Investigative sites’ eye view of the clinical trials industry

CW’s first site focus groups uncover frustration with ‘progress,’ but a passion for their mission

By Ronald Rosenberg
CenterWatch Staff Writer

Ask an experienced clinical researcher how trials have changed over the past few years and you’re likely to hear about the good—more accurate data due to EDC and advanced technologies; the bad—tougher patient recruitment and retention; and the downright ugly—problems getting paid appropriately and on time.

Is conducting clinical trials easier today? The data is more accurate, and the availability of more tools and technologies has led to greater efficiencies. But along with automation has come a loss of personal interactions and relationships between patient volunteers and trial staff. Site budgets are tighter amid rising costs, and competition for studies has intensified.

Still, principal investigators and site staff passionately enjoy their work, despite some longing for “the good old days,” when the processes were simpler and more informal. However, few want to leave the field, which constantly is changing as sponsors continue to outsource more clinical management to CROs, complicating the playing field for sites.

These are among the many insights gleaned from CenterWatch’s first investigative site focus groups, which included a mix of clinical research coordinators (CRCs), research practice managers, medical directors and principal investigators talking informally about the state of clinical trials today, how things have changed and what’s in store for the future.

The sessions were held during the Association for Clinical Research Professionals (ACRP) annual conference in San Antonio in April with two groups of participants, one from independent sites and the other from hospitals/academic medical centers.

CenterWatch has agreed not to identify the participants by name, except where they have agreed to be quoted in follow-up interviews.

The big picture

Study conduct has changed drastically, and site personnel feel the difference. Many are nostalgic for the good old days of paper and phone calls and the more personal touch—while acknowledging technological advances such as electronic data capture (EDC), clinical trial management systems and electronic trial master files can make their work lives easier.

“When EDC works, it’s better than paper,” said one CRC at a large university health system.

Added a CRC at a California site, “I’m looking forward to eConsent.”

Despite the growth in management and performance metrics, protocol complexity and compliance requirements, site staff still strive to have personal relationships both with their patients and with the sponsors and sites with which they work. While they see the advantages of technology, they have a wistful longing for simplicity.

“People who are passionate about their work find a way to make it work, even when the process is difficult,” said one site principal investigator.

Investigator turnover rates by region

Investigators who have not returned to conduct another clinical trial since initially submitting a 1572 in 2006

<table>
<thead>
<tr>
<th>Region</th>
<th>% Turnover</th>
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<tbody>
<tr>
<td>U.S.</td>
<td>35%</td>
</tr>
<tr>
<td>Canada</td>
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<tr>
<td>Europe</td>
<td>55%</td>
</tr>
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<td>South America</td>
<td>53%</td>
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<tr>
<td>Asia Pacific</td>
<td>53%</td>
</tr>
<tr>
<td>Africa</td>
<td>47%</td>
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Source: CenterWatch, 2011
“If your site has a new doctor, you have to update it in the database. You can’t pick up the phone and talk to anyone,” said a CRC at a Southwestern site.

“For device trials, our PI picks up the phone and calls the company,” said a CRC from a site in Tennessee. “It’s a newer industry.”

“Things have gotten more complex and complicated,” said Terry Poling, M.D., CPI, medical director of Heartland Research Associates in Wichita, Kan. “I regret not enjoying the golden days—10 years ago.”

Poling said today’s landscape is financially tougher. “We’ve seen an increase in demand, but the costs have increased more than the rewards. Twenty years ago it was simpler to start up—if I were faced with the current demands, I would not have survived.”

Sponsors v. CROs

One common theme from both focus groups was a preference for working directly with sponsors rather than with CROs, citing greater stability, more knowledgeable personnel and quicker answers to site coordinators’ questions.

“While it depends on the team, CROs often don’t have the information or the authority to respond to our questions, and working in an academic center means you have to wait awhile,” said Lea Becker, MT, CCRC, advanced CRC at the University of Virginia Health System. “I have several studies in which I work with sponsors, and those trials go faster, smoother and are better planned. With CROs, CRA turnover often is a big factor. I had one highly complex CRO study in which we enrolled four patients—and had 24 monitoring visits with 10 different monitors. So there was no continuity. You can’t expect much from a person who was just trained last week.”

“We’ve seen it take so long on the contractual end, one study closed before we ever got it up and running!” said a CRC from a large northeastern site. “CROs are demanding more. The CRO is working in a silo.”

Others cited having good relationships with CROs, but often better ones with sponsors.

“The key people at CROs keep changing, so there is a lot of mobility in the CRO world but more stability working with sponsors,” said Alex White, M.D., president and principal investigator at Progressive Medical Research in Port Orange, Fla.

In his 16 years as a PI, he takes pride in personally knowing key people at sponsors, but he acknowledges it is harder today to reach those key people and have a frank discussion about a particular study.

“You now are judged by sponsors on specific things,” said White, referring to the feasibility questionnaire process of site selection. “You can’t talk to anyone, so you’re going to lie—everyone does. Frankly, sponsors are separating themselves further and further from sites.”

One issue cited by most of the focus group participants is the effect of monitor turnover—on time, work and cost. For some site staff, every visit brings a new monitor. One solution the group liked, from a research coordinator at a large, southern university, is that after the third new monitor, her site charges a $1,500 fee for each new monitor on the study.

To get sponsors and CROs to comply with its sites’ financial requirements, the University of Wisconsin Medical School now provides a list of all of its fees.

“We have non-negotiable fees,” said Lauren Godbole, MPH, CCRC, former director of clinical research at University of Wisconsin Medical School’s Department of Surgery. “We give each of them a packet with every fee listed. If they walk away, a couple of months later they come back, having changed their minds. Now, if we all do that, it would reinforce how we do business. Why should we take on the risk and accept additional costs? If we start sending this message as sites, we’ll get a lot less pushback.”

Patient recruitment

Focus group participants recognize that a crucial part of patient recruitment is partnering with study volunteers. Several downplayed the use of outside recruiters and emphasized the importance of community outreach to find patients.

“Leaders at our medical center met with leaders in the minority communities here...”
to improve communications, resolve problems, build trust and educate them about clinical trials, so they can help reach out to their people,” said Deborah Hannah, MT, CCRC, research practice manager at Duke University Medical Center. “It has allowed our researchers to ask questions, and the improved communications has enabled Duke to take steps to recruit some community patients for trials.”

Others prefer to use a site database of local populations of potential volunteers.

“Central recruiters will use radio, TV and the newspaper, and you might get one or two people out of 20—a very small percentage,” said Virginia Bridges, MLT, CCRC, CRC at Carolina Clinical Trials in North Carolina. “People use a call center, which is not really able to do good pre-screenings, and I have to do that because the recruiters don’t ask the right questions. So it wastes my time to have a central recruiter.”

She also cited a common recruitment problem: finding young and middle-aged patients, particularly men, as most work and have difficulty participating in trials that require specific site visit schedules.

“If you want patients who have not retired you have to be flexible, because you can’t get everyone in at 8 a.m. So patient-centric appointments are lacking,” said Bridges. “Often, working men can’t fulfill the requirements because of the time windows, which prevent getting a good representation of men and women trial participants.”

Overall, patient recruiting is a lot harder today, according to several participants, and there are no signs it will get easier.

“I’m seeing more resistance from patients who are more cynical, often finding reasons to quibble about consent forms, the level of details and not understanding it, plus the bad press they read about research trials,” said Poling. “Today, it is more difficult than five to 10 years ago, when they had paper diaries. Now, with electronic diaries, they have more specific details to answer and are just bothered by it.”

But others, including White, said patient recruitment generally is positive compared to 10 years ago, as more people are aware of clinical trials and their benefits.

“I think we are seen as stewards of the community who know the needs of people living here, and we can help them select studies to participate in. We are seeing more people coming to us than ever before, as they realize the significant benefits. "I think we are seen as stewards of the community who know the needs of people living here, and we can help them select studies to participate in,” said White. “We are seeing more people coming to us than ever before, as they realize the significant benefits. We often give out cell phone numbers for after-hours access.”

What participants agreed on is that partnering with patients goes well beyond the recruitment phase, to the critical need for deep site staff-patient relationships through the life cycle of the trial, and beyond.

“You have to love your patients like you love your children,” said a CRC from a California site.

“Administrative costs are increasing, and CRO expectations of what sites will do are increasing, but not the willingness to pay extra.”

Deborah Hannah, MT, CCRC, research practice manager, Duke University Medical Center

### The patient recruitment challenge

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<tr>
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<th>2012 randomization to completion rates</th>
<th>Increase in planned study duration to reach target enrollment</th>
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<tbody>
<tr>
<td>Overall</td>
<td>56%</td>
<td>94%</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>59%</td>
<td>99%</td>
</tr>
<tr>
<td>CNS</td>
<td>61%</td>
<td>116%</td>
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<tr>
<td>Endocrine/Metabolic</td>
<td>41%</td>
<td>113%</td>
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<tr>
<td>Oncology</td>
<td>78%</td>
<td>71%</td>
</tr>
<tr>
<td>Respiratory</td>
<td>59%</td>
<td>95%</td>
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Source: Tufts CSDD, 2012 <csdd.tufts.edu>

“Doing more for less”

Many of the focus group participants say sponsors and CROs are asking sites to do more but are not covering those additional costs. From extra compliance steps and increased paperwork to more complex protocol procedures and repetitive staff training, sites say the study grant dollars are not rising to meet these added costs.
“Administrative costs are increasing, and CRO expectations of what sites will do are increasing, but not the willingness to pay extra,” said Hannah. “There’s heavier regulation, but sponsors and CROs want to pay the same amount. Our overhead doesn’t go down.”

Site staff agree both patient screenings and informed consents are taking longer, with no extra pay written into contracts. “Consents are getting way bigger, and they want to pay us half what we made three years ago,” said the founder of a site in Missouri.

“Fewer people are expected to do much more than five years ago,” said a CRC for a large southern university site. “Extra amendments, new monitors—it goes into your screening and enrollment time.”

White cited his annoyance with repetitive GCP training requirements of different vendors that often are unnecessary and do not take into account an individual’s years of experience.

“Instead of simplifying this training, vendors are complicating it,” he said.

Others cited a similar theme of taking mandatory training classes for different trials, often for the same vendor, in which the information is either repetitive or simply widely known based on their experience.

“I had a sponsor recently that required over 40 hours of training for each person listed in the study—a coordinator and two back-up coordinators—for a total of 120 hours of training, when most of it was completely unnecessary,” said Godbole. “Sponsors should not be selecting sites unless coordinators working there have had GCP training, know the history of human subject protections and have had a basic introduction to clinical trials, instead of repetitively going over the same information as part of site training.”

Protocol amendments are another sticking point with site staff. Too many sponsors try to write protocols in-house rather than hiring knowledgeable medical writers, said one CRC from a California site. “We just started one study, and we already are on the sixth amendment.”

“Often, we are pushed to get a study set up and ready to go, and just as we do [the sponsor] will issue an amendment,” said a research administrator at a large Midwestern site. “We have to do a lot of work to meet some arbitrary timeline that’s there typically from a business perspective, not a scientific one.”

Advice for the next generation

Given their collective experience, focus group participants were asked what advice they would give a young person who approached them seeking their input about entering the clinical research field.

“If you are going into clinical trials for the money, you’re not going to find your way,” said White. “It’s still good, but it’s being ruined by the government, the FDA and the trickle-down fear factor that’s become crippling.”

Some suggested clinical trials conduct is not a good career choice if you are not self-motivated, while others cited having a personal passion to make a difference and the importance of having a mentor.

“Industry needs good people,” said Hannah. “Get your foot in the door, then find a mentor and learn everything you can. If you ever feel like the job’s a drag, you need to get out.”

A research nurse coordinator at a southern medical center summed it up best: “If you find that passion, care about that group of patients, there’s nowhere to go but up.”

Added a CRC from a southwestern site, “When you hear ‘this helped me so much, thank you,’ it’s all worthwhile.”

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