

# The CenterWatch Monthly

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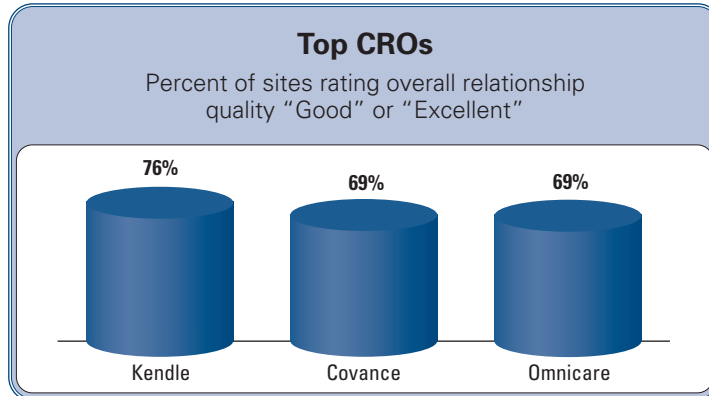
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## U.S. Sites Rate Kendle, Covance, Omnicare as Top CROs in 2007

► The Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. finds that sites have rated Kendle as the top CRO to work with. It is the first time that Kendle has been rated number one.

► Being organized and prepared for a study was the attribute rated most important for CRO performance with more than 86% of sites listing it as of the highest importance. Three other attributes had more than four out of five sites giving them highest ratings for importance: responsiveness to inquiries, CRAs/managers being knowledgeable and maintaining open communications.

**C**ontract research organizations (CROs) serve two main customer bases—sponsors responsible for the overall progress of a development program and sites charged with the responsibility for conducting clinical trials. CROs are frequently blamed for



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).

problems during the drug development process but are rarely credited with solutions by sites. Traditionally, this has been reflected by the fact that sponsors typically receive higher ratings for satisfaction by sites than CROs do in CenterWatch site surveys.

While that remains the case, the satisfaction gap between sponsors and CROs is narrower this year, with 72% of sites rating sponsors "Good" or "Excellent." For CROs the average rating was 65%, largely unchanged from 2005's score of 66%. The results indicate that individual companies have made strides in some

areas but do not suggest a general change.

Kendle took the top spot in the Thomson CenterWatch 2007 Survey of Investigative Sites in the United States, with 76% of sites rating the company's performance "Good" or "Excellent" across the 29 attributes CROs were rated on in 2007. This result represents a 28% improvement over ratings received just two years ago, a truly impressive performance.

"We are pleased to receive this level of recognition from our investigators who play such an important role in study delivery. We commend CenterWatch for its role in consistently meas-

uring investigator site feedback. Over the last few years our staff has done a lot to strengthen our relationships with sites, so I'm very, very pleased for the team," said Candace Kendle, PharmD, chairman and chief executive officer of Kendle.

Omnicare joined Kendle as the only other CRO to improve

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# Kendle

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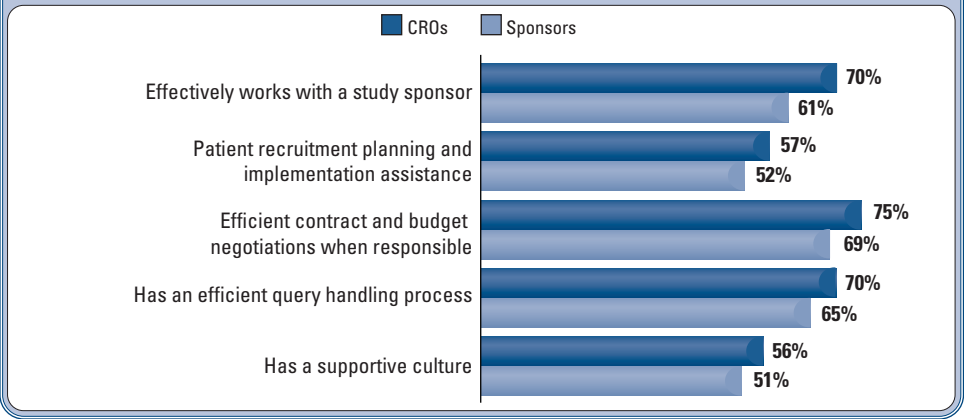
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**Attributes More Important for CROs Than Sponsors**

Percent of sites rating very important



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).

across the board with 69% overall, representing an eight-point improvement compared with its 2005 results.

“We are very pleased that the investigators have ranked us so high, as we strongly believe in a close working relationship with all our customers—and that includes both sponsors and investigators. It’s quite an honor to receive this recognition from investigators,” said Anita Clavier, vice president of Global Clinical Investigator Relations at Omni-care Clinical Research.

Covance maintained its consistent quality with 69% to tie Omnicare for second place. Omnicare and Covance were also in a tie, with 41% rating each company “Excellent” at being organized and prepared—considered by sites to be the most essential attribute to study success.

i3 received the top score in six categories, including the entire category of the grant payment process.

Being organized and prepared for a study was the attribute rated most important for CRO performance with more than 86% of sites listing it as of the highest importance. With only 36% of sites finding CROs “Excellent” in this regard, it remains a critical area in need of improvement by all CROs. Professionalism of monitors/CRAs was of high importance to 85% of sites. Three other attributes had more than four out of five sites giving them highest ratings for importance: responsiveness to inquiries (83%), CRAs/managers being knowledge-

able and maintaining open communications (81% each).

**Survey Methodology**

Thomson CenterWatch conducted the survey of investigative sites in the United States between January and March 2007. An 11-page survey was mailed or emailed to 16,000 sites conducting trials in the United States. Our survey instrument, which has been used since 1997 in both North America and in Europe, and in the last two years globally, was developed with input from clinical research professionals at sponsor companies, CROs and investigative sites. A total of 522 investigative sites completed the survey, representing a 3% response rate.

Approximately 24% of the sample are investigators with the remaining 76% describing themselves as study coordinators or administrators. Investigators had an average of 10 years of experience with clinical research. Eighty percent of researchers conduct clinical research on a full-time basis, while 20% reported part-time involvement in clinical research.

Investigators were asked to rate the CROs that they have worked with during the past two years on a range of attributes and responsibilities. Investigators were also asked to provide ratings for the three companies that they have worked with most frequently and to rate these companies on more than 25 relationship attributes involving project management, personnel, work-style, study initiation and ongoing study support. For this year’s survey, sites were also asked to rate the importance of all the attributes to the success of their clinical studies.

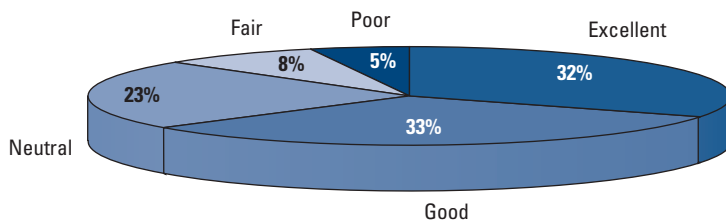
Among the companies assessed in this year’s survey are Covance, i3, ICON, Kendle, MDS Pharma, Medpace, Omnicare, Parexel, PPD, PRA, and Quintiles.

**Detailed Highlights**

Generally, sponsor scores in the CenterWatch investigative site surveys are about 10 percentage points ahead of the ratings given to CROs, but this year the CROs narrowed the gap to just six points, with 65% of sites calling CRO performance “Good” or “Excellent.” Sponsors achieved a score of 71% this year. The average rating for CROs is basically the same (65%) as two years ago.

In addition to assessing companies by 29 different attributes, the survey also asked sites to assess the importance of those attributes in both CROs and sponsors. Some comparisons between the two give a bit more insight on the tasks sites rely on CROs more for than they do sponsors, and vice versa. Almost half of the attributes show lit-

**Average Rating for the Typical CRO**



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).

tle or no difference in importance between CRO and sponsor.

The attributes more important in sponsors tend toward laying the overall framework of the study—the alignment of the protocol to scientific and clinical realities, timeliness of drug availability, realism of enrollment goals, protocol design and informative nature of investigator meetings. These can be described as the base upon which study success rests.

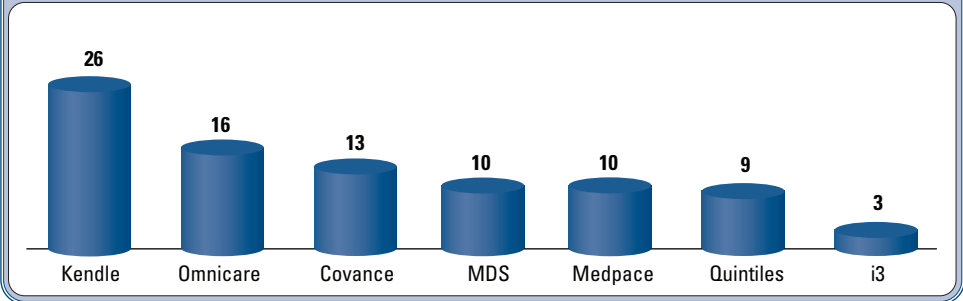
On the other hand, sites rely on CROs for more day-to-day activities. Minimal amendments to protocols, the efficiency of query handling and responsiveness to inquiries, low staff turnover, and patient recruitment planning are more critical tasks for CROs.

Attributes that sites value sponsors and CROs equally for tend toward the financial, professionalism and communication skills. The promptness of grant payments, their fairness and scheduling, as well as funding for recruitment efforts all relate to the financing of trials, and of equal importance in all cases is to keep these activities predictable and sufficient. Professionalism of all staff groups as well as their knowledge levels are important no matter if they work for a sponsor or a CRO. Communications issues also have equal weight. Openness of communications, ongoing help in running the studies, being organized and prepared, flexible and realistic are all important and must be “Excellent” on all sides for studies to succeed.

### General Project Management

The attributes making up this category explore whether sponsors are organized and prepared, how realistic their project timelines are, sponsor responsiveness to inquiries, how realistic patient enrollment goals are, whether sponsors work effectively with

### Highest Frequency as a Top 3 Rated CRO Across 29 Relationship Attributes



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).

CROs and how well open communication is maintained. “Organization and preparation” was rated very important by 86% of sites, the attribute that received the highest rating of importance. Covance and Omnicare were rated “Excellent” by 41% of sites in this critical area. Kendle was rated “Excellent” in maintaining open communications by 50% of sites, and Kendle led or tied in the realism of project timelines, responsiveness to inquiries, and effectiveness of work with sponsors (tie with Omnicare).

“We’re a metrics-driven organization. We use metrics as a way to help us identify and solve problems as well as to celebrate successes. Having a patient feasibility plan and finding out what the patient access and retention issues are in specific environments is key to study success. A good recruiting and retention plan, reasonable metrics—not asking investigators to over-promise, realistic goals and a working knowledge of how

each site develops their patient recruitment capabilities are the keys to identifying capacity for individual investigators. We provide tools that help investigators calculate the number of patients they realistically can recruit and retain. So I think the metrics really, really help us,” said Candace Kendle.

Omnicare’s Clavier said, “We have professionals who specialize in handling certain aspects of the process. For example, in addition to CRAs, we have office-based experts focused specifically on negotiating agreements, managing grant payments and providing study initiation services like site recruitment and regulatory document submission. This strategy enhances our team’s expertise and overall effectiveness in these areas.

“Our organization upholds a commitment to communication and responsiveness. The ability to work collaboratively with both sponsors and sites is an essential component

### Quality of General Project Management

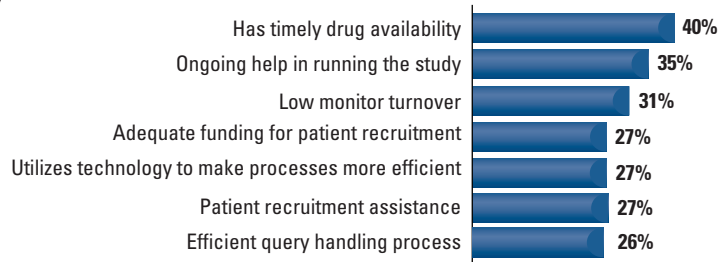
Average percent of sites rating sponsor “Excellent”



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).

**Quality of Ongoing Study Support**

Average percent of sites rating sponsor "Excellent"



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).

of success, ensuring, for example, that we all have the same expectations for deliverables during site recruitment and initiation. We maintain an ongoing dialogue between all team members in order to quickly answer any questions and, ultimately, achieve our timelines. We strive to be proactive, anticipating potential challenges and implementing solutions, as needed," said Clavier.

**Study Initiation**

Attributes making up this category include ability to carry out the protocol, good case report form (CRF) design, informative investigator meetings, and scientific rationale aligned with good clinical practices realities. Eighty percent of sites listed the ability to carry out the protocol as a very important task for CROs. i3 (38%), Kendle (38%), and Covance (35%) were the top three CROs with scores of "Excellent" for this attribute. Other attributes important to sites were: efficiency of contract and budget negotiations (76%), led by Kendle and i3, and providing good overall protocol design, with Kendle (44%) and Covance (37%) at the top.

"The way you enable investigators to communicate with patients about the study and answer questions is critical, not just at the outset of the study but on an ongoing basis throughout the process. We use professionally prepared educational materials to train investigators and study coordina-

tors and we provide materials they can use and distribute to patients. This allows everyone involved to feel knowledgeable about the study, their participation, their benefits and their risks. This benefits our staff, the investigative site professional staff and, most importantly, the patients who feel that they're working with a professional team who has their best interests in mind," said Kendle.

**Ongoing Study Support**

The attributes of good drug availability, good support of patient recruitment, good funding for patient recruitment, the use of technology to improve efficiency, ongoing support, low monitor turnover and an efficient query handling process comprise the category of ongoing study conduct.

A trend has been observed in recent CenterWatch surveys: while adequate funding for patient recruitment was considered very important by 72% of sites, only 57% thought that patient enrollment planning and assistance was very important. Some sites have their own preferred methods for recruitment, needing only funding to succeed, according to the survey. Kendle was the leader for funding patient recruitment.

Kendle was considered "Excellent" by 51% of sites for timeliness of drug availability. Medpace is keeping monitors in place with 41% of sites rating the company "Excellent" at keeping monitor turnover low. In terms of providing ongoing help in running the study, MDS Pharma was the best (40%), with i3 showing the way in the use of technology to make processes more efficient.

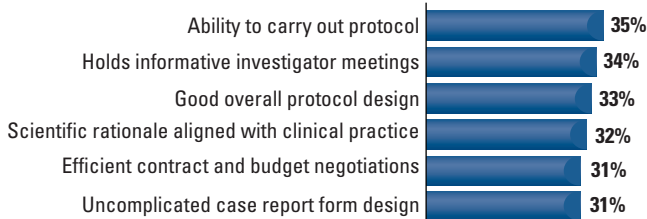
**Staff Professionalism**

Eighty-five percent of sites consider the professionalism of monitors and CRAs to be a critical success factor, and slightly more than 80% ranked the knowledge level of managers/CRAs as "Essential." Fortunately for the CRO industry, this is also a strong point across the board. This is the category that received the highest percentages of "Excellent" ratings from the sites, suggesting an area of strength for most CROs. On average, all companies were considered "Excellent" for these attributes 36% of the time. Kendle led in every category, and with a 50% average, is the only company to be rated "Excellent" by half of sites in any category. It is also a score that is 20% higher than Kendle achieved in 2005, a big jump in a key area of site relations.

"We have increasingly over the last few years had team education by our medical officers. The result is our project leaders and CRAs really understand the disease and the protocol for each study and they can really participate in the discussion of how to access patients and keep them in the study. They also understand the issues that sites are going to face clinically once a study is underway. We've made a lot of strides in the clinical training that we provide our project

**Quality of the Study Initiation Process**

Average percent of sites rating sponsor "Excellent"



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).

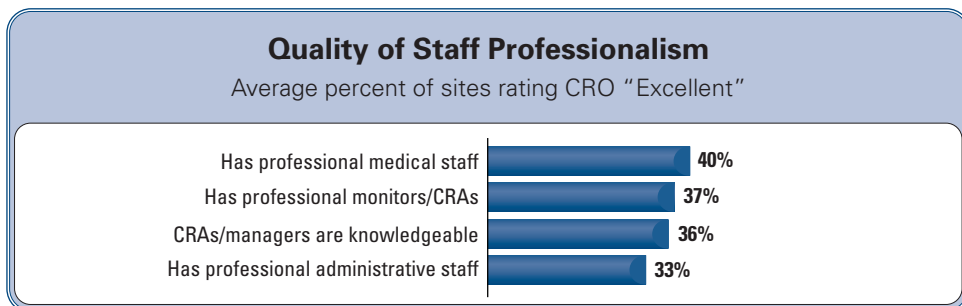
leaders and CRAs, and it shows in the working relationships we have with sites,” said Candace Kendle.

**Workstyle**

The attributes in this category are flexibility, supportive culture and the ability to create a collaborative team environment. This is an area to focus on for improvements. Slightly more than one in four investigative sites give CROs a top rating in terms of their flexibility—or willingness to modify protocols and budgets. This was the lowest rating of “Excellent” in the survey. Kendle was considered to have a supportive culture by 47%, followed by MDS Pharma with 41%.

**Grant Payment Process**

The grant payment process is made up of several attributes, including fair grant payment



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).

amounts, realistic grant payment schedules and promptness of grant payments.

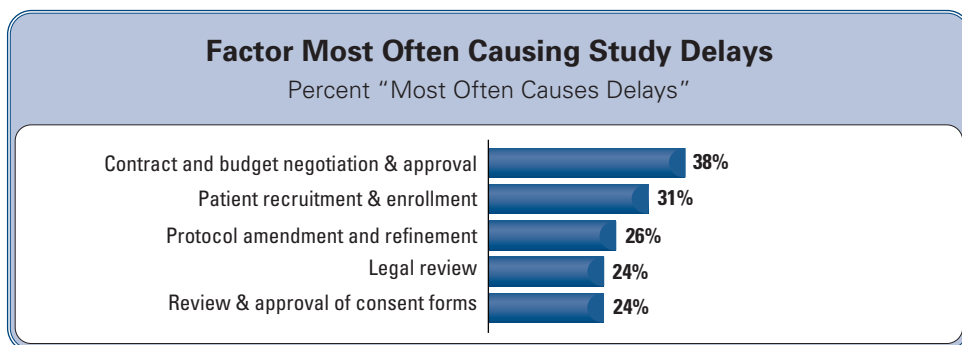
Sites have not traditionally been generous when assessing the grant payment process, but steady if unspectacular progress is being made. No CRO was considered “Excellent” at the promptness of grant payment by one-third of sites. i3 and Kendle received the best scores at 30%. i3 was considered “Excellent” at overall grant payment

fairness by 32% of sites. For realism of the grant payment schedules, i3 (34%) found itself the only company rated “Excellent” by more than one-third of sites in any attribute in this category.

**Conclusions**

The overall performance of CROs was rated almost the same as in 2005, with around two-thirds of sites satisfied with performance. Kendle, Omnicare and i3 all showed remarkable improvement over their previous results, with almost universal improvement across the 29 areas assessed in the survey. They all seem to have done a fine job of responding to the need of sites, critical in these days of change and uncertainty for all sides in drug development.

—Paul Dewberry and Sara Gambrill



Source: Thomson CenterWatch 2007 Survey of Investigative Sites in the U.S. (n=522).