

Mismatched Expectations Between Sponsors and Service Providers

This article describes a survey that focused on the causes and consequences of mismatched expectations between sponsors and clinical service providers.

In an era when outsourcing is a routine and essential business practice for many pharmaceutical companies, it is of paramount importance that we understand the factors that contribute most to the efficiency of outsourcing relationships. The vital nature of a shared set of objectives and expectations is discussed frequently by commentators in the pharmaceutical outsourcing arena,¹⁻⁵ and surveys designed to look broadly at challenges within the industry have identified mismatched expectations between sponsors and providers as a primary source of dissatisfaction with outsourcing experiences.^{6,7}

Mismatched expectations can result from lack of common understanding about the tasks to be performed, the roles of both contract research organizations (CROs) and sponsors, the timelines for completion of tasks, and other important aspects of outsourced work. Despite their apparent importance, as mentioned in industry publications,⁸ methods for achieving and maintaining shared sets of expectations appear not to have been studied in detail.

In 2008, the Avoca Group launched a survey focused on the causes and consequences of mismatched expectations between sponsors and clinical service providers, and on methods for arriving at and maintaining shared operating models (i.e., common sets of expectations about the processes, priorities, and responsibility designations according to which a project will operate). The survey was administered to 123 industry executives and managers from 79 sponsor and service provider companies in the clinical research industry. The specific objectives of this study were

- to assess the level of impact of mismatched expectations felt by respondents in their work;
- to gather self-assessments and partner assessments on the topic of defining expectations; and
- to explore the methods used, successfully and unsuccessfully, in attempts to define and adhere to shared operating models.

This article provides a summary of the key findings from this survey.

Methodology

The survey took place from February to May of 2008. The study employed two unique web-based survey instruments: the first for pharmaceutical

companies and other clinical research sponsors, and the second for CROs and other providers of clinical research services. The surveys included background questions, yes/no questions, multiple-choice questions, agreement-rating statements, and free text response areas. Participants were offered copies of the survey results for their participation in the survey.

Respondents overwhelmingly affirmed the importance of arriving at a shared set of expectations prior to beginning a project and of maintaining shared expectations throughout a project's duration.

Key Findings

Sponsor Companies

Fifty-one respondents from 40 sponsor companies participated in the survey. Seventy percent of respondents were employed by pharmaceutical companies, 14% by biotechnology companies, 14% by device companies, and 2% by other sponsor companies. Thirty-seven percent reported that they were employed by “top 10” companies in the industry. Twenty-two percent were executives; 50% were middle management personnel; 24% were project managers; and 4% held other positions.

Respondents overwhelmingly affirmed the importance of arriving at a shared set of expectations prior to beginning a project and of maintaining shared expectations throughout a project's duration. Ninety-six percent of sponsor respondents agreed that mismatched expectations between

sponsors and CROs cause difficulties, both in these relationships and in accomplishing study objectives (Figure 1). Most felt that their own companies were doing their part by establishing expectations, but that CROs were less effective at soliciting information.

Sixty-seven percent of respondents felt that their companies' project teams agreed on study expectations at a sufficient level of detail before introducing the project to a provider, and 67% felt that their companies thoroughly and effectively communicated their expectations at the beginning of each study. In contrast, only 25% agreed that CROs are effective at proactively gathering needed information about sponsor expectations prior to study start; 34% disagreed with this statement.

The majority (68%) of respondents stated that they understood what it meant to launch a project based on a shared operating model. Of these, however, only 37% stated that their companies actually launched each project with a CRO in this manner.

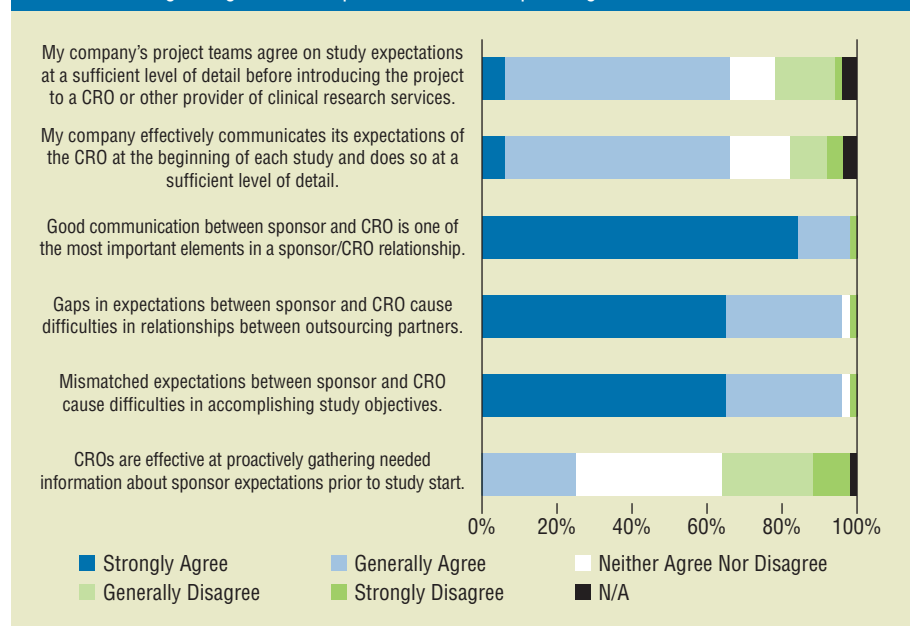
With respect to process, 59% of respondents stated that their compa-

nies had clearly defined processes for developing internal expectations prior to initiating work with clinical service providers, and 76% stated that their companies possessed tools and templates for communicating study expectations with providers at the beginning of a study.

The problem areas most frequently discussed were quality and quantity issues not covered in typical RFP or MSA templates.

When asked to describe the tools used by their companies to share their expectations with service providers, respondents most often mentioned Request for Proposal (RFP) or Master Service Agreement (MSA) templates and associated forms. Less commonly, document templates, standard operating procedures (SOPs), and kickoff meetings were mentioned. Rarely men-

Figure 1 Distribution of Agreement Ratings of Sponsor Respondents (*n* = 51) Regarding the Development of Shared Operating Models



tioned was the use of detailed expectation-setting documents such as CRO Management Manuals, Expectations Guidelines, and Task Guidelines.

Not surprisingly, then, when respondents were asked to describe specifically where challenges with mismatched expectations were most likely to arise, the problem areas most frequently discussed were quality and quantity issues not covered in typical RFP or MSA templates, such as:

- Work effort expected of service provider and sponsor to oversee the project and to complete deliverables.
- Sponsor's expectation that service provider will be proactive with problem and solution identification and contingency planning.
- Sponsor's expectation that service provider will be accountable, particularly for site and patient recruitment.
- Handling of changes in study needs and associated costs.
- Project and performance tracking.
- Data quality (monitoring and query resolution).
- Issue escalation.

When sponsor respondents were asked what they could do to better ensure that clinical service providers understood their expectations, the most common responses involved greater clarity and detail in descriptions and more regular and thorough interpersonal communication. Some mentioned the need for better internal communication within the sponsor, and better sets of internal standards, processes, metrics, and templates. Others felt that listening more carefully to the input of providers and to their understanding of the sponsor's expectations would be useful.

Sponsors also felt that there were specific things that clinical service providers could do to better ensure the sharing of a unified set of expectations. Most commonly, suggestions included more open questioning of

the sponsor, and proactive and honest identification of areas where the meeting of sponsor expectations might be difficult. Proactive confirmation that the provider's assumptions and understandings were correct was also mentioned. Other respondents commented that minimization of staff turnover would help the shared set of expectations to be maintained once achieved. Along these lines, there was a suggestion that CROs would do well to maintain "historical" notes about the expectations of given sponsor teams.

The majority of [provider] respondents felt that most sponsors communicate their expectations at a sufficient level of detail prior to onset of the work.

When asked what mechanisms their companies had in place for articulating and adjusting expectations with providers when expectations were not being met, the most frequently mentioned mechanisms involved scheduled project management meetings and formal governance structures. Formal issue escalation processes were also mentioned. Sixty-three percent of sponsor respondents reported that their companies conducted end-of-study "lessons learned" meetings with CROs to assess the effectiveness with which both parties worked in a shared operating model. However, 45% of these reported that such meetings occurred in half or less of cases.

Forty-nine percent of respondents reported that their companies conducted mid-project lessons learned meetings. Of those reporting this prac-

tice, 51% stated that these meetings occurred only occasionally.

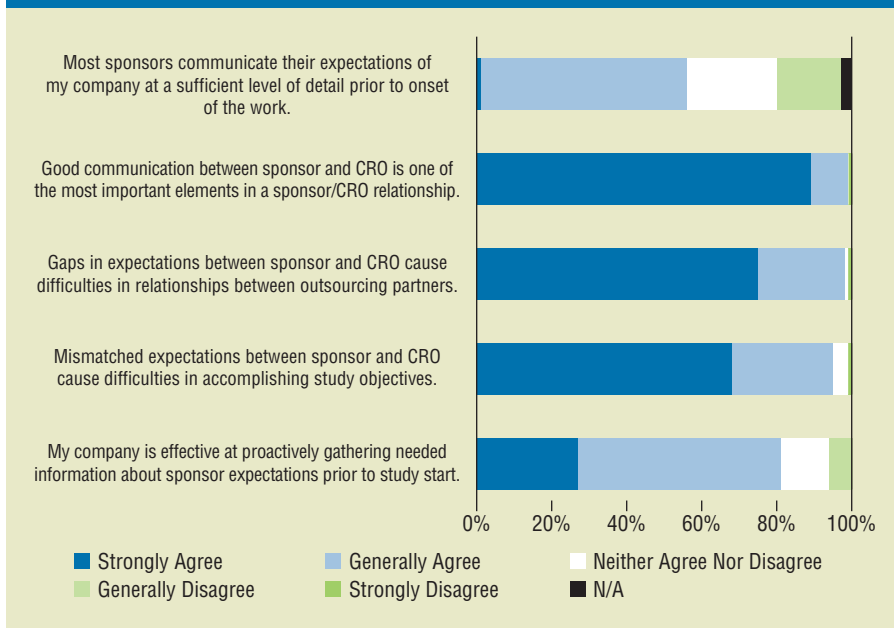
Clinical Service Providers

Seventy-two respondents from 39 clinical service provider companies participated in the survey. Of these, 75% were employed by CROs, 3% by imaging companies, 3% by central laboratories, 4% by consulting companies, 11% by other niche service providers, and 4% by others. Fifty-one percent reported that their companies were in the "top 10" in their industry. Clinical service provider respondents were largely company executives, with 69% in executive management roles and 28% in middle management roles. Numerous functional areas were represented.

The great majority of service provider respondents agreed that mismatched expectations between sponsors and CROs cause difficulties in accomplishing study objectives, with most expressing strong agreement with this statement (Figure 2). Similarly, nearly all respondents agreed that gaps in expectations between sponsors and CROs cause difficulties in relationships between outsourcing partners. However, agreement was lacking on what was felt to be the principal cause of discrepant expectations. The majority of respondents felt that most sponsors communicate their expectations at a sufficient level of detail prior to onset of the work, and only 17% disagreed with this statement. The majority also felt that their companies were effective at proactively gathering needed information about sponsor expectations prior to study start; only 6% disagreed.

Seventy-eight percent of respondents stated that their companies had clearly defined processes for coming to a strong understanding of a sponsor's expectations prior to initiating work. In addition, 80% stated that their companies had tools and templates for understanding and communicating with sponsors about study expectations.

Figure 2 Distribution of Agreement Ratings Among Clinical Service Provider Respondents ($n = 71$) Regarding the Development of Shared Operating Models



When asked to describe the tools they employed to ensure the existence of a shared set of expectations, service providers commonly mentioned written tools such as standard document templates, assumption tables, project plans, communication plans, task-ownership matrices, worksheets, and checklists. Reportedly, however, such tools were often not consistently employed and/or had insufficient depth and detail. Kickoff meetings and other communications facilitated by account representatives and/or senior management were also mentioned.

The theme of insufficient depth of tools and templates was also mentioned when respondents were asked to describe specifically how problems with mismatched expectations arose. Many felt that written RFPs and Scopes of Work tended to lack clarity, to lack sufficient detail (e.g., work effort expected for communications and follow-up, need for use of specific tools that are not standard for the CRO, etc.), and to fail to discuss contingencies (such as expectations of providers when sponsors or third-party providers fail to meet their own timeline or other commitments).

Some also felt that even when expectations had been effectively set at the beginning of a study, clarity often ceased as assumptions changed and shifting expectations and work priorities were not discussed. Issues of cultural (both geographic and corporate) differences in expectations were also raised.

Only 53% of those respondents [who stated that they understood what was meant by a shared operating model] stated that they launched each project with a sponsor based on one.

Sixty-four percent of service provider respondents stated that they had an understanding of what it meant to launch a project for a sponsor based on a shared operating model. However, only 53% of those

respondents stated that they launched each project with a sponsor based on one.

Seventy-nine percent of respondents reported that their companies used end-of-study lessons learned meetings with sponsors to assess the effectiveness with which the parties worked in a shared operating model. Of these, 52% did this in half or less of cases.

A smaller percentage of respondents (69%) stated that their companies utilized mid-study lessons learned meetings. Fifty-six percent of these respondents stated that such meetings were used in half or less of cases.

Conclusions

The responses to this survey demonstrate widespread recognition of both the importance of working under a shared operating model and the failure of many sponsor-provider teams to achieve harmony in this regard. Although the majority of both sponsors (67%) and providers (56%) felt that most sponsors articulate their expectations of providers at a sufficient level of detail at the beginning of each study, significant percentages (14% and 17%, respectively) felt that this was generally not the case. Moreover, although most service provider respondents (82%) felt that their companies were effective at proactively gathering information about sponsors' expectations prior to engaging in a project, most sponsors (73%) did not agree.

The majority of both sponsors (76%) and providers (80%) reported that their companies had invested in tools and templates in order to ensure arrival at a shared set of expectations. However, many also reported that these tools lacked the depth and detail required for the establishment of a thorough shared set of expectations, and that they did not adequately address the need to maintain a shared operating model over the dynamic course of a clinical trial.

Continuous feedback is essential to the maintenance of a shared operating model.

Continuous feedback is essential to the maintenance of a shared operating model. “Lessons learned” meetings are used by the majority of sponsor respondents as one source of feedback, but they are infrequently used during the middle of studies, when adjustments in expectations might be expected to positively impact the projects. Instead, such meetings are reportedly used primarily at the end of studies, presumably to inform future endeavors.

The results of the survey suggest that pharmaceutical companies and their service providers have significant room for improvement when it comes to the development and maintenance

of a detailed, shared set of expectations. Further, they suggest that improvements in this area could have a significant impact on the efficiency with which clinical projects are conducted. Enhancement of the tools and templates currently used for this purpose, and extension of the use of these tools and other tools (including “lessons learned” meetings) through the course of projects, are some suggestions for how such improvement might be achieved.

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Denise Calaprice-Whitty, PhD, is senior director of relationship management programs for the Avoca Group, Inc., a Princeton, N.J.-based consulting firm for the pharmaceutical industry. With a bachelor's degree in biology from Harvard University plus master's and doctoral degrees from Princeton, she has been a National Institutes of Health postdoctoral fellow at Columbia University's College of Physicians and Surgeons, a clinical research project and program director at Quintiles, senior director of clinical research at Altana Pharma, and director of clinical sciences at Regeneron Pharmaceuticals. She can be reached at denise.calaprice-whitty@theavocagroup.com.