



Outsourcing is increasingly the strategy of choice for most industry players, according to a recent survey of more than 100 sponsors and CROs. **Harold E Glass** analyses the study's findings and outlines those areas that respondents wanted more information or training in

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Pharmaceutical industry leaders consider continued R&D productivity to be one of the industry's foremost challenges. The rising costs and increasing complexity of developing drugs demand that pharma companies find more effective ways to streamline clinical research, the single longest and most expensive part of the R&D process. To further explore this problem, the University of the Sciences in Philadelphia and drug development data company, TTC, with support from Informa Healthcare, embarked on a multi-year research programme to explore ways to improve the speed and cost-effectiveness of clinical studies. Since pharma companies outsource many aspects of clinical development to CROs, these organisations play a vital role in the overall drug development landscape.

The survey

Both pharmaceutical sponsor companies and CROs were invited to participate in a web-survey,¹ with the primary aim being to better understand the following aspects:

- The current and anticipated future use of outsourcing

- The training needs for industry professionals to improve CRO selection and CRO project oversight
- Specific outsourcing processes and techniques such as project budgeting, CRO selection, managing studies, bid grids and managing cost overruns
- Perceptions of how CROs and sponsor companies interact in the areas of business development, CRO selection and project management.

When constructing the data collection questionnaire used in this survey, the project team conducted a series of interviews with drug development professionals and the questionnaire was pre-tested with several individuals experienced in selecting and managing CROs. All suggestions were considered when designing the final version of the survey.

The questionnaire was sent to 2,502 individuals. Of these, responses were received from 419 individuals representing 116 companies.² Pharmaceutical sponsor companies comprised 70% of the respondents and CROs the remaining 30%. More than half (53%) of the respondents representing

	Preferred provider (%)	Functional provider (%)	Single-area provider (%)	In-sourcing* (%)	Full-service provider (%)
Company size					
One of 20 largest	48	28	23	26*	26
Smaller company	39	29	27	17	32
Total	44	28	25	23	29
* p=.05					
Type of organisation					
Sponsor	50**	30	25	28*	38
CRO	41	29	25	22	40
* p=.05					
**p=.01					

Figure 1: Expected scope of outsourcing providers in five years time according to pharmaceutical sponsor companies and CROs who took part in the USP/TTC survey.¹

sponsor companies were employed by the 20 largest sponsor companies, while a third (29%) of CRO respondents were employed by the 20 largest CROs. Of those surveyed, 45% were based in Europe and 40% in the US, with an average of 13 years' industry experience.

Present and future of CROs

The survey confirmed the widespread use of outsourcing in clinical trials.² Respondents from pharma companies reported that only a third (36%) of all post-Phase I studies were conducted entirely in-house, and even in the very largest companies a significant proportion of post-Phase I clinical research involved outsourced activity.

The degree to which aspects of trials were outsourced largely depended on the size of a sponsor company. Almost half (48%) of large sponsors' Phase I studies were conducted entirely in-house, and CROs were employed to handle overload requirements and provide specific expertise. Within small companies, only 12% of post-Phase I studies took place in-house. Outsourcing was usually sought because these companies lacked permanent in-house staff to conduct all aspects of clinical trials, especially those studies involving multiple sites across several countries.

While outsourcing to CROs is common today, it is likely to grow even more over the next five years. Most survey participants (77%), regardless of whether they represented a sponsor or CRO, large or small company, expected increased outsourcing over the next five years. Very few (4%) expected CRO employment to decrease, but those that did tended to have limited industry experience – and possibly had less knowledge of current practices and were unaware of expected long-term trends.

CRO exclusivity and scope

While almost everyone involved in outsourcing expects the employment of CROs to increase, most see the basic pattern of use remaining more or less consistent with current practices. CROs have many different relationships with sponsor companies, but their patterns of use can basically be broken down into two-dimensions: the 'degree of exclusivity' and the 'scope of work'.

Looking at the first dimension, exclusivity, a sponsor company uses a CRO as a sole provider, a preferred provider, or simply as one of many competitive providers. Sponsor companies can decide on a particular degree of exclusivity – they can contract work to one company, or to a small set of preferred providers, or to any qualified CRO for competitive bidding.

Some sponsor companies, such as Solvay, work at one end of the continuum, using one major CRO to conduct a very large portion of their clinical studies. In the 1990s, in a substantial though less comprehensive agreement, Aventis sold part of its US-based clinical development facilities to a large CRO. As part of the agreement, Aventis promised the CRO a sustained level of work over a five-year period, with the CRO committing to provide its services at progressively decreasing rates. Other companies provide large amounts of work exclusively to specific companies to perform in a designated functional area. Pfizer outsources much of its field monitoring and Wyeth R&D has used a major information technology and consulting firm to handle its information processing and data management.

Preferred providers constitute a less exclusive, but more widely used, practice in clinical development. With preferred providers, sponsor companies limit the potential CRO pool to between three and

five providers, usually agreeing on a rate card with each provider. In the least exclusive arrangements, a sponsor company will open the competition for every project to any qualified CRO, making the selection based on the perceived capabilities of the bidding CROs. A CRO's successful track record with a sponsor company may appreciably improve that CRO's selection chances, but, in principle, the competition is open to all bidders.

In the second dimension, scope of work, a company uses a CRO for a range of activities, from covering whole development programmes, to entire functional areas and designated parts of individual studies. The four main areas of provider scope are:

- **Full-service providers:** In this instance a CRO assumes responsibility for all outsourced aspects of an individual clinical trial
- **Functional providers:** A CRO takes responsibility for a functional area such as data management across most or all clinical trials
- **Single-area outsourcing:** A provider takes responsibility for a particular aspect, for example, biostatistics, of an individual clinical trial
- **In-sourcing:** A sponsor company contracts individuals to perform certain activities, such as monitoring.

While the two dimensions of exclusivity and scope of work are related, a CRO's relationship with the sponsor company can be viewed as a function of both dimensions.

The scope of CRO outsourcing used by large and small sponsor companies surveyed was relatively evenly spread. Most used preferred providers, and only in-sourcing was found to be significantly different as a result of company size, but there were some major differences between how companies currently use CROs and how they anticipate using them in five years time (see Figure 1).

Representatives of sponsor companies expect the use of preferred providers to increase slightly, but the greatest predicted shift in use is for full-service providers – from 29% of all outsourced work today to 38% in five years time. Whether or not these expected changes are accurately reflected in future outsourcing practices, it appears that few pharma company professionals plan to make any radical changes in their use of CROs over the next five years.

CRO and sponsor company respondents have a fairly similar outlook on how CROs will be employed five years from now. But two differences do exist: sponsors expect that half of their outsourcing will involve the use of preferred providers, compared with 41% of the CRO respondents, and sponsors anticipate a greater use of in-sourcing than CROs presume will be the case. However, from the larger, longer-term perspective, sponsor companies and CROs generally agree on the outsourcing topography in five years.

Training and information

Although the employment of CROs may remain clearly defined and stable, their expanded role in outsourced clinical trials will increase the need for training across the board. So, do industry professionals feel equipped to handle the increased outsourcing?

Many respondents said they would value more training in several areas. Foremost was the request for specific communications training, and both CROs and sponsor companies agreed on the need to improve the ability of sponsor company teams to handle communications between sponsors and CROs. More than 60% of all those surveyed thought this type of communications training could improve the management of outsourced projects.

While communications between employees within the same company and same site presents its own set of challenges, even more daunting is ensuring smooth communication between employees working at different companies and at different sites around the world. Involving an additional company in the form of a CRO, for example, can only make the communications challenge more acute. Desired training and information areas for all respondents are outlined in Figure 2.

While the idea of developing effective partnerships between CROs and sponsor companies is a recurring theme at many industry meetings, half of

Areas of interest	%
Training of sponsor company personnel on how to improve communications between sponsor company and CRO team members	62
Measuring the true cost of outsourcing	59
Training of sponsor company personnel on how to develop effective sponsor/CRO partnerships	58
Best practices information on managing CRO outsourcing	52
Improved transparency with CROs in terms of their resource allocation and management	52
Best practices from other industries about project management and outsourcing	45
Understanding a CRO's cost structure	41
Best practices on contracts which reward superior performance	35
Case studies on sponsor oversight of CROs	34
Information on how to structure contracts with CRO penalties for poor performance	30
Case studies on successful negotiations	30
Case studies where CROs have some ownership of the compound	16
Improved information on intellectual property protection in outsourced clinical trials	10

Figure 2: Areas in which survey respondents wanted more information and/or specific training.



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respondents thought there was little formal training available on how to achieve this. The same number also felt they lacked the necessary knowledge to determine the internal and external costs of outsourcing and wanted better information on how CROs allocate and manage resources, as well as best practices in CRO outsourcing.

A third or more of respondents cited other training needs, including learning about how other industries approach project management and outsourcing. Respondents from both sponsor companies and CROs wanted to know more about the CRO cost structure and many saw a need for case studies on successful sponsor selection and CRO oversight, as well as learning how to structure contracts that reward superior performance and penalise CROs for poor performance. A smaller group of respondents wanted case studies presented on how CROs had taken some level of compound ownership and intellectual property protection in outsourced clinical trials.

Key groups

Key differences were seen between CRO and sponsor company respondents in certain areas of the survey. Understandably, respondents from sponsor companies expressed significantly more interest in understanding the true cost of outsourcing and receiving best practice information on outsourcing. Nearly two-thirds (64%) of respondents from sponsor companies, compared with 48% of respondents from CROs, wanted training on how to measure the true cost of outsourcing. Sponsor company staff were also more interested in case studies on CRO oversight and performance-based contracting. However, sponsor companies and CROs differed most in their quest for information about contracts with penalties for poor CRO performance – 40% of sponsor company respondents versus 9% of CRO respondents.

Survey respondents' requirements also dif-

fered in some cases by geographical location. For example, respondents from both sponsor companies and CROs in the US were considerably more likely to want training on performance-related contracts. Around 45% of US respondents were interested in learning how to create contracts with CROs that reward superior performance (compared with 23% of European respondents), while 40% of US respondents wanted to know how to penalise poor performance (compared with 23% of European respondents).

Conclusion

Outsourcing to CROs is now a major part of clinical research – and both sponsor companies and CRO respondents participating in the UPS/TTC survey generally agreed that this is not likely to change radically over the coming five years.

Clearly, the operational challenges for those working in clinical outsourcing will not diminish with time. More studies, more complex designs, more countries and more patients will all contribute to intensifying the operational challenges of conducting clinical trials. Personnel from both sponsor companies and CROs identified a number of training needs that, if addressed, will help them meet these challenges. The need for formal training in inter-company communication, improving inter-company partnerships and managing the outsourcing process were all commonly cited. Industry professionals, particularly those working for pharma companies, wanted help to understand the comparative costs of outsourcing, the cost structure of CROs, and training on how to structure performance-based contracts.

As companies expand their use of outsourced providers in the future, buyers and providers alike will need increased training on how to select, work with and manage this complex activity. **GCPJ**

• *Harold Glass will be presenting his findings at this month's 6th Annual Partnerships in Clinical Trials meeting in Amsterdam, the Netherlands.*

References

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