

# Investigator insights; CRO or sponsor preference?

As CRO-run studies grow in prominence, do the physicians that conduct clinical studies at the site worry about trial management? **Professor Harold Glass** investigates if clinical investigators respond better to sponsor-run or CRO-run clinical trials.

**T**he use of CROs is a widely accepted practice in the clinical development of new and marketed drugs. For example a survey conducted by University of the Sciences in Philadelphia (USciences) and TTC confirms that only 36% of all post Phase I studies are managed entirely in-house.

CROs are used in a wide variety of settings to perform a range of activities for pharmaceutical companies conducting clinical research. These activities range from handling a single element in one clinical trial, for example, field monitoring, to managing all the elements of a clinical development programme. Throughout the industry, both pharmaceutical sponsors and CROs expect the use of outsourcing to remain, and probably grow.

However, concerns may occasionally continue to exist in sponsor companies about the use of CROs. Traditionally, sponsor company clinical research personnel have been

sensitive to CRO staff turnover levels, along with the possible lack of knowledge the changing CRO staff may have of the study compound. Some sponsor companies may express concern that this lack of study compound knowledge may limit the CRO project team's ability to answer compound specific questions in-depth, or with the timeliness, that sites expect. For many sites then, working with a CRO might be a distinct second choice.

CRO-managed studies constitute a significant portion of all clinical research activities, yet there has been only limited analysis of investigator preferences about whether a CRO or sponsor company directly manages that investigator's clinical trial. Drawing upon a global sample of current investigators, our data indicate that about a quarter of investigators prefer working directly with sponsor companies, while the remaining investigators either do not care, or actually prefer a CRO.

**Table 1: Who Do You Prefer to Run Your Clinical Trial by Major Geography (in %)**

	Total	US	Europe	Latin America	Asia
CRO	29	22	31	35	39
Pharma/biotech sponsor company	23	29	11	26	10
No preference	48	49	58	39	51

Source: TTC & University of Sciences, Philadelphia

Table 2: Who Do You Prefer to Run Your Clinical Trial by Type of Site (in%)

	Private Practice	Hospital	Academic Medical Center	Teaching Hospital
CRO	23	33	31	35
Pharma/biotech sponsor company	26	23	14	22
No preference	51	44	55	43

Source: TTC & University of Sciences, Philadelphia

### The study

TTC and USciences have been conducting a multi-year global analysis of why some clinical trials finish faster than others. Included, among the specific research topics is an understanding of clinical investigators' preferences about who they would like to have managing their study.

As part of this larger TTC and USciences project, researchers conducted a 4,000-site survey of clinical investigators around the world. The basic questionnaire was initially used in a survey of US sites, following a pretest of the instrument for other countries. The study sample consisted of all the valid names and addresses available in the ClinicalTrials.gov and the Bioresearch Monitoring Information System maintained by the FDA. This database contains information submitted to the FDA identifying clinical investigators, CROs, and institutional review boards involved in the conduct of Investigational New Drug studies with human investigational drugs.

Each site in the study was sent a mail questionnaire. Two mailings were conducted. A web-based survey was sent to the remaining non-responsive sites, for an overall response rate of 21.4% through regular mail, and 9.1% through e-mail. Data collection ended in the winter of 2010.

As with any voluntary mail and web-based questionnaire, there is always the potential for an appreciable skew in the responses. Those responding may be appreciably different in important respects from those not responding. However, comparing the data from the survey respondents by country and therapeutic area to the site activity reported in ClinicalTrials.gov, there does not appear to be substantial biases in the responses by either country or therapeutic area.

### Results by geography and type of site

Whatever the remaining concern within pharmaceutical companies about possible negative site reactions to CRO study management, clinical investigators generally appear to accept the role of CROs in running clinical trials. Nearly half of all active investigators have no preference whether a CRO or sponsor company runs the study. The remaining investigators are roughly evenly divided between a preference for a CRO running the trial and the sponsor company. This general pattern holds for every major geographic location in which clinical trials are conducted.

Preference for sponsor company trial management is highest among US investigators. Latin American investigators demonstrate the next highest desire for sponsor company study management. Support for sponsor company trial management drops precipitously though in the other geographies, constituting a distinct minority of investigators. The percent of sites who either prefer a CRO, or are indifferent to the organisation managing the study, ranges from about two thirds to 90%.

Among the major types of sites, preference for sponsor company clinical trial management is especially limited in academic medical centres and teaching hospitals. This is more the case outside the US. Similar to the overall responses within each of the major geographies, the percent of sites who either prefer a CRO, or are indifferent, ranges from about two thirds to 90% within each major type of site.

### Motivation to participate in clinical research

Investigators, as part of the study, indicated the importance of a number of possible reasons for their participation in clinical research. Several broad reasons explain why individual investigators take part in clinical research. Through the use of factor analyses the researchers determined that there two most important reasons, the desire to participate in medical innovation and financial reward.

Research shows that an innovative compound reduces the cost per patient that a site is generally willing to accept to participate in a clinical trial. In addition, site recruitment often goes more quickly with an innovative compound. However, investigators who prefer that a sponsor company manage their study are no more likely to stress the importance of medical innovation than are the investigators who do not prefer sponsor company trial management. This is probably unsurprising as a CRO does not generally have much control over the innovativeness of the compound or drug involved in a clinical trial run by that CRO.

When it comes to money though, there were clear differences by trial management preference. Investigators who want a CRO to direct their study are more financially motivated than are the other investigators. Those who have a sponsor company preference are the least motivated by financial considerations.

Our global site survey data results demonstrate that most sites do not have strong preferences about whether a sponsor company runs their study. There may very well have been a time when most investigators clearly wanted to work directly with sponsor companies. That time seems to have passed. Investigators have become accustomed to CRO management of clinical trials. ■

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