% (17)	68% (30)
Senior management meetings	42% (13)	61% (27)
CRO-conducted web-based surveys	32% (10)	25% (11)
Third-party conducted telephone-based surveys	29% (9)	41% (18)
CRO-conducted paper-based surveys	19% (6)	20% (9)
CRO-conducted telephone interviews	13% (4)	14% (6)
Third-party conducted web-based surveys	10% (3)	23% (10)
Third-party conducted paper-based surveys	0% (0)	5% (2)
Number of respondents	31	44

Figure 12 Sponsor Responses to Question: "If you believe there are gaps between sponsors providing feedback and CROs responding by taking action, why do you think this is so?"



- A failure to adequately solicit and deal with customer feedback.

These gaps hinder the ability of the CRO-sponsor team to optimize collaboration and develop a shared vision. Beginning the project with defined expectations that are clearly articulated and measuring how the expectations are being met during the study are paramount to project success.

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agreed, and an additional 36% somewhat agreed, that all CROs should possess formal client feedback programs, and 93% felt positively about participating in feedback collection surveys.

- A failure to handle change orders (or the activities that lead to change orders, including the definition of expectations) in a manner that promotes the relationship and preserves trust; and

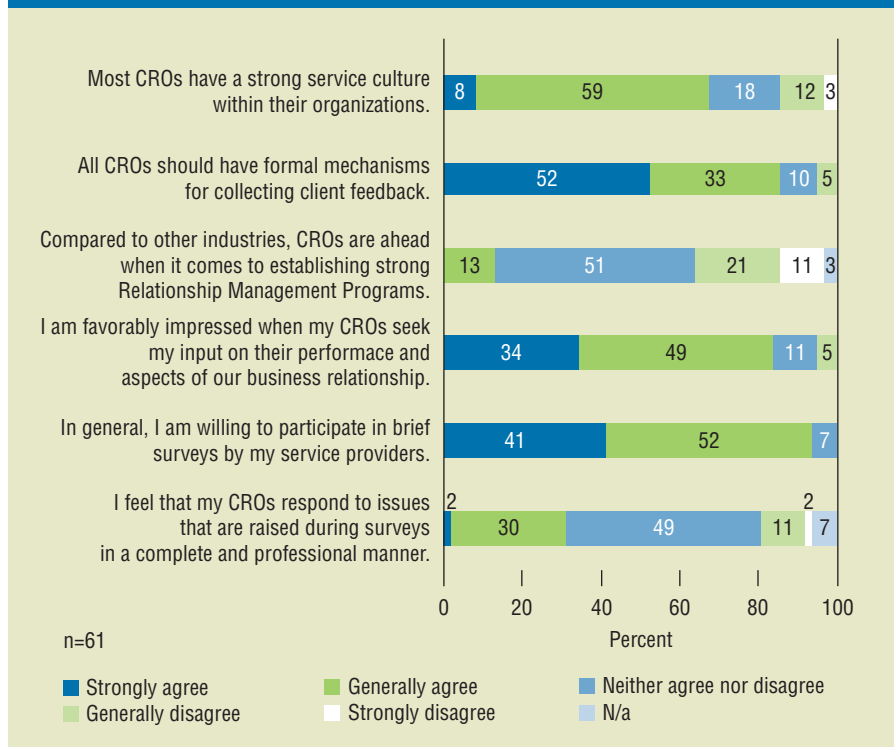
Discussion

In the years ahead, pharmaceutical and biotech companies will likely continue to rely heavily on service providers to ensure the success of their research projects. Over the last decade, tremendous improvements have been made in processes surrounding pre-contract activities, including the development and implementation of structured approaches to identifying and contracting with service providers.

In addition, the outsourcing of clinical research activities has become sufficiently routine that, for the most part, post-contract relationships are managed in a manner that leads to satisfaction by the majority of participants. The data from Avoca's industry survey does, however, point to significant gaps in post-contract relationship management, such as:

- A failure to fully develop shared sets of expectations sufficiently at the beginnings of projects;

Figure 13 Distribution of Ratings for Sponsor Statements Regarding CRO's Relationship Management and Client Feedback Programs



Sponsor teams have shared case studies with Avoca that clearly illustrate a breakdown in the relationship that is directly the result of mismatched expectations. The strain this can have on both project teams is critical, since it can impact project success with missed timelines and deliverables.

One example of this was shared during a recent meeting with a sponsor organization's clinical teams. For a large study, there was no in-depth discussion around what the exact expectations were for interim monitoring visits, what trip report forms to use, the time the sponsor anticipated would be necessary for visits, and other details. This resulted in the sponsor not trusting that the CRO monitors were performing as expected, or as their internal monitors would. Once they addressed this at a meeting where both teams discussed all details surrounding the visit, the sponsor admitted that they assumed things without clearly articulating them. They agreed that these aspects of monitoring should have been considered before the study

launched, explained in detail with the CRO as the study began, and reiterated during the study as visits were occurring on a routine basis to determine whether expectations were being met or needed refinement. Even the most experienced clinical research professionals may lack the leadership and communication skills required to manage these challenging and often uncomfortable aspects of sponsor-service provider relationships, and many companies do not provide procedures for, or training in, their handling.

The data suggest the existence of a significant opportunity. Respondents reported that when companies invested in more formal systems for handling change orders and customer feedback, there was potential for improved relationships. Over the years, the most consistent trend from Avoca's research is that the way that relationships are managed has a direct effect on the success, efficiency, and cost of the clinical trial outsourcing experience. The importance of fostering

functional relationships cannot be ignored. Such relationships require a focus on, and structured process for, establishing shared operating models when launching clinical trials and establishing frameworks and skills for managing their many challenging aspects. **ACRP**

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