CLINICAL TRIALS
ADMINISTRATOR
An essential resource for managers of clinical trials

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IN THIS ISSUE

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Research organizations closely analyze sponsors and studies for a good match

Key strategy: Send sponsors questions

Both new and mature clinical research organizations can reduce clinical trial problems and failures through initiating or improving protocol feasibility analysis processes.

"We don't want an investigator to sign a contract with a pharmaceutical company and not fulfill that contract because we don't have the resources or patient population," says **Marietta Barton-Baxter**, CCRC, administrative director of the Clinical Research Development and Operations Center (CRDOC) at the University of Kentucky in Lexington, KY.

So the key is to thoroughly analyze each protocol to make certain its patient population, enrollment goals, timeline, and other aspects will fit with a particular research organization, she says.

For new central clinical trials offices, protocol feasibility analyses are a way to create a more efficient and effective CR process from the start, says **Rachel Sheppard**, MBA, CCRA, CCRC, project director of the Office of Clinical Research Services and Support at the University of Louisville in Louisville, KY.

Although the University of Louisville central clinical trials office was established in July, 2008, the office's core group has been working together for about nine years as a departmental research institution, Sheppard says.

The office now has 120 trials entered in its database, and 17 protocols have been rejected, mostly based on inclusion/exclusion criteria, but also some rejected based on timeline, she says.

The protocol feasibility process is voluntarily offered to investigators and departments and not everyone participates, she says.

Sheppard estimates the study's success rate in enrollment is close to three times greater for protocols that have been through the feasibility process than for those that were not submitted to the process.

"Over time we saw that many of the projects we accepted were not appropriate," Sheppard says. "We had many instances where we felt we could have done a better job of investigating the research before we accepted it."

The old paradigm was that sites should accept any research protocols

sponsors offered.

"That, of course, is not the case," Sheppard says. "So we wanted to evaluate protocols in a more efficient, standard way."

The key is to develop a protocol feasibility analysis process.

This can be a formal process in which various people are assigned roles and have tasks to complete, or it can be an informal process in which experienced CR employees make recommendations based on their past experience.

For instance, the CR office at the University of Kentucky has a less formal process that relies on the expertise of its staff to weed out inappropriate protocols, Barton-Baxter says.

Here are suggestions for establishing or improving a protocol feasibility analysis process:

1. Find out more about the protocol and sponsor.

Both the University of Kentucky and the University of Louisville CR offices send sponsors questionnaires as part of their protocol feasibility process. **(See story on sponsor questionnaires, p. 136.)**

If a CR organization has had no past experience with a particular sponsor, then it'd be wise to research the sponsor's reputation and past performance, Sheppard and Barton-Baxter suggest.

"I'm a member of a number of different site manager list servs," Barton-Baxter says. "I know which pharmaceutical companies are not on the up and up."

Also, the University of Kentucky contracts with many sponsors repeatedly, so the CR office knows how each handles studies and issues that arise during a trial, she adds.

"Every time I have this discussion with people who are new to this field, everyone wants a fail-safe way to see if it's feasible for them to do this study," Barton-Baxter says.

But there are no guarantees, she adds.

Sites can do their best to make certain a sponsor is reliable and fair, and then only experience will show if their judgment is correct.

2. Ask for opinions from various experts in your organization.

"When we're just starting to look at a study, we get all of our troops together to look at where we are," Barton-Baxter says. "We have a working meeting at the beginning of every study."

Usually, this means the principal investigator (PI) will meet with the regulatory manager, clinical manager, and marketing and recruitment manager, if the clinical trial will be utilizing all of these resources, she notes.

At the University of Louisville, various CR disciplines also are involved in the protocol feasibility process, including the investigator, regulatory manager, and clinical team, Sheppard says.

Various individuals give a recommendation for whether the organization should do this particu-

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lar study, she adds.

Then, one person reviews the recommendations and makes a final decision.

"We leave it up to each individual department to decide how they want to approve feasibility," she says. "For some it's the department chair that makes the decision; for others it's the principal investigator."

3. Use a feasibility form to document criteria and decision.

"We have a feasibility form that we complete internally for evaluation of the protocol," Sheppard says. "The form is important to us because it provides information on the protocol in an organized way, based on functional areas."

For instance, there's a section on impact, which is very important to PIs, she notes.

"Investigators look at the impact of the protocol on patient care, reputation, academic activity," Sheppard says.

The PI will answer the questions in this section and then make a recommendation about whether the study should be done based solely on the study's expected impact, she adds.

The form asks PIs to make a small explanation for their recommendation.

"If there is no other treatment for the patient or patient population then they are encouraged to give more information on the form," Sheppard says. "They might say, 'This protocol is very important to this population, so unless there are considerable financial issues, I'd like to proceed.'"

The form also has a section on enrollment. PIs and the clinical team will examine the protocol's inclusion/exclusion criteria to see if they're appropriate for the site's patient population, Sheppard says.

Another section involves procedures.

"We look at whether the protocol's procedures are in line with our standard practice," Sheppard says. "We address whether they are ethical for the patient population and whether they'll be difficult to schedule."

Clinical trial coordinators, PIs, and the clinical team collaborate on making a recommendation regarding the procedures section.

A financial section is reviewed by the CR financial manager, who answers questions about whether the site has worked with this sponsor or clinical research organization (CRO) in the past and if there was a successful financial relationship, Sheppard says.

"Is the company solvent? Have all the expenses of the trial been identified in a draft budget?" she adds.

The general protocol section discusses whether the protocol agrees with ethical judgments for patient treatment, she notes.

"Is this study similar to other projects we've performed in the past? Are there any issues related to placebos or standard of care, special equipment, subject compliance?" Sheppard says. "We take an overall look at the protocol and ask whether we anticipate any problems in IRB approval."

The clinical team and regulatory manager review this section.

Another section relates to sponsor expectation, and this one will include information from the sponsor questionnaire about the study's timeline, number of subjects expected to be enrolled, and the duration of the project, Sheppard says.

After each section of the six-page form, an assigned person makes a recommendation, putting his or her initials beside either recommended or "not recommended."

Occasionally, reviewers will disagree and they might write a note documenting the disagreement, such as the following: "I don't think this is a problem, but the rest do," Sheppard says.

Also, the person who makes the final decision should document reasons for turning down a particular study, and these typically are sent to sponsors.

"We encourage that person if they reject the study to identify the reason for rejection so we can send it back to the sponsor," Sheppard says. "If they decide to have a protocol amendment then it could impact our decision whether to participate in the study."

At times, the organization has heard from sponsors who have asked the research team to take a second look at a study after they made changes based on the feedback, she says.

There was at least one case where the institution did reconsider and accept a protocol that had been changed, she adds.

The protocol feasibility program has been successful thus far.

"Study coordinators are very happy with this feasibility process because they feel like they finally have a say in how trials are accepted," Sheppard notes. "The PIs also feel they get a say in the evaluation because of the impact section."

The process is being tweaked as it evolves.

"Since this is a new process, we're still defining how to make it a better and faster process

because it does add time at the beginning of a study," Sheppard says. "But we feel like we're doing a better job of selecting trials now and in the long run there are fewer people spending time on a trial that won't be successful." ■

Getting quick answers to important issues

Sponsors are fine with questions

Pharmaceutical companies routinely send out their own feasibility questionnaires, asking clinical research (CR) sites whether they have the appropriate patient population and the resources necessary for a specific clinical trial.

CR directors are accustomed to answering these types of questions, says **Marietta Barton-Baxter,** CCRC, administrative director of the Clinical Research Development and Operations Center (CRDOC) at the University of Kentucky in Lexington, KY.

"But what I kept finding out was that sponsors would come to us at different levels of a study's progress," Barton-Baxter says. "Some would come to us early on when a study was just getting off the ground and they'd need a lot of patients."

Other times, sponsors would knock on the door at the very end of a study when there were just a few months left in which to enroll subjects and they suddenly realized they needed more sites involved.

"And they're doing this big push and need 60 patients now, so we take on the project and then can't get the trial up and running on time," Barton-Baxter explains. "So we have a huge cost because of the start-up expenses and we never enroll a patient."

These types of experiences are what convinced Barton-Baxter that her organization needed its own feasibility questionnaire.

A feasibility questionnaire to sponsors makes it far simpler for CR sites to make informed decisions about whether a particular study is worth pursuing, says **Rachel Sheppard**, MBA, CCRA, CCRC, project director of the Office of Clinical Research Services and Support at the University of Louisville in Louisville, KY.

"When sponsors send out a project there is no normal practice," Sheppard says. "They might send you a CDA and synopsis, or they might send a questionnaire and synopsis."

There's no standard way they send information, and some of what they send to sites might have a lot of details that are not useful in making a decision about whether to pursue a study, she adds.

"So one of the things we've started doing is the moment we receive a project and the sponsor wants to approve our site, we send them a questionnaire for the sponsor or CRO," Sheppard says.

The questionnaire asks for information that sponsors have no problem with sending to sites, but they didn't know the sites need it, she says.

For instance, here are some questions:

- What is the overall timeline of the project?
- How many sites do you anticipate recruiting?
- How many already are initiated?
- When do you expect the last patient in?
- How many sites currently are enrolling?
- May we contact any of these sites to ask them about the protocol?
- Have there been any recruitment issues identified?
- Have there been any recruitment barriers?
- Are you providing a consent template?
- Is there a patient diary?
- If there is a patient diary, will it need to be keyed into a case report form (CRF) by the research personnel?
- Do you use paper or electronic case report forms?
- How many tabs or pages does each patient CRF have?

"These questions help us calculate the budget for a trial," Sheppard says.

For example, there was one recent project where the questionnaire's answers indicated there would be an electronic case report form with 293 tabs, she adds.

"Our budget person used this information to calculate a budget for the coordinator's time," Sheppard explains. "The sponsor saw the budget and said, 'I don't understand why you put in all this coordinator time.'"

So they gave the sponsor their budget calculations for how many hours it would take for the coordinator to handle the excessive number of tabs, and the sponsor finally understood, she adds.

"Having answers to these questions helps in a number of ways," Sheppard says. "It helps us

evaluate the protocol and budget once we decide to accept a study."

And sponsors typically respond positively and within a couple of days, she adds.

At the University of Kentucky, the sponsor questions are submitted formally or informally, based on the site's experience with a particular sponsor, Barton-Baxter says.

"If the protocol is from a new company we've never worked with I'll send them a formal document to fill out, including their contact person for contracts, budgets, etc.," she says. "If it's someone I've worked with for a long time then we'll email them back and forth until we get it resolved."

Questions she might ask include the following:

- What phase is the study?
- How many patients are you planning to enroll nationwide or worldwide?
- How many patients have you enrolled?
- When do you anticipate the study closing?
- Are there any unusual considerations in this study?

"I check to see if there are any unusual circumstances that could affect starting the study," Barton-Baxter says. "We've been doing this for five or six years, and the response from sponsors usually has been very positive."

So far, no sponsor has refused to answer the questions, although occasionally they might not have answers to everything asked, she adds.

"This is in their best interest, as well," Barton-Baxter says. "If we can't complete the study or meet their timelines or requirements, it's not going to be successful for either one of us, so it's in everybody's best interest to get all the information on the table, and I haven't run into any issues." ■

Recruitment: Get bang for buck by tracking returns

Social Web sites opening new doors

Advertising for recruiting subjects to clinical trials used to be easy, if expensive. All a site had to do was buy ad space in a major daily newspaper or regional magazine or fund multiple radio spots, and the task was done.

It doesn't work quite so simply anymore. Big print media outlets are losing readers, and alternative sources are numerous and a little daunting to understand. But on the positive side, clinical research (CR) sites can save money and gain a bigger return for their investment with a little extra work collecting data and tracking results.

"The most heavily used advertising strategy involves print newspapers and magazines," says **Christopher Novak**, MS, LCPC, NCC, director of the Center for Psychiatric Research at Alexian Brothers Behavioral Health Hospital in Hoffman Estates, IL. Novak speaks about recruitment advertising strategies at national conferences, including MAGI's 2009 Clinical Research Conference West, held Oct. 4-7, 2009, in San Diego, CA.

"With the economy and what's going on with electronic mediums, we're seeing decreasing readership of all kinds in print," Novak says. "We've seen a decline in potential subjects' response from our newspaper and magazine advertising."

So Novak looked at other options, including buying ads in niche publications and placing electronic ads on Facebook. The results have been promising with recruitment costs as low as $100 per enrolled participant.

Here is a brief look at the research site's advertising strategies:

- **Buy space in specialty publications:** "With specialty niche magazines we've seen a really good return, and the cost of advertising is cheaper," Novak says.

For example, when researchers were recruiting for a clinical trial about pediatric autism, the site bought ads in a regional parents magazine, he says.

"A lot of times those magazines carry a lot more credibility, and the ad cost can be less expensive," he explains.

- **Track results to monitor a particular advertising medium's returns:** The Center for Psychiatric Research tracks its overall responses to any advertising campaign. So if the center has purchased 20 spots on a local radio station, then the time of the radio ads is noted and compared with phone calls from potential subjects. A morning ad that coincides with commuting traffic might bring in 10 phone calls. Of these calls, two people might end up being randomized to the clinical trial, Novak says.

Those numbers are used to come up with a cost per enrolled subject, and then this data can be presented to sponsors in requests for more advertising dollars, he adds.

"We select our radio stations based on our data," Novak says.

For instance, they might select a radio station based on its ads resulting in more enrolled subjects.

"When we recruit for schizophrenia, we go to news radio on the AM stations," Novak says. "If we're looking for a different population, say for a geriatric depression study, we'll probably look more toward stations on FM or Easy Listening or Oldie stations."

Whenever a particular ad venue works for a population, it probably will work again for a study that targets the same population, he notes.

"The beauty of tracking these data is this becomes great evidenced-based practices to go back and look at," Novak says. "We say to sponsors, 'Here's the response we got from the initial $5,000 you gave us, and this is what we need so we can go forward.'"

• **Place ads on social-networking sites online:** Clinical trial sites could purchase inexpensive ads on Facebook, Craig's List, and using Google ad word buys, Novak suggests.

"I think we'll see more and more usage of social networks, especially Facebook," he says. "The beauty of Facebook and with Google ad words is you can control your destiny as far as how much money you want to spend."

These types of ads are called paper-click marketing campaigns. It means CR sites define how much money they're willing to spend for every click someone does on the ad. The more they're willing to spend, the more frequently their ad will come up, Novak explains.

"Facebook has some intelligent technology," he says. "There are a variety of groups and fan pages people join that are of interest to them, and we can target those pages."

For example, if a CR site is recruiting for a study about bipolar disorder, then it can advertise on Facebook's bipolar support group page.

Also, many Internet sites permit advertisers to target a specific geographic area, so their ad money isn't wasted on populations far outside their recruitment reach, Novak says.

"The technology within Facebook allows your ad to be a pop-up ad on the pages of people who have interest in this topic," Novak says. "Then you know how many clicks you've gotten, and you can track the data to find out how many of these turned into phone calls and pre-screened subjects."

Another advantage is that CR sites can test Internet ads with a relatively small amount of ad money, he adds.

"On our first campaign using the Internet, we spent $200 to see what it would do," Novak says. "We got 200 clicks in the first couple of days, and we got two patients brought into the study out of it."

It's a fairly easy and immediate way to respond to an ad from a potential subject's perspective, as well.

"They see our ad in the right-hand corner; they click on it, and it gives them contact information," Novak says.

• **Use direct mail selectively:** "We've found direct mail to be very successful for depression studies," Novak says. "This population is always looking for other opportunities and support."

Direct mail has an advantage over radio ads because it is the type of advertisement someone can put on a dresser until they have a chance to discuss it with family members. With radio ads, a person has to find a phone and call instantly or else they'll forget the phone number, he notes.

People with behavioral health issues have to opt-in to have their contact information and health concern available for distribution. But if they have opted in then CR sites can purchase this information for direct mailings, Novak says.

"We're a very large practice, but we can't just take the hospital's list of patients and send everyone a letter," Novak says. "People have to fill out a card that says they're interested in learning more about clinical trials."

• **Assess benefits of other options:** Other possible Internet advertising sites might include MySpace and Twitter.

Also, some sites might find it worthwhile to advertise on newsletters or other venues run by local support groups and advocacy associations, Novak says.

"If we're running an anxiety study, we'll contact a local support group for depression and anxiety and buy a banner ad to run on their newsletter or on their group's Web page," he says. "We've had mixed results with these because they tend to not have as good a return as we would have expected, but the cost tends to be pretty low."

These sorts of ads could be used just to increase awareness of a CR site, however.

"You need ongoing awareness, ambient marketing, raising brand awareness, and helping people connect your center or organization with what you do," Novak says.

Another option that has worked well is transportation advertisements, he adds.

"We do a lot of bus and rail advertising because we have a huge commuter population here," Novak says. "We can get these ads for less than $5,000, and they stay up for a month or longer."

The response from these ads has been tremendous, he adds.

"The problem is it reaches the general population, so you do get a fair amount of people who call but who don't have what you're looking for, and maybe they just want to talk with someone," Novak says. ■

Sum > parts: Building a high performance CR team

Strive for shared responsibility

Most clinical trial sites rely on a group working together, but the big question is: Do they have a high performance team?

"A high performance team's total is greater than the sum of its parts," says **Barry Sagotsky**, MBA, owner of Magnolia Lane Consulting in Princeton, NJ. Sagotsky also is a partner of Asherman Associates, a New York, NY, firm that focuses on negotiation in pharmaceutical drug development.

Clinical trial sites, as well as sponsors and clinical research organizations, can work to create high performance teams, he says.

Members of a high performance team will support each other naturally and automatically. Their work is effective, efficient, and of higher quality than the work of groups of people placed together, but focused on their own silo or specialty, Sagotsky explains.

Here are the steps clinical trial sites can take as they strive for developing a high performance team:

1. Begin a chartering process.

"Chartering a team is something many people know about, but not too many do," Sagotsky says.

"A charter involves persons understanding the purpose of the team, as well as each person on the team understanding each other's roles and responsibilities to achieve that purpose," he adds.

Each member of the team understands the overall business purpose of why they exist as a team, and each member understands how he or she supports the team's purpose. "It's focusing on the end results first, with details being strategic and operational ways of realizing that end result," Sagotsky notes. "Also, the charter involves knowing who your customers are, who you serve, and who provides you with the information, products, services you need."

Understanding those suppliers and customer needs and interests is key, he says.

2. Keep organization's mission and goal in mind with each study.

Each time a clinical trial site considers conducting a new study, the high performance team should consider whether this study fits in with the site's overall mission or purpose, Sagotsky says.

They should address these questions:

- How important is the trial to medicine, to caregivers, and to providers?
- How important is the trial to patients, family members, and payers?
- What are the pharmacoeconomics (cost/benefit) of the treatment you are helping to prove?

The goal is for each team member, whether their role is study coordinator or investigator, etc. to keep his or her eye on the overall purpose of the organization, as well as on the goal of the study and how the team is functioning, Sagotsky says.

"High performance team members are constantly improving and focusing on the process equally with attainment of goals," he explains. "High performance team members are clear on who they are and what they do, with the team and outcomes coming first."

An analogy is the story of a person walking up to a mason chopping a brick near a huge building. The visitor asks the mason what he's doing, and the mason says, "I'm building a cathedral," Sagotsky explains.

"The gist is that if you're on a team then you're part of the bigger picture," he says.

3. Form small, team-building groups at the start of each trial or when membership changes.

Choose a leader, someone who is an experienced facilitator, and hold a kick-off meeting or an alignment with the team, Sagotsky suggests.

The trial coordinator or contract manager could fill this role. Larger CR organizations might hire a professional facilitator.

Then, CR sites could have the entire team meet to discuss and agree on their personal and team

goals, roles, and responsibilities related to this trial, Sagotsky suggests.

"One activity might be to have each person write down what they think the roles and responsibilities are for the other team members and what are their own roles," he says. "You can sit in a circle, and each person can say, 'Here's what I think you do and what you're responsible for.'"

That person can then correct the others, one at a time, and negotiating when necessary, Sagotsky says.

This exercise will be enlightening for most CR employees, he notes.

"They'll find out that multiple people believe they are responsible for doing the same thing, and sometimes they find out that no one is doing something that's important," Sagotsky says.

This type of group exercise could be revisited each time a team loses or gains a member.

"A high performance team is an aspiration, but it's not really sustainable through any membership changes," Sagotsky says. "Once you've achieved it, a new study coordinator or other team member is brought in, and you have to start all over again."

The team might not start from the beginning, but the team must agree on roles, responsibilities, team norms, and especially issue escalation, he adds. **(See story on four stages of team-building, right.)**

4. Focus team on thinking through their deliverables.

"We deliver clinical research results to a contract," Sagotsky says. "Many people from the CRO to the sponsor try to manage through a contract."

So it's a good idea for CR professionals to know where their site is going and how they'll accomplish their goals of delivering what they contracted to deliver to the CRO and sponsor, he says.

"I speak at the MAGI conference twice a year, and I come in touch with hundreds of people involved in contracting and running clinical trials," Sagotsky says. "And one common sense approach is that CR professionals carefully think through what the site can do and why it should do this."

For example, a site might say it will deliver 20 subjects to a trial, but if the investigator and CR coordinators do not have a clear understanding of what the protocol's inclusion/exclusion criteria entail, then they may be setting the site up for failure.

"If you have a high performance team then the person who is managing the site knows what the site can deliver," Sagotsky says. "A high performance team can negotiate better and deliver results as expected by sponsors."

Members of a high performance team know that even if they make a mistake, there will be someone else on the team ready to cover them, he notes.

"The focus is not so much on you as on the team," Sagotsky says. "The organizational culture of a high performing team includes the attitude of 'Here's how we do it; we know where we're going; we know what our processes are; we know how to execute our mission flawlessly, and if we have a flaw, we know how to fix it.'" ■

Forming, storming, norming, performing

Four-stage evolution of a top team

High performance teams are created through an evolutionary process that at least one model characterizes as having four stages from forming, storming, norming, to performing.

The four-stage model, which dates to the mid-1960s from a classic book by Katzenbach and Smith, called, *The Wisdom of Teams*, and further enhanced by the work of Glenn Parker in a number of books and articles, characterizes the evolution of a group to a high performance team, says **Barry Sagotsky**, MBA, owner of Magnolia Lane Consulting in Princeton, NJ. Sagotsky also is a partner of Asherman Associates, a New York, NY, firm that focuses on negotiation in pharmaceutical drug development.

Here are the basic stages:

- Forming: At the very beginning, individuals in a group form personal relationships characterized by dependence, safe pattern behavior, guidance, and direction, Sagotsky says.

The team will get together, listen to the leader's introduction, address rules and responsibilities, and everyone looks to the leader for guidance, he adds.

- Storming: "A team is at this level the minute someone says, 'I don't agree with this role you have me pegged in or some other issue,'" Sagotsky says. "Or someone might say, 'I don't like the way you're treating me.'"

In the storming stage, individual members are comfortable enough to openly disagree, and arguments can occur. This is not necessarily bad, though unmanaged it can slow a team down or stop progress, Sagotsky notes.

"Well-managed storming can lead to increased trust in the relationship, competition in favor of highest quality in on-time deliverables, and effective bargaining," he adds.

- Norming: "The ground rules become the team's culture," Sagotsky says. "If a ground rule is that one person speaks at a time, and it's enforced, then eventually it becomes automatic, and people manage themselves and each other."

Typically, teams reach the norming stage after the storming stage, he says.

"This is a sequence where sometimes segments happen quicker than at other times," Sagotsky explains. "Norming might happen a year or more after a team is put together, and sometimes it never happens, simply because no one takes the time to agree on and enforce ground rules and processes."

Whenever a member changes, the team should understand they are now a new team, and at the forming stage.

- Performing: "This is where everything is automatic, and personal relationships are not function-based," Sagotsky says. "People move from silos to a team, and the results are that 'All of us are more than the sums of our parts.'"

Problem-solving is more efficient and interdependent. The attitude has shifted from 'It's not my problem to solve' to an attitude that 'It's our problem, and here's my take on it,' Sagotsky says.

In the performing stage, the high performance team is fully formed and there is a group identity and intense group loyalty, he adds.

"It's worth the work and discipline involved to get to the fun, excitement, support, respect, and learning available on a high performance team," Sagotsky says. ■

Research site finds success with electronic recruitment

Don't underestimate Internet's value

Researchers at the decade-old Medex Healthcare Research Inc. of St. Louis, MO, recognized the value of having a Web presence about five years ago.

"The value of that grows exponentially," says **Mark Pinson**, MA, CCRC, vice president of Medex Healthcare Research, a multidisciplinary site that runs 40 to 60 trials at four sites.

Watch how quickly false celebrity death stories spread on Twitter, and one quickly sees the power of the Internet, he notes.

"They have to run real news stories saying the person still is alive, which is an example of how pervasive Internet usage is anymore," Pinson says. "Seventy-four% of North Americans use the Internet, so that's a large penetration rate for getting in touch with people."

Electronic media has the advantage of being available 24/7, he says.

"For TV ads and newspapers, the ads have to be placed at the right time, but the Internet is always available," Pinson says.

"Five years ago we started with a simple Web page where people could identify our current trial activity and contact us about those studies," he says. "They were included in our database."

As the database grew with people interested in the organization's research, Medex Healthcare Research expanded its electronic reach to using the email addresses people had voluntarily given the Web site and which were stored in its database, Pinson says.

"Email marketing has been tremendously successful for us," he says. "We capture the email addresses of individuals interested in studies, and we work with companies that have email databases of people with specific conditions."

For example, the CR site sent out an email message about a new hypertension study and at one location consented 50 subjects based on that email marketing effort, Pinson says.

"The great thing about email marketing is it almost costs nothing per patient or the cost per patient is staggeringly low compared to traditional forms of advertising," he adds.

One key to its success is the connection potential subjects already have with the research organization.

"If you're marketing to subjects you already have a history with then the return is much greater than 1%," Pinson says.

Another resource is the study participant recruiter company called ClinicalConnection of Miami, FL, he adds.

The company obtains email information and other data about people who voluntarily signed up to learn more about clinical research, and their

information is divided by disease state and geographical location, Pinson says.

"So we'll take that data and send information to people in our zip codes around our sites, and we let them know about our study," he says. "Our largest database is in St. Louis, and it probably has information about 75,000 individuals."

The organization's New York database is the fastest growing with more than 40,000 names so far, he adds.

It takes years to develop a good database, but CR organizations can expedite the process by making certain they have an inviting Web site, Pinson suggests.

"The most important tool a site has is their own Web site," he says. "If you're doing Google ads, where are people going to go? If you're doing email marketing, where do they go?"

CR sites should have a credible Web site that discusses their research and studies, Pinson says.

"Without a Web site, there's no reason to do any other form of advertising," he says.

And the Web site should be a key way to capture potential subjects' email addresses, he adds.

"Once you implement your strategy, it's important to recognize that you'll have to dedicate some time to dealing with referrals," Pinson says. "In our experience, we get much more response to something like this versus a radio ad, and so it takes more staff time to process the referrals."

Medex Healthcare Research has a dedicated recruiting department that handles these inquiries, he says.

"Plenty of sites don't have a recruiting department, so they probably shouldn't take on another project when they're swamped and wouldn't be able to deal with having 150 people calling to screen for a study," Pinson adds.

The site's no-show rates are the same as for clients brought in through traditional advertising, Pinson says.

"Subjects who come in through the Internet are more likely to appreciate electronic contact when they're in the trial," he notes. "So if a coordinator has questions or wants to reschedule an appointment, then these people are more open to receiving emails from our coordinator."

A CR site's Web site should first serve as a marketing tool that explains what research is for people who don't know anything about clinical trials, and it could serve as a way to reach both people who want to enroll in a trial and those who might not be considering study enrollment in terms of their treatment options, Pinson says.

CR sites can reach these types of potential subjects by placing advertisements on Google that will come up when people type in a particular disease name or symptom, he suggests.

For example, if someone suffers from shingles pain and types on that word on Google, the CR site's ad will pop up.

"This might be the perfect opportunity to place a Google ad because you're pushing your message out to these individuals, who might not have considered a study before, and now they have something in their face and talking about research opportunities," Pinson says. "We use only Google because we feel like it's the largest search engine for providers."

A CR organization's Web site also must be listed on all other ads, no matter the medium.

"Our traditional media advertisements list our Web site on every posting," Pinson says. "This helps individuals who may not be ready to call you on the phone yet, so before they call they'd like to learn more about you by checking out a Web side address." ■

CR Industry News

AAHRPP revises standards

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) recently issued the final version of the first major revision of its standards since AAHRPP was founded eight years ago.

AAHRPP, a nonprofit accreditation organization, streamlined the number of standards and increased flexibility in how to interpret them, even as it added or strengthened standards on global research, conflict of interest, community-based research, and data and safety monitoring, according to the organization's news announcement.

The organization comprehensively reviewed its standards, strengthening, updating, and streamlining them.

There are no major changes in the requirements for accreditation, but the changes provide a more logical framework for a human research protection program, according the **Marjorie A. Speers**, Ph.D., President and CEO of AAHRPP.

Overall, AAHRPP has reduced the number of standards from 22 to 15, and the number of elements, from 77 to 60.

AAHRPP began developing a set of Proposed Revised Accreditation Standards at the end of 2008, and presented them for public comment on June 1, 2009. When the comment period ended on July 30, 2009, AAHRPP used those comments to develop the Final Revised Accreditation Standards issued on Oct. 1, 2009.

Research organizations that apply for accreditation through Feb. 28, 2010, may follow the revised standards or the current standards, which were in effect before Oct. 1, 2009. Then on March 1, 2010, all new applicants will have to follow the revised standards, which will be called the AAHRPP Accreditation Standards.

To view the Final Revised Accreditation Standards, visit AAHRPP's Web site at aahrpp.org. The Evaluation Instrument for Accreditation based on these revised standards also is available on the Web site. ■

Researchers have new online social network

The American Association for the Advancement of Science (AAAS) of Washington, DC, has recently launched the Clinical and Translational Science Network (CTSciNet), a social network for people involved in careers in clinical and translational research.

AAAS also launched My Science Network, MySciNet, a social network that connects minority women scientists, engineers, and students.

The sites were developed with funding from several scientific societies, corporate and foundation funding. CTSciNet was funded by a grant from the Burroughs Wellcome Fund, and CTSciNete received funding from Genentech and Pfizer.

The goal is to promote the professional development of scientists and to meet key science policy objectives, according to Jim Austin, a principal investigator for the CTSciNet project.

Scientists may access the social networks for free, joining virtual groups, reading articles, and passing along information from outside sources.

The networks have features similar to other social network sites online, including Facebook, Twitter, MySpace, etc. The sites will be monitored by Science Careers staff and are exclusive to scientists, science trainees, science career experts, and science professionals, according to a news announcement by AAAS.

Also, Science Careers provides free resources for scientists, including online articles, booklets, webinars, and workshops. ■

CNE/CME Objectives / Instructions

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

- **review** pertinent regulatory mandates;
- **develop** practical clinical trial oversight strategies;
- **review** 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

- Here's the good news/bad news in CR employment
- CR sites need better education strategies for clinical nurses
- Create better timeline for contracting and IRB submission
- Improve your compliance audits with this strategy
- Tips on conducting peer reviews

CNE/CME *questions*

21. When conducting a protocol feasibility study, it is a good idea to include financial questions such as which of the following?
    A. Is the sponsoring company solvent?
    B. Have we worked with the sponsor before and how was the financial experience?
    C. Have all the expenses of the trial been identified in a draft budget?
    D. All of the above

22. Clinical research sites that send sponsors a questionnaire as part of the feasibility process should ask all except which of the following questions?
    A. How many sites currently are enrolling?
    B. Have there been any recruitment issues identified?
    C. What are the precise dates and times of all monitor visits?
    D. Do you use electronic or paper case report forms?

23. What is an advantage to placing subject recruitment ads on social networking sites?
    A. Their cost is relatively inexpensive and the sites often collect valuable data that can be used in making future advertising decisions
    B. It's a good way to get general name recognition
    C. The phone calls resulting from the ads are more plentiful than other forms of advertising
    D. All of the above

24. A high performance team goes through four stages, according to one 40-year-old model. What are the four stages?
    A. Initiation, connection, integration, completion
    B. Forming, storming, norming, performing
    C. Greeting, meeting, repeating, treating
    D. None of the above

Answers: 21. D; 22. C; 23. A; 24. B.

CLINICAL TRIALS ADMINISTRATOR

An essential resource for managers of clinical trials

2009 Index

When looking for information on a specific topic, back issues of Clinical Trials Administrator *newsletter, published by AHC Media LLC, may be useful. To obtain back issues, contact our customer service department at P.O. Box 740060, Atlanta, GA 30374. Telephone: (800) 688-2421 or (404) 262-7436. Fax: (800) 284-3291 or (404) 262-7837. E-mail: ahc.customerservice@ahcmedia.com. Managing Editor: Gary Evans.*

OSHA enforcing N95 respirators for HCWs treating H1N1 flu patients

OSHA: 'We're looking for a good-faith effort.'

By **Gary Evans** and **Michelle Marill**
Editors
Hospital Infection Control & Prevention
Hospital Employee Health

Particulate respirators — a controversial step beyond common surgical masks — are now mandated by the Occupational Safety and Health Administration (OSHA) to protect health care workers from acquiring H1N1 pandemic influenza A from patients. With respirator shortages feared, "good-faith efforts" by health care employers will be recognized by OSHA, which nevertheless is warning that citations and fines may result from inspections that will be primarily prompted by employee complaints.

"Employers should do everything possible to protect their employees," said **Jordan Barab**, acting assistant secretary of labor. He emphasized, however, that where respirators are not commercially available, an employer will be considered to be in compliance if the employer made every effort to acquire respirators. Health care employers will need to be able to show documentation of orders that have been placed or statements from a manufacturer that the respirators are on back order. N95 respirators — already used by many hospitals for the treatment of tuberculosis patients — are the minimum level acceptable for H1N1.

"We're looking for some evidence that the employer has attempted to purchase N95 respirators," Barab said. "We're looking for a good-faith effort."

OSHA is issuing a compliance directive to enforce the Centers for Disease Control and Prevention's recently issued "Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel." (Available at http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm.)

The CDC disappointed infection preventionists in the guidance by reaffirming its stance that surgical masks are not sufficient to protect workers from H1N1 patients. The CDC recommends the use of respiratory protection that is at least as protective as a fit-tested disposable N95 respirator for health care personnel who are in close contact (within 6 feet) with patients with suspected or confirmed 2009 H1N1 influenza. The president-elect of the Society for Healthcare Epidemiology of America said the CDC decision appeared to be made for reasons other than science, which has not shown burdensome, scarce N95s to be more effective in clinical studies.

"They are recommending a respirator that is not readily available, for transmission that has never been shown to be clinically relevant," said **Neil Fishman**, MD. "It presents a hardship to health care workers and health care providers that is unnecessary and offers nothing in [additional] degree of protection."

On the other hand, the CDC is under considerable pressure from health care unions and worker safety advocates since at least four nurses nationally have reportedly died of complications related to H1N1. Noting that H1N1 surveillance systems do not provide occupational data, the National Institute for Occupational Safety and Health (NIOSH) is asking for information from the public on health care worker H1N1 illnesses and deaths. (Information can be e-mailed to nioshh1n1data@cdc.gov.) NIOSH is asking for contact information so the agency can follow up on cases that have primarily been reported through the media.

"Once we get that information, we can make decisions about whether we want to do a more thorough investigation, whether it is a Health Hazard Evaluation or another kind of study," says **Christina Spring**, health communications specialist with NIOSH in Washington, DC.

Meanwhile, OSHA inspectors will ensure that health care employers implement a hierarchy of

Supplement to *AIDS Alert, Critical Care Alert, Clinical Trials Administrator, Contraceptive Technology Update, Case Management Advisor, Discharge Planning Advisor, Drug Formulary Review, ED Nursing, ED Management, ED Legal Letter, Emergency Medicine Reports, Hospital Case Management, Hospital Peer Review, Hospital Medicine Alert, Hospital Home Health, Healthcare Risk Management, Infectious Disease Alert, IRB Advisor, Medical Ethics Advisor, Occupational Health Management, Patient Education Management, Primary Care Reports, Pediatric Emergency Medicine Reports, Same-Day Surgery, State Health Watch,* and *Travel Medicine Advisor.*

controls, including source control, engineering, and administrative measures, and to encourage vaccination and other work practices recommended by the CDC. Where respirators are required to be used, the OSHA Respiratory Protection standard must be followed, including worker training and fit testing. While the ruling clearly applies to hospitals, as this report was filed OSHA had not responded to a written request for clarification regarding other medical settings. Employee complaints from clinics and physician offices could potentially result in an inspection because OSHA's respiratory protection standards also apply to small businesses.

CDC casts wide net

The CDC clarified that the scope of its guidance includes a wide range of medical settings: "This guidance provides general recommendations for health care personnel in all health care facilities," the CDC stated. "For the purposes of this guidance, health care personnel are defined as all persons whose occupational activities involve contact with patients or contaminated material in a health care, home health care, or clinical laboratory setting."

Since a shortage of disposable N95 respirators is possible, employers are advised to monitor their supply, prioritize their use of disposable N95 respirators according to guidance provided by CDC, and to consider the use of reusable elastomeric respirators and facemasks if severe shortages occur, OSHA advised. Health care workers performing high-hazard, aerosol-generating procedures (e.g., bronchoscopy, open suctioning of airways, etc.) on a suspected or confirmed H1N1 patient must always use respirators at least as protective as a fit-tested N95, even where a respirator shortage exists. In addition, an employer must prioritize use of respirators to ensure that sufficient respirators are available for providing close-contact care for patients with aerosol-transmitted diseases such as tuberculosis.

Where OSHA inspectors determine that a facility has not violated any OSHA requirements but that additional measures could enhance the protection of employees, OSHA may provide the employer with a Hazard Alert Letter. OSHA will inspect health care facilities under the Respiratory Protection Standard "to ensure that health care workers are protected and that protection is in line with CDC [guidance]," Barab said.

The CDC guidance to use respirators has been controversial and hotly debated almost since the onset of H1N1 last spring. Many infection preventionists argue that H1N1 is comparable to seasonal influenza in its virulence and transmission routes, and that droplet precautions (e.g., surgical masks) are sufficient. In fact, some state health departments diverged from CDC and called for surgical masks unless health care workers were performing aerosol-generating procedures.

The Healthcare Infection Control Practices Committee, a CDC advisory panel, endorsed the use of surgical masks rather than respirators. But an Institute of Medicine (IOM) panel charged with reviewing the available science concluded that surgical masks would not protect workers from airborne influenza particles. "[T]here is evidence that work-related exposures to patients infected with H1N1 virus result in health care workers becoming infected," the IOM report stated.

The answer, decided CDC director **Thomas Frieden**, MD, is to use respirators but to limit their use through other measures. "Use a scarce resource carefully," he said in a briefing on the guidance. "Follow a hierarchy of controls and limit the number of people who are potentially exposed and would need a higher level of protection."

The CDC is no longer recommending contact precautions — the use of gowns and gloves — but Frieden noted that influenza is spread through droplet, fomite, and aerosol transmission. "It is an unfortunate fact that we do not have definitive evidence on the portion of transmission that occurs from each of those three routes," said Frieden, noting that "the preponderance of belief" was that droplets were the most common route. "With that lack of knowledge and with the newness of H1N1 . . . we are recommending that N95s . . . would be clearly superior to surgical masks."

Still, CDC is providing some flexibility to hospitals. That means in some circumstances, health care workers may reuse respirators, continue to wear them while caring for more than one patient, or may even wear surgical masks as a last resort option. CDC states that extended use (in which the respirator is not removed while the health care worker cares for more than one patient) is preferred over reuse.

"We recognize that there may be shortage situations," said Frieden. "The need is for us not just to provide respiratory protection now, but the flu season lasts through May. We need to ensure we have a reliable supply."

The CDC guidance states that "when in prioritized respirator use mode, respirator use may be temporarily discontinued for employees at lower risk of exposure to 2009 H1N1 influenza or lower risk of complicated infection." ■