CLINICAL TRIALS ADMINISTRATOR

An essential resource for managers of clinical trials

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IN THIS ISSUE

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Growing pains: Institution merges two very different CR centers

Staff morale was major obstacle

Research institutions often have more than one clinical research office or departments in which each handles its own CR duties, creating some duplication and inefficiencies along the way.

So what happens when an institution decides to merge two or more CR offices in hopes of creating a more efficient research organization?

The University of Kentucky in Lexington, KY, discovered the answer to this recently as it implemented major changes by merging two physically and philosophically different clinical research operations.

"We've undergone some growing pains in merging two, long-standing units with different focuses," says **Linda Rice**, RN, clinical operations director at the University of Kentucky Clinical Research Development and Operations Center (CR-DOC).

"We're in the process of looking at how we could create our center for clinical and translational science, and our leadership pulled together the two research groups and said, 'How could we look at an economy of scale to make ourselves efficient?'" Rice explains. "'Do we have duplicates of effort in these two groups? What if we brought the units together as one?' And that's where the journey begins."

The two units were put into the CR-DOC, a centralized unit, where there are inpatient and outpatient units, Rice adds.

There were two major obstacles to the merger: the first involved funding since each CR unit had very different budgeting structures; the second involved staffing and personnel needs, says **Marietta Barton-Baxter**, CCRC, administrative director at the University of Kentucky CR-DOC.

"The two units were so vastly different, and my biggest challenge was in figuring out how to manage that," Barton-Baxter says. "We had to look at our staffing needs and then figure out how we would merge the two to get economies of scale."

The unit Barton-Baxter managed operated under a service center model in which pharmaceutical companies and other sponsors funded trials. The second unit, which Rice managed, was a grant-funded model, Barton-Baxter explains.

"We ran into problems because we couldn't cross-cover one another, and that's what we needed," she adds. "So we had to look for other ways to accomplish that, and so we reallocated our positions in a way that will allow us to accomplish it."

When an institution merges two separate research units, the first question typically is whether it should start from scratch or reorganize existing staff, Rice notes.

"We decided to keep everyone we had and restructure from within," Rice says. "I'm glad we did it the way we did — it was less traumatizing to staff."

There remained morale and staffing problems because even the best-handled sort of change is difficult for people who have been at their jobs for a number of years, she adds.

"It was painful at times for me as a manager because I didn't always have buy-in," Rice says. "Change takes time for people to deal with, and this was a much longer process than if we'd shut down both units and started over with new employees."

Workers typically want stability in their jobs, Barton-Baxter notes.

"We were merging units and moving staff, and although we tried the best we could to manage the change, it was difficult for everyone," she explains. "Overall, we came up really well, but the challenge of change is tough."

Another major issue was that employees in the two units had never worked together, and so when they first were merged there was tension, Rice says.

"When we did any kind of event together, one group sat on one side of the room, and another sat on the other side," Rice says.

Research staff also had a lot of anxiety over their jobs, recalls **Roxane Poskin**, BA, manager of participant recruitment and marketing at the University of Kentucky CR-DOC.

Research employees feared losing their positions or their current job duties, she adds. **(See story on improving staff morale during change, p. 3.)**

"We had a little bit of anxiety over whether we were keeping our jobs or not," Poskin says. "But they did find a way to pull us all together, and it's great now."

Clinical research employees also were concerned about changes in their work duties, says Poskin, who is a 10-year employee.

"They were trying to define everyone's roles," Poskin says.

As it turned out, Poskin's job duties did change, but in a positive way, she says.

"I'm back to doing quite a bit more graphics — I have a graphics artist background," she says. "I design posters, fliers, and Web sites, and I use all of these toward recruiting research participants."

Before the merger, Poskin was spending more

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of her work time talking to pharmaceutical companies about placing studies at the university.

Rice, Barton-Baxter, and Poskin describe some of the lessons learned during the CR units' merger:

• **Identify the units' differences and commonalities:** "We had to find our commonalities," Rice says. "What was it that both groups did that was duplicated? How could we consolidate functions?"

As they looked for tasks and roles that overlapped, they found these differences:

- The units' staff had different knowledge and expertise and in different areas, Rice says;
- Nurses from the grant-funded unit predominantly were involved in data collection and nursing activities, while nurses from the private sponsor-funded unit were accustomed to being research coordinators, Rice explains;
- The sponsor-funded unit was a service unit that charged for services and recouped its costs, including infrastructure costs, and its employees were not as busy, Rice says;
- The grant-funded area had a busier study caseload, she adds.

"There wasn't a lot of staff we could use on both sides," Barton-Baxter notes.

"Until we started changing the model, the only positions we could utilize on both sides were those that were fully subsidized -- positions that were set in the service center, but weren't 100% reliant on the recharge [to grants]," she explains. "These were jobs that were subsidized by the university, including my position."

For example, Barton-Baxter works on specific studies only in the capacity of overseeing staff. But other employees, such as regulatory specialists, were assigned to specific studies, and their salaries had to be paid through grant recharges.

"If a principal investigator has a study contract with us to provide regulatory support, then our regulatory person works on his study and tracks her time to the quarter of an hour," Barton-Baxter says. "We charge that time directly to the grant."

• **Divide positions into tasks and duties:** "I did some homework, checking with local clinical research organizations (CROs) to see what kind of services they offered," Rice says. "They broke down the coordinators position and found a cheaper way to manage studies."

For example, nurses were given tasks that had to be performed by someone at the nursing level, Rice says.

Then data managers would handle the paperwork, scheduling, and transcriptions, she adds.

"The CROs had a document and quality assurance manager who made sure data were in good shape," Rice says. "My supervisor liked the idea of a staffing model where you no longer had a nurse coordinator who ran everything and was managing the study by herself."

Since one of the goals of the merger was to reduce costs, they opted to adopt the staffing model approach, she adds.

"This created major duress," Rice says. "This created a lack of a sense of identity for some nurses who felt very tied to being a coordinator and controlling their environment and studies."

But it did save the organization money because it moved lower-skills tasks to lower-paid disciplines, rather than having high salary nurses drawing blood, scheduling patients, and transcribing information, Rice explains.

"The nurse is one of the highest-paid positions on our team, so if we can save nurses' time and let them do more nursing tasks while utilizing other people who can do the duties that do not require nursing skills, then it saves money," she adds.

The staffing change also made it possible for the merged unit to take on additional research projects without having to add more staff, Barton-Baxter says.

"That was a bonus for us, and that was the primary way in which we were able to achieve some economy of scale," Barton-Baxter adds. ■

Morale issues are major challenge when jobs change

Merger revealed staff chasm

One of the biggest obstacles to a successful clinical research unit merger is employee morale.

If CR employees are unhappy with the change, their attitudes and work habits suffer, and the organization's efforts will not be as successful as planned.

This is a difficult lesson to learn, says **Linda Rice**, RN, clinical operations director at the University of Kentucky Clinical Research Development and Operations Center (CR-DOC) in Lexington, KY. The CR-DOC is the result of the merger of two research units.

"We met many times as leaders, trying to make this merger as smooth as possible," Rice says. "I anticipated it going much smoother than it did

because I'd under-estimated the staff's sense of professional value."

Whenever there's a merger or change, employees fear the unknown, and this fear should be acknowledged and handled.

"Employees were affronted by losing some of their duties, and they felt it was a loss of their identity," Rice explains. "They had very strong feelings about it, and it took them some time to get over it."

When these morale issues began to bubble over into the workplace, Rice and other supervisors arranged for the merged staffs to meet at a one-day retreat in which they'd learn about the powerful emotions of change and how to deal with them.

The retreat also served as an icebreaker event in which the merged staffs could get to know one another in a more casual setting.

"At the retreat, I intentionally mixed staff from the two units," Rice says.

Attendees were forced to sit next to someone from the other unit, so they couldn't segregate into their old unit cliques as they learned coping strategies for their work transformation.

"We had a human resources person come in and do exercises about change and facing the challenges of change," Rice says.

"We participated in a video about dealing with change that included breakout sessions to discuss the different topics the speaker was presenting," she recalls.

"The speaker used humor as a tool to make his points," she adds. "For the first time since the initial changes were made, many of the staff were able to laugh and internalize the process of change as it related to them."

The video was instrumental in helping the staff learn how to deal with change, Rice says.

"We tried to focus on the challenges of change, and we did team-building activities," says **Marietta Barton-Baxter**, CCRC, administrative director at the University of Kentucky CR-DOC.

For example, one exercise involved dividing the coordinator's duties task-by-task and placing job titles on a wall so that employees, who were divided into teams, could match job titles to tasks, Rice says.

The teams would decide who should wheel patients down the front lobby and who should ship off blood samples, she adds.

Since the teams included mixed disciplines, nurses who had been coordinators found they couldn't simply say that all of these tasks were their own to do, and eventually team members had buy-in for the job role changes, Rice explains.

"I was totally impressed by the teams as a whole," she says.

On another retreat, the staff watched a video of a motivational speaker who compared employees' reactions to work changes to the experiences of a cancer patient, says **Roxane Poskin**, BA, manager of participant recruitment and marketing at the University of Kentucky CR-DOC.

"The video was great," Poskin says. "It talked about all of the things a cancer patient goes through to reach the last stage of acceptance."

Although the retreat helped considerably, staffing and morale still needed tweaking over time.

"We have monthly staff meetings to keep people seeing each other face-to-face and talking things through," Rice says.

There have been some studies in which one nurse from each unit was assigned to work together, she adds.

"That's worked out very well," Rice says. "Also, new employees have come on board, and they've been very gregarious and have helped morale, as well."

It also helped morale and helped staff understand what each did when various employees were invited to give in-house talks about their jobs, Poskin says.

"I did a presentation on marketing, and it helped educate our department of what different units did," she explains. "We had each person do a presentation for the whole group."

The talks lasted 30 minutes, and coworkers asked each other questions about their jobs, sometimes revealing good ideas for improvements, Poskin adds.

Other talks came from an operations manager, nurses, and the education and training manager, she says.

These presentations led to more conversations and a greater understanding about what one's colleagues were struggling with and who to go to if one had a problem, Poskin says.

Morale has continued to improve since the retreat, and employees are becoming more accepting of the whole process, Rice adds.

Since the merger took place during the current economic crisis, some of the anxiety was related to fears of job losses, and now those fears are easing, she notes.

"Now they know the worst is over, and people feel a little more at ease now," Rice says. "We've had a lot of business come our way, and employ-

ees are seeing that progress, and they're much more positive." ■

Economic crisis continues some CR sites see gains

Better qualified people apply for CR jobs

When clinical trial industry experts look back at the 2008-2010 period, perhaps they'll see a few bright spots in an otherwise uncomfortable year.

For some clinical trial sites, increased federal funding for research as included in the 2009 stimulus package meant a little more business than they might otherwise have seen. For others, the economic crisis meant first-time salary and staffing cutbacks.

"One of the interesting things is we're getting a lot more research right now," says **Elizabeth Hill**, PhD, an associate chief of staff for research at the VA Sierra Nevada Health Care System in Reno, NV. Hill is an editorial advisory board member for Clinical Trials Administrator.

So the VA Sierra Nevada Health Care System has had new clinical research (CR) jobs to fill, Hill says.

"We need more study coordinators, and I've had a couple of experienced study coordinators apply," Hill says. "They were laid off somewhere else and are looking for jobs, so it's been easy to recruit new staff."

This is a turnaround from previous years when it's been hard to find experienced CR staff, particularly those with nursing backgrounds, she notes.

"It seems like you can find experienced staff now," she adds. "I know the hospital in general had openings for nurses and there were many more nurses who applied than there were positions open."

Typically a clinical research office has found it difficult to hire new employees who have three years or more of experience, but that situation is turned around, says **Ramesh Gunawardena**, MBA, director of clinical trial operations in the clinical trial office of Beth Israel Deaconess Medical Center in Boston. Beth Israel is a Harvard-affiliated facility.

"There's a bigger pool now of more experienced people that we can tap into," Gunawardena says.

This has been a silver lining in the CR job market, he notes.

"What comes with experience is the learning curve is much shorter," Gunawardena says. "They come on board fully aware of the industry and the language, jargon, and documentation," he adds. "They can hit the job running with departmental-specific and institutional-specific training in place, and their quality of work is a lot better, so we certainly benefit from that."

But even for CR professionals who are fortunate to have jobs at academic or health care institutions, the news has been fairly bleak.

Many hospitals and academic institutions made across-the-board major cost-cutting changes in staffing and salaries that have had an impact on research units, as well.

Harvard University-affiliated medical centers have frozen all merit pay for the next year or two, Gunawardena says.

"Beth Israel has decided for the upcoming fiscal year that salaries will be frozen, and that's a first step," Gunawardena says. "Then they've made minor benefit-related changes."

For instance, staff no longer can cash in vacation time, and retirement fund matching contributions have been frozen, he adds.

In past years the CR office has sent its staff to at least two conferences per year, and this also has been cut.

"The restrictions are that the conferences have to be local, in New England, and within driving distance," Gunawardena says. "They won't just send you across the country, but they'd allow people to do it on their own and pay for it on their own."

Since CR professionals need to stay up-to-date on regulatory changes and other issues, the CR office participates in teleconferences and other less-expensive educational measures, he adds.

"We still can pay for those kinds of things, as long as it doesn't require other expenses like accommodations and travel," Gunawardena says.

One measure that has made staffing clinical research offices more difficult involves an across-the-board hiring freeze, he notes.

Before a CR director can hire study coordinators to replace staff or to work on new studies, the director has to obtain a requisition to hire someone through the position control committee, Gunawardena says.

"We have to justify an operating account for the position," he explains. "If you have a grant or clinical trial with money coming in, then you have to provide data about how much you've gotten with the award and how much of the

staffing expense will be covered."

Hiring at the Mayo Clinic in Rochester, MN, also requires justification.

"You have to justify every position you hire and you have to justify even the positions you lose," says **Stephen L. Kopecky**, MD, a physician in cardiovascular diseases and internal medicine and a professor of the Mayo Clinic College of Medicine in Rochester.

There have been more people applying for clinical trial jobs, Kopecky notes.

"We're seeing more qualified people apply for jobs, which is nice for a change," he adds. "We've also started seeing more requests for applications from headhunting firms that are looking for certain positions."

It's been a rough year for people in the clinical research industry, notes **Janet F. Zimmerman**, MS, RN, an assistant clinical professor and coordinator of the clinical trials research track at the College of Nursing and Health Professions of Drexel University in Philadelphia, PA.

"I keep tabs with friends I worked with in industry, different CROs, and there's been tremendous downsizing," Zimmerman says. "The individuals who are being let go are people who are in clinical work, which is unusual."

Another result of the current economic crisis is that some CR professionals who lose their jobs or who want to be prepared in case they lose their jobs might choose to return to college to earn advanced degrees. **(See story on what to do during downsizing phase, below.)**

"We see more students, but a lot of it depends on whether or not the students have financial assistance from their employer," Zimmerman says. "The interest is there for students to go back to school at the graduate level, but it's expensive." ■

Losing your job in the CR industry? 3 tips: Education, education, education

Make the most of transition opportunities

Most people working in the clinical research industry will find themselves unemployed at some point in their careers, and it's wise to prepare by updating your skills and improving your resume through advanced education.

One veteran of the industry offers a few pointers on how to weather a job loss and rocky economy without losing your CR career:

1. Prepare for job loss while you are still employed.

All industries shift, change, and evolve, and the well-prepared professionals are the ones who are in the best position for handling economic storms.

One way to do this is to take advantage of your employer's continuing education benefits and study evenings and weekends for a degree that will make you more marketable as an employee, suggests **Janet F. Zimmerman**, MS, RN, an assistant clinical professor and coordinator of the clinical trials research track at the College of Nursing and Health Professions of Drexel University in Philadelphia.

For example, Drexel University has an online program that offers a master of science in nursing for clinical trials research.

Online programs give working professionals the opportunity to make their own schedules and pursue advanced degrees without jeopardizing their daytime jobs.

"Most of our students, probably 75%, are currently working in a clinical trials nursing role as study coordinators, monitors, or in pharma in regulatory affairs or safety," Zimmerman says. "They're all RNs, and so these are individuals who want to validate their contributions and expand their understanding of the clinical trial process while getting a graduate degree in the process."

Many of these students receive reimbursement from their employers for their tuition costs, she adds.

"It's a tremendous incentive for a lot of people to go back to school when you work for an employer who offers X number of dollars for an academic education in an accredited school, college, or university," Zimmerman says. "That's why a lot of people will take advantage of it."

2. Make networking a top priority.

"I'm not sure people understand the importance of networking in this economy," Zimmerman says. "It's all about making contacts, being assertive, taking the initiative, being resourceful."

Some people may understand its importance, but many do not, she adds.

"You have to market yourself," Zimmerman says.

This might be difficult for many nurses, but it's essential in today's marketplace, and it's especially crucial in a slow economy, she adds.

3. Earn an advanced degree to enhance your

resume.

For clinical research professionals who lose their jobs during this downturn, the best career strategy might be to return to college for an advanced degree.

"Getting further education adds to your portfolio," Zimmerman says.

While it used to be true that a professional with a bachelor's of science degree or nursing degree would have a job in clinical research, this no longer is true, she notes.

"It's an advanced role, and one thing we promote here at Drexel is that it's not for entry level people," Zimmerman says. "It requires a higher level of education, and it's very much based on the nursing model."

Today's pharmaceutical industry isn't hiring as many people as it once did, so increasing numbers of CR students are looking for work at investigator sites and academic sites, she says.

"They're using their advanced degrees to distinguish themselves from their colleagues who either are not nurses or who don't have a graduate degree," Zimmerman adds.

There are a growing number of universities that offer master of science degrees in clinical research operations, including online programs, such as the one at Drexel.

"I do feel the economy is going to pick up and clinical research is not going to go away, but there may be a readjustment in the allocation of resources," Zimmerman says. "Nurses who are studying for graduate degrees now might find themselves positioned in the right place when things resume in a more normal pattern, whether it's in clinical research or the pharmaceutical industry."

The best time to go to back to college is when the economy is floundering, she adds.

"Go back to school and get yourself prepared for whatever you might need when things return to normal," Zimmerman says. ■

Voice-over Internet phone system helps emergency CR

Five physicians are contacted at one time

Clinical research sites have many limitations imposed by federal and state regulations, as well as ethics review boards that help carry out federal requirements.

One limitation that can be particularly frustrating to principal investigators (PIs) involves obtaining informed consent in emergency situations.

There are a number of life-saving medical interventions that are not routinely adopted because of the lack of clinical trials proving their value. And one of the chief obstacles to obtaining these data is the difficulty CR sites have in obtaining informed consent during an emergency situation.

Now, a new study involving stroke patients shows that such emergency informed consent can be obtained in a way that meets regulatory and IRB requirements and which can be done fast enough to be practical. The solution is the use of simultaneous ring, voice-over-Internet phone system technology.[1]

Stroke is one of those emergency diseases where patients need to be treated very early, so there isn't time to wait until paramedics wheel them into the hospital to obtain informed consent, notes **Nerses Sanossian**, MD, an assistant professor of neurology and an associate director of the Stroke Center in the department of neurology at the University of Southern California in Los Angeles.

Investigators wanted to test the hypothesis that magnesium administered very soon after a person has a stroke can protect the human brain, Sanossian says.

Magnesium treatment showed protective potential in animal studies, but they needed to find a way to test it in clinical trials, and it would take too long to wait until patients were triaged in the hospital, he adds.

The key was to enroll patients in the study within two hours of the onset of their stroke.

"The earliest time we could enroll a stroke patient in clinical research was when they had paramedic contact," Sanossian says. "But paramedics won't wait for a page, and they won't wait more than 30 seconds to be connected with a physician."

So Sanossian and co-investigators designed a study in which paramedics would carry a kit with two bags. One contained 20 mg of magnesium, and the other had a salt water placebo.

When paramedics arrived a the home of a stroke victim, they would call an investigator physician via a virtual Internet phone number that simultaneously rings up to five physicians at one time, Sanossian explains.

The first physician to pick up the phone provides the informed consent. With this phone system, paramedics haven't had to wait more than 30 seconds for someone to answer the phone, he adds.

The key is for a number of physician investigators to carry phones at all time with the understanding that they will be called to conduct emergency clinical trial enrollment and informed consent.

"I just enrolled a patient earlier," Sanossian notes. "I was making rounds, and the phone rang four times; I won't let it ring five times, so during my hospital rounds I picked up the phone and spoke with the patient, getting permission and consent, and I enrolled the patient."

Altogether, the study has six physicians who are stroke specialists and researchers who can take these calls. Also, there's a dedicated line for Spanish-speaking patients, and three physicians are on the Spanish line while five are on the English-speaking line.

The investigators can remain on call for the study wherever they are because the calls go through the Internet.

"I was traveling in Estonia, and I was able to do enrollment from Estonia because all communication is online," Sanossian says.

While the Internet simultaneous phone ringing system made it possible to enroll patients within that two-hour critical window, there were other obstacles investigators had to overcome for the study.

One involved recruiting paramedics.

"We went to all Los Angeles county paramedic agencies," Sanossian says.

It took years of planning to obtain the necessary documentation, convince paramedics to assist with the study, and to obtain all regulatory approvals, he says.

"We had to do community education and have a dedicated person in charge of community education," he adds. "One-third of hospitals will allow us to enroll patients without explicit consent because we went to the community and showed how magnesium was safe and how the study will benefit society."

The study's target enrollment is 1,298, and investigators have enrolled more than two-thirds since first enrolling in the study in January, 2005, Sanossian says.

"We're only enrolling people with symptoms clearly showing an onset of less than two hours," he says. "We want to get to them before they're irreversibly damaged, and the faster we get to them the less likely there will be damage."

This study is the earliest stroke therapy trial ever attempted, Sanossian notes.

"This method has never been done before to our knowledge, and we did it because of necessity," Sanossian says. "We made a commitment to man our phones 24/7."

Investigators wanted to be connected to paramedics within five seconds of their call, and the simultaneous ring voice-over-Internet phone system was the best way to make this happen, he adds.

"If a paramedic is put on hold for 40 seconds, he won't call us back," Sanossian says. "The only way to get hold of a physician within five seconds is to have one person sit at a phone in an office or to use this system."

Since all of the investigators are busy stroke physicians with active clinical practices, the Internet phone system was their best option.

"This is a good model for future pre-hospital studies if you want to get on the phone with no delay," Sanossian says. "In one month of intense monitoring we were not able to identify any cases where they weren't able to reach us."

Three patients dropped out because of poor telephone reception, however, so the system has limitations, he says.

Forty percent of the calls from paramedics resulted in enrolled patients, Sanossian says.

"A lot of what we do is talk to paramedics and see if patients qualify for the study," he says. "Their patient could be a person with a brain tumor who doesn't qualify, or if the person has only two months to live he wouldn't qualify."

The point of the Internet phone system is to get the physician and paramedic talking as soon as possible, and so far it appears the paramedics involved are happy with the situation, Sanossian says.

"Rarely is there a situation where the paramedic is on the line a little longer than usual," he says. "I think this system could be useful in any kind of acute clinical situation, like someone having a heart attack, and it's ideal for stroke patients."

Reference

1. Sanossian N, Starkman S, Liebeskind DS, et al. Simultaneous ring voice-over-Internet phone system enables rapid physician elicitation of explicit informed consent in prehospital stroke treatment trials. *Cerebrovasc Dis.* 2009;28:539-544. ■

Know the must-do's for improving billing

Q&A: Expert details her site's best practices

Clinical trial sites sometimes fail to look at the big picture when initiating a quality improvement process by not addressing billing compliance as thoroughly as needed.

In this Q&A interview, **Suzanne M. Rivera**, PhD, MSW, associate vice president of research services and special assistant to the president for strategic initiatives at the University of Texas Southwestern Medical Center in Dallas, provides her expert advice on how to ensure your quality improvement and compliance programs work well:

CTA: What are some of the most common issues that arise in clinical trial research compliance, and how can these be resolved?

Rivera: One thing we all recognize as an area of vulnerability that needs to be addressed very carefully is billing compliance in clinical trials. Often the offices responsible for approval of a study, negotiation of a contract, performance of a trial, and billing of charges all report up through different chains of command. Frequently, their data management systems don't share information back and forth. So what you end up with is a series of blind hand-offs, which can lead to billing of subjects or insurers for charges that really ought to be borne by study sponsors. Some institutions have recognized the problem and rather than bill inappropriately, they simply don't charge anyone for certain study-related expenses. This means they are absorbing trial costs out of fear. So this is one issue that can be resolved by establishing cross-departmental teams charged with establishing methods for communication that will ensure proper charging of trial expenses. The other important thing is to audit charges and correct mistakes. It's not enough to suspect you may have a problem; you need to investigate and verify that your systems of checks and balances are working properly.

Another thing many institutions are struggling with is how to deal with disclosure of financial interests and assessment of those interests to determine whether they may constitute a conflict. Much attention has been paid to this problem in the media and by government officials. I think we all are learning a great deal about the importance of preserving trust with the public. People expect universities and hospitals to keep a watchful eye on their research programs to prevent impropriety, and avoidance of financial conflicts of interest is a really hot topic right now.

CTA: Would you please tell us more about your data management system investment and how this has helped with compliance and improving quality?

Rivera: We are implementing new data management systems for IRB review and study oversight, for clinical trials management, and for enterprise-wide financial and personnel management. These efforts are being coordinated closely to ensure that data flow in all the directions necessary to prevent problems on the front end and to identify issues requiring resolution. We have accomplished this coordination through a research administration advisory council that has representatives from the information technology department, business affairs, institutional compliance, research administration, post-award accounting, and all the regulatory committees.

The council also has faculty representatives who help us understand how things really work in the trenches. Without a way of collaborating across institutional lines, these software implementations merely would have re-inscribed the same old organizational silos. Instead, we are taking this opportunity to re-engineer the way research administration gets done.

CTA: How has your institution changed its compliance focus in recent years due to industry and regulatory trends?

Rivera: We have invested significantly in three areas: education of investigators and research personnel, dedicated staff to perform post-approval monitoring, and data management systems to make reporting, trend-analysis, and sharing of information across departments much easier. Investing in education is an obvious way to improve. The vast majority of researchers want to conduct trials properly, but there are so many rules, and the landscape seems to change frequently. If we can help them understand their obligations on the front end, we'll have fewer problems showing up during the post-approval monitoring on the back end.

For monitoring, we do two types: not-for-cause program improvement reviews, which are done to help. And for-cause audits, which are done to

investigate a concern or allegation. In either case, we work very hard to convey that we are there to support the research enterprise.

CTA: What are your best practices? For instance, how do you prevent compliance issues, monitor for problems, and fix/resolve issues that arise?

Rivera: The best method of prevention is education. That includes formal training classes, Web-based tutorials, informative Web sites, use of list servs, and messaging through various other communication media. We think our not-for-cause program improvement reviews also are a form of education.

When a problem is discovered, we try to facilitate resolution and not to come down like a hammer. This is very important for establishing trust. In cases of minor paperwork infractions, we assist the investigator to get everything in order quickly. When done well, this will establish that the staff add value and are here as a resource, not a police force.

When serious or continuing problems are identified, we follow a structured standard operating procedure for involving the institutional review board and, when warranted, making a report to federal authorities. Even in those cases, it is almost always possible to develop a corrective action plan that will ameliorate the infraction and prevent something of a similar nature from happening again. This could involve training, mentoring, requiring frequent reporting to the IRB, or any number of other steps to ensure we are meeting our mandate to protect the rights and welfare of subjects while conducting first-rate science. ■

CR education should extend to clinical care nursing staff

Efforts can help with patient recruitment

Clinical care nurses often have a vague idea about research projects at their medical institutions, and their knowledge about how clinical trials work can be limited.

"Our concern is that staff nurses need to know more about what kind of research is going on here," says **Elizabeth Hill**, PhD, an associate chief of staff for research at the VA Sierra Nevada Health Care System in Reno, NV.

"They need to know what the issues are around research and what the requirements and regulations are," Hill says. "It'd be a benefit to patients and the people doing research."

For instance, staff nurses who fully understand the research enterprise can be a great resource for recruitment because they're the ones who continually see patients who might be candidates for clinical trials, she adds.

"I also think it'd be good for them to know what kind of study the subjects are enrolled in because a patient could come out of the hospital and be given a drug that counteracts with a study medication," Hill says. "Staff nurses might identify that issue, and they can look for potential complications."

Also, clinical care nurses can play an important role in the checks and balance of the research enterprise. "I have had — more than once — nurses and others involved in the care of patients identify what was wrong with a study," Hill notes. "Nurses are just a good source of information if you educate them about what's required."

Educating clinical nurses about research serves a dual purpose: first it ensures that nurses are more aware of what clinical trials entail, and, secondly, it gives nurses information they need to inform patients, Hill says.

"Families and patients will ask staff nurses about a study," she adds. "The idea is to educate those staff nurses and personnel so they understand the whole research process better and then can educate patients."

For example, a research participant who goes through the informed consent process but has lingering questions down the road might ask a staff nurse for information, Hill says.

"If you had nurses who were educated in the study they could explain it to patients," she says.

A first step might be to offer continuing education units to nurses who voluntarily take courses about clinical research.

Research institutions can encourage this by providing time for staff to complete such credits, Hill says.

Academic medical centers also could place educational posters in hospital lobbies, Hill suggests.

"One year we had a research week where we put up posters of research going on in the lobby of the hospital, and that was one place where people came up to me and said they didn't know there was research being done there," Hill says.

Another strategy is to provide brief educational sessions at changes of shift, Hill says.

"You could give nurses some general information about the research, what it is, and the kinds of patients they're looking for," Hill explains. "So if

the nurse sees someone who might be interested in the study, she can give the patient a flier." Research institutions need to do a better job of marketing clinical trials research to the public, and educating staff nurses is a good way to start, she says.

"We'd like people to understand that research is done to improve things for people, and that's really a key issue for the VA," Hill says. "The VA does a lot of good research, but I think we sometimes need to sell it better to the general public and also in our own facility so people have a more positive outlook about research."

Ideally, staff nurses would be trained to understand what a particular study is about, what it involves, what are its risks and benefits, and what are its inclusion and exclusion criteria, Hill says.

"You could give nurses fliers to distribute to patients, and you could discuss with them what goes into enrolling patients in studies, including the informed consent form, explaining adverse events, and what to look for in potential study participants, Hill explains.

"Talk to them about what the benefits could be, if not for their patients, then for future patients," Hill says. "Explain how this study is important because it helps if you make people feel like they're a part of something big."

The key is to make the effort to talk with staff nurses and to build trust and rapport.

"If nurses understood that research relates to the people they're taking care of and could improve outcomes of the people they're caring for, then they might be willing to do anything they can to help with research," Hill says. ■

CR Industry News

FDA proposes mandatory e-safety reporting rules

Rules strengthen data collection

The U.S. Food and Drug Administration (FDA) has proposed to amend postmarket safety reporting regulations to require that manufacturers and other facilities subject to current reporting requirements submit reports in an electronic format, according to an FDA news bulletin.

The proposed rules apply to electronic medical device adverse event (AE) reporting and electronic drug and biologic product adverse experience reporting. The rules only change the way incidents are reported, but do not change what sites are required to report.

Most mandatory medical device AE reporting to the FDA's Center for Devices and Radiological Health (CDRH) have been in paper format, which requires manual entry into the center's AE database, which is called the Manufacturer and User Facility Device Experience (MAUDE) database. The extra step of data entry hinders CDRH's ability to review safety data quickly to uncover potential public health problems, and it's costly, FDA officials say. ■

CNE/CME Objectives / Instructions

The CNE/CME objectives for *Clinical Trials Administrator* are to help physicians and nurses be able to:

- **explain** pertinent regulatory mandates
- **develop** practical clinical oversight strategies;
- **discuss** best practices shared by facilities that successfully conduct clinical trials.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you. ■

COMING IN FUTURE MONTHS

- Need an affordable electronic system? Here's what to do
- Experts explain the Medicare Secondary Payer Rules
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CNE/CME *questions*

1. Which of the following is not a good strategy for improving the way two separate clinical research units merge?
   A. Assess the units before the merger, identifying the units' differences and commonalities
   B. Divide staff positions into tasks and responsibilities to find new and better fits
   C. Hold ice-breakers and retreats to discuss change and to help improve staff relationships
   D. All of the above are good strategies

2. Researchers used a simultaneous ring, voice-over-Internet phone system technology to obtain rapid informed consent because they found that paramedics would not wait more than how long to speak with a doctor by phone?
   A. 5 to 30 seconds
   B. 1 minute
   C. 90 seconds
   D. 2 minutes

3. According to a CR billing compliance expert, what's the best method for preventing billing compliance problems?
   A. Monthly monitoring audits
   B. Education
   C. Hefty institutional penalties
   D. Thorough IRB review

4. CR sites should make efforts to educate their facilities' clinical nurses about research. Why is this a good strategy?
   A. Staff nurses who fully understand the research enterprise can be a great resource for recruitment because they're the ones who continually see patients who might be candidates for clinical trials
   B. These nurses could be potential employees down the road
   C. Offering educational sessions to non-research employees helps build good will about CR
   D. None of the above

Answers: 1. D; 2. A; 3. B; 4. A.

CLINICAL TRIALS ADMINISTRATOR

An essential resource for managers of clinical trials

Economic worries, salary freezes remain issues as recession drags on

Still, many respondents manage modest wage hike

Clinical research (CR) directors and staff have experienced stagnant salaries, job cutbacks, and benefit cuts as a result of the recession in 2009, according to experts and results from the 2009 *Clinical Trials Administrator* salary survey.

Most CR salaries this past year have been stagnant, or the raises are small and in the 1% to 2% range, says **Janet F. Zimmerman**, MS, RN, an assistant clinical professor and coordinator of the clinical trials research track at the College of Nursing and Health Professions at Drexel University in Philadelphia.

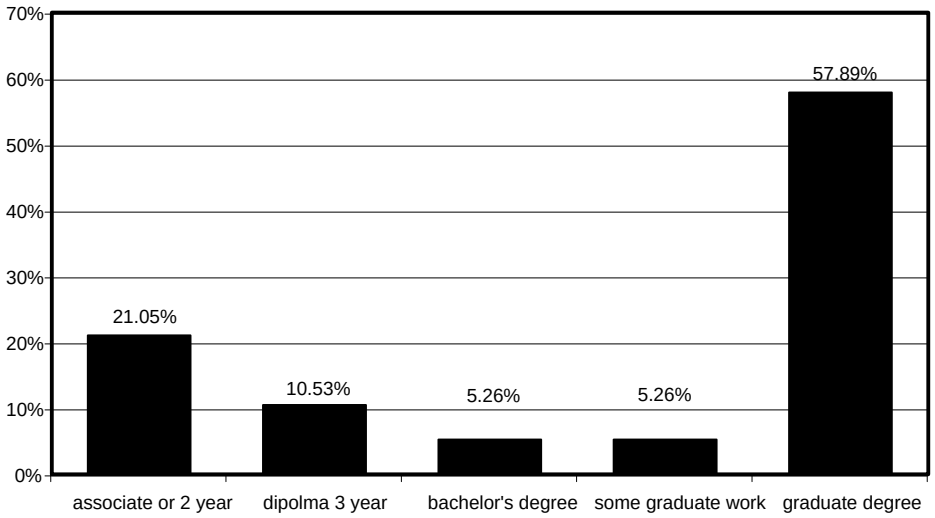
For instance, the 2009 salary survey shows that nearly half of respondents reported no change in their salary over the past year. By comparison, the 2008 salary survey showed that 90% of respondents received a raise.

Also, in 2009 about 37% of respondents reported modest raises of 1% to 3%, while only 15.79% reported raises in the 4% to 6% range.

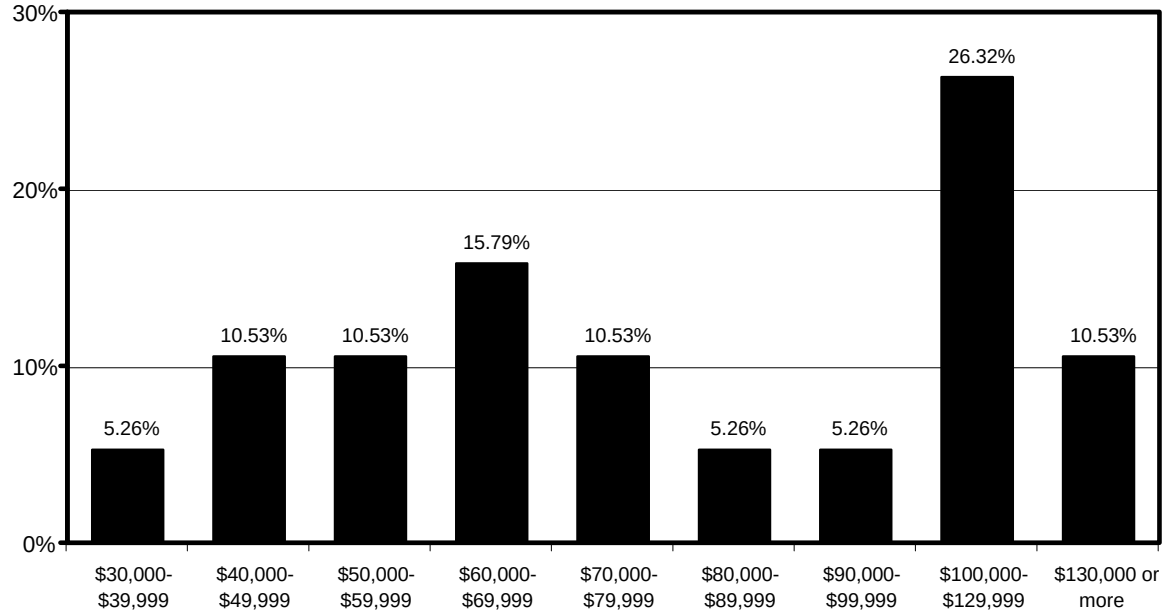
This trend likely is due to across-the-board salary freezes at major research institutions and health systems.

Institutions like Harvard University in Boston are freezing all staff salaries and making it more

What is your highest degree?



What is your annual gross income?



difficult to hire new employees or replacement staff, notes **Ramesh Gunawardena**, MBA, director of clinical trial operations in the clinical trial office of Beth Israel Deaconess Medical Center in Boston. Gunawardena is an editorial advisory board member of *Clinical Trials Administrator*.

"I have staff meetings every week, and I tell them about the financial status of the institution and how privileged we are to still have our jobs," he says.

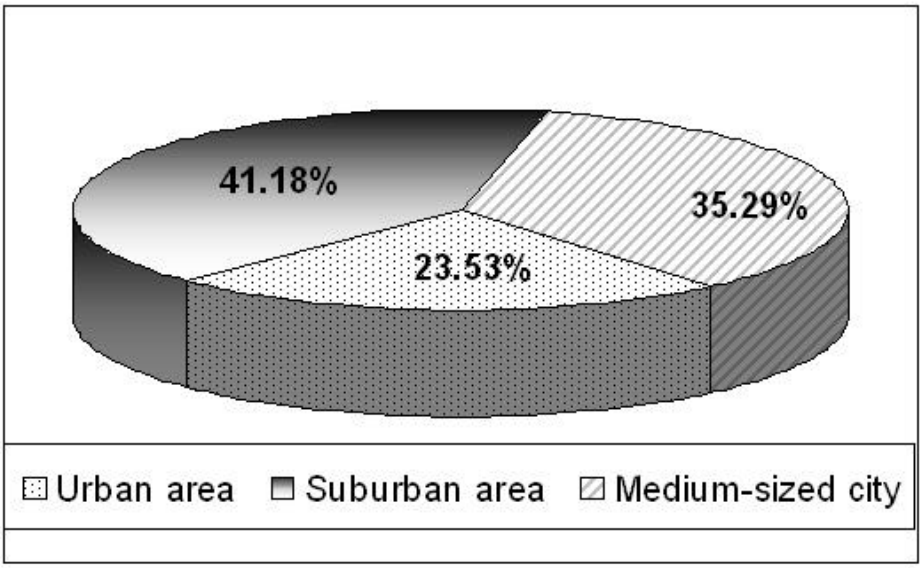
The salary and benefits cutbacks are not personal and are across-the-board, he says.

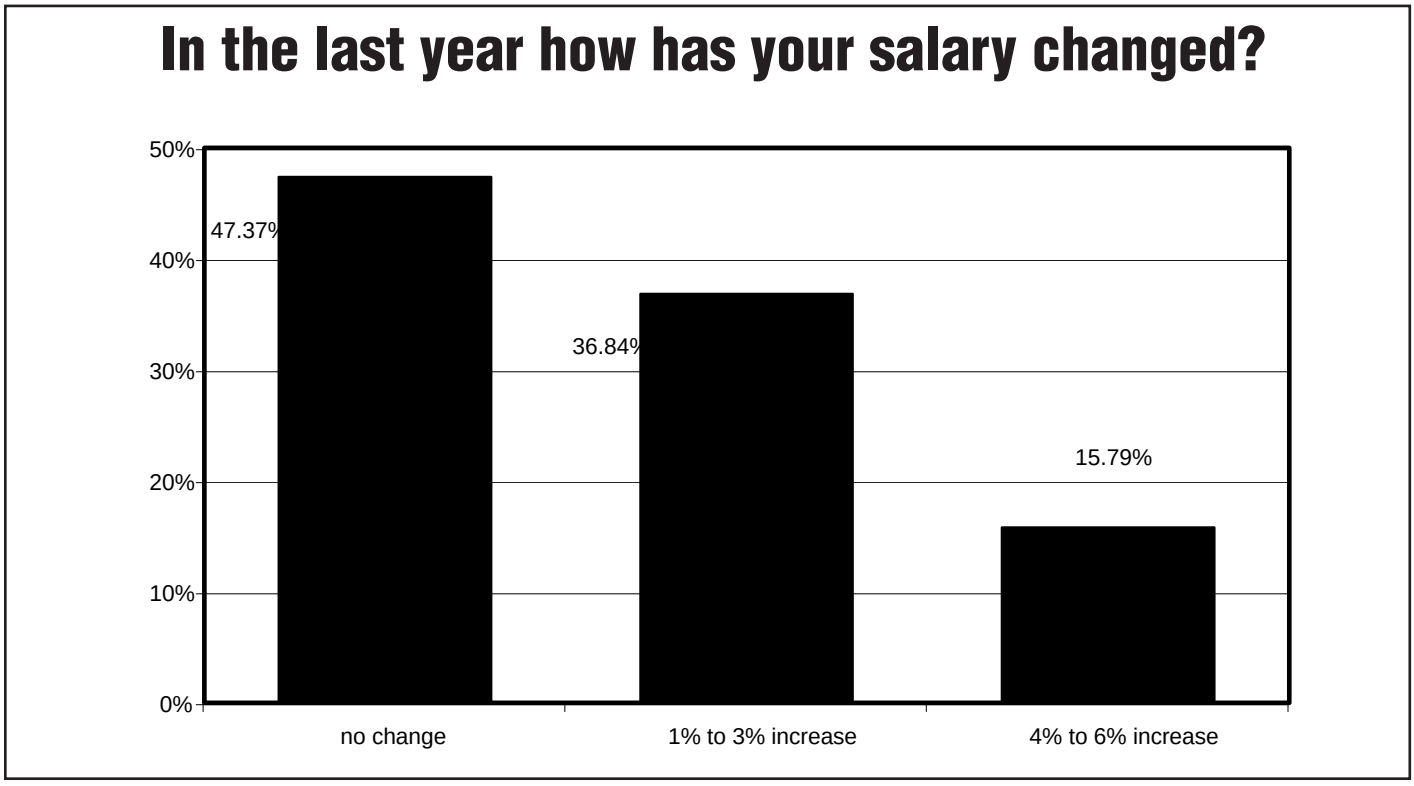
"We reassure staff that the cuts are not because they're not doing a good job, and we'll praise them even more, recognizing the work they do," Gunawardena adds.

It's been difficult to maintain employee morale in CR offices, but it helps to offer frequent positive reinforcement and to structure jobs where everyone is cross-trained, Gunawardena suggests.

"Everyone here is cross-trained, and if there's a need and someone is stressed, then we can reassign another staff member to that position," he says. "That's one of the most important things —

Where is your facility located?





to cross-train staff so we can have stopgap measures."

One trend reported by respondents to the 2009 salary survey is that CR offices are short-handed, and it's been difficult to obtain funding for hiring additional staff.

Some predict this trend soon will change.

"From the research perspective, I think this is a momentary lull, and I think we're going to see some hiring in the next year or so," says **Stephen L. Kopecky**, MD, a physician in cardiovascular diseases and internal medicine and a professor of the Mayo Clinic College of Medicine in Rochester.

However, the domestic CR industry faces some long-term problems, Kopecky adds.

"I do believe in the long run that research in the U.S. is still a difficult road," he explains. "We're pricing ourselves very high compared with the rest of the world, and the rest of the world is starting to improve their research."

The 2009 federal stimulus package and its funding for research will benefit U.S. clinical research sites in the near future, however, he adds.

In other results from the 2009 salary survey, CR respondents were somewhat younger, less experienced, and less highly-paid than in previous surveys. While about 95% of respondents in the 2008 survey had worked in health care for 13 or more years, only about 79% of respondents reported 13 years or more experience in the 2009 survey.

Also, the last survey found that 94% of respondents reported making $60,000 or more per year. In the 2009 survey, about 74% of respondents reported making $60,000-plus annually.

The percentage of salary survey respondents who reported losing staff this past year has increased, as well. In the 2008 survey, about 20% of people surveyed said they had lost staff; in the 2009 survey, 31.58% of those surveyed said they'd lost staff. Conversely, an increased number of sites have gained staff. While about one-quarter had gained staff in 2008, now 36.84% have reported gaining staff.

In at least one way the recession has helped with staffing issues: fewer people are voluntarily leaving their current CR job to seek better pay.

"We haven't had anyone leave in the last two years," Gunawardena says. "The economy has in a sense helped because we don't see too many people jumping around in jobs anymore."

Also there have been more people applying for clinical research positions, although many of the unsolicited resumes show no CR experience, he says.

"What we've seen is a whole slew of people randomly applying for positions," Gunawardena says. "These are people with 10 years, 20 years of unrelated experience applying for clinical research jobs because they had some biology classes in college and think they can turn their attention to that."

At the same time it's also been easier to hire

people with more experience, he adds.

"For the cancer center in the study coordinator role we have four different levels, a CR1, CR2, CR3, and a clinical trial specialist, which is the highest role," Gunawardena says.

"What we found in the past is it's fairly easy to find candidates for the CR1 and CR2 levels because the CR1 is the level of new college graduates, and there's a new batch each spring," he explains. "The second level requires two years of experience, and that's fairly easy to hire too."

But traditionally the two highest levels proved a challenge to fill, and now that has changed with more candidates applying for jobs with several years or more of experience, he adds.

The key is to match candidates and their experience to the CR site's needs, and this can be tricky.

"You don't want to hire someone just because they have 10 years of experience," Gunawardena says. "They could be just trying to find a temporary job while they're looking for the ideal job, and you don't want to be that transition job."

So while there's a bigger pool of experienced CR professionals available than there has been in the past, the key is to not hire people with too much experience and then find out they weren't planning to stay for long, he adds.

Some of the trends noted in the 2009 *CTA* salary survey are mirrored in other health industry surveys.

For instance, a Georgia Hospital Association (GHA) survey conducted earlier in 2009 found that 60% of its hospitals had considered reducing staff, largely due to budget problems resulting from increases in patients who are uninsured.

Also, the Hospital Nursing Study 2009: Vermont Health Workforce Assessment Survey found that nursing vacancy rates have declined because of the recession.

Other findings in the 2009 salary survey were that 63.15% of respondents reported having six or more people in their departments, and only 10.53% reported working 40 or fewer hours per week. More than 26% reported having work weeks of 51 hours or more.

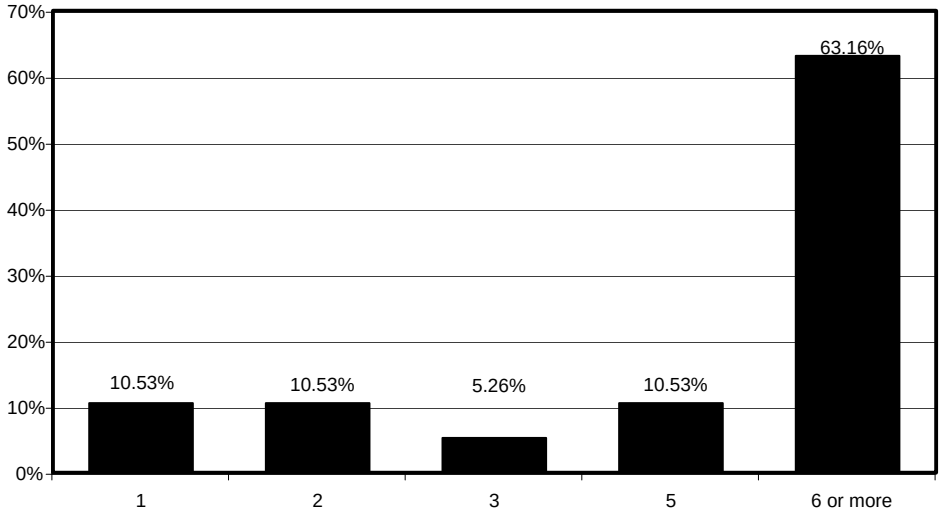
Some of the chief personnel concerns listed by respondents of the 2009 salary survey included these comments:

- "Finding qualified, experienced staff;"
- "Payroll in a down economy;"
- "I need more positions approved to grow the clinical research department;"
- "Lack of study coordinator pool;"
- "Maintaining the quality of my work and being able to meet the deadlines for deliverables."

More than 65% of the 2009 salary survey respondents reported having earned a bachelor's degree or higher education, continuing a long-term trend of better-educated CR professionals.

"I've looked at many job postings, and across-the-board they will ask for an advanced degree," Zimmerman says. ■

How many people are in your department (trial coordination)?



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