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Key clinical research industry problems stem from dysfunctional, indecisive teams

Experts offer behavioral-based solutions

The clinical research industry's paralyzing delays, millions of dollars wasted on dead ends, and resource inefficiencies are the result of faulty team mechanics, several experts say.

The pharmaceutical-biotech industry has an alarmingly high rate of failure on all projects, and three-quarters of the industry's revenue now comes from collaborations, which means there are systematic team and communication problems, says **Curtis Sprouse**, president and chief executive officer of EurekaConnect and Boston Market Strategies of Ipswich, MA.

"The quickest way for these companies to build research and development is to salvage and save more of these collaborations and alliances," he adds. "They need to manage better what they have, and it's all affected by individual and team behavior."

First, organizations need to know where their problems lie.

"With this industry in general what we have found is that the problem is not the talent; it's not the lack of ability; it's the mechanics that need to be tweaked," says **Ross Giombetti**, MBA, vice president of Giombetti Associates in Hampden, MA. Giombetti is a Six Sigma Greenbelt.

Giombetti and colleagues analyze team performance and team members' behavior in the clinical research industry, helping companies improve their efficiency and develop high performance teams. The assessment takes 20-minutes, per-person, analyzing reflectivity, delegation, discipline, collaboration, avoidance, accommodation, communication, and other social skills. Called Performance Dynamics, developed by Giombetti Associates and Behavioral Dynamics of EurekaConnect, these types of assessments provide insight into what is causing a particular company or team's delays and obstacles.

"We analyze 17 characteristics, mapping these and drawing a graph," Sprouse says.

"We also look at influence models and three internal behaviors that

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drive how we influence people," he says.

One telling trend appeared during assessments of research teams.

"Our research validates that this industry has the talent, intelligence, science, and compassion to solve any problem that comes its way," Giombetti says. "But there's a systemic problem caused by their actions and behavior."

Taking this observation to the micro level, you could blame most of the industry's problems on passive-aggressive behavior — or the proverbial bad apples.

"We see passive-aggressive behavior on every team we interact with," Giombetti says. "What's commonly seen in this industry is what we refer to as the cholesterol of the industry because it blocks their ability to survive and live."

Passive aggressive behavior hinders progress and can be the demise of whole projects," says **Kara Cleveland**, a principal with Colby Management Group, a San Antonio, TX, biotech/pharma/IT consulting company. Cleveland has used the Performance Dynamics assessment to analyze a collaborative research team's performance and found it to be very accurate and useful.

"People don't realize how much it undermines the process of what needs to be done," she adds. "Aren't we here to get drugs to market?"

Yet, some bad apples hinder the process for their own personal and political gain.

While passive-aggressive behavior among team members is not rare, there is a strikingly high amount of this behavior in the research industry, experts say.

"People are either afraid of losing their jobs, afraid of hurting other people's feelings, or they just don't like conflict," Giombetti says. "So as a result they don't deal with real issues directly and operate more behind the scenes subtly, and the real result is a lack of trust."

Research professionals are afraid of exposing themselves and putting themselves out there, Sprouse says.

This type of behavior also becomes indecisiveness, which contributes to delays and blockages in the research pipeline.

Another common issue involving research teams is the way leaders are selected. The research industry tends to reward scientific excellence based on knowledge and experience, but not leadership.

"If someone is a great scientist, we will tolerate bad behavior, and that's a fundamental problem," Sprouse says.

Sprouse consults with companies to provide team-building guidance after each team and individual members are assessed for leadership, team-enhancing, and maladaptive behaviors.

"I worked with one team in its 18th year of collaboration, and the product was not on the market yet," Sprouse recalls. "I said, 'Do you think this is normal?' And they said, 'Yes. It's how long we take to get something done.'"

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EDITORIAL QUESTIONS

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The research industry possibly is unique in tolerating and even accepting that type of delay. The industry will be able to change this counterproductive culture and legacy only after addressing dysfunctional team behaviors, Sprouse and Giombetti say.

The key is that individuals and teams can change their behavior and dynamics, and if they change, so can the industry improve. *(See story on strategies to improve team performance, p. 28.)*

Sprouse offers this example: he worked with a man who had 25 years of experience and a number of important professional and personal skills. Yet his bad behavior was hurting the team and reducing its productivity. The behavioral specialist showed the man data explaining how the man was seen as a know-it-all who spent almost no time listening to others.

"He said to me, 'No one ever told me I'm a jerk;' You defined for me why I'm a jerk," Sprouse recalls.

The man did not realize he was jeopardizing the team's success.

"They were considering getting him off the team because his performance was unacceptable," Sprouse says.

But after the individual profile in which the man heard objective feedback about his strengths and weaknesses with regard to his behavior on the team, he turned everything around, quickly becoming a key member of the team.

"Intellectually, we helped him see why people didn't like him," Sprouse says. "His listening scores were awful, and no one had taken the time to tell him where his deficiencies were."

This example is emblematic of what the research industry is facing right now, he notes.

"Because of behavioral dynamics, the industry has an underlying condition that is dangerous to teams, and they're doing nothing to manage it," he says. "We talk to heads of pharma companies, and they think they're different, but these behavioral traits go across the industry."

On a positive note, research teams also are very bright and are capable of making measurable and relevant change quickly, Sprouse says.

"But management has to recognize they need to define the situation and take action based on specific team needs, alliances, and collaborations," he adds.

The first step is to assess teams for their performance motivation and obstacles to success.

When problems occur because of one or more team members' behavior then management should require the team members to correct the problematic behavior or have them moved off the team, Sprouse says.

"When you have a bad apple, can this person be developed into a proficient player?" he says. "Make them a contributing member of the team if you can."

The assessment also can help leaders improve their own deficiencies.

For instance, Cleveland learned from her own assessment that she was very high in leadership qualities, but was low in goodwill. This was in the context of a team that had a high number of people with very high goodwill scores, high accommodation scores, and low scores on the leadership qualities involving competitiveness and decision-making. While Cleveland's approach on the team was assertive and goal-driven, many team members had qualities that point to passive-aggressive behavior. This also meant that goodwill was highly valued on the team.

Cleveland's no-nonsense management approach was viewed negatively by some members of the team, and she learned that she might elicit better responses from them by improving her goodwill.

"I had to address things in my personality that I didn't realize were affecting people," Cleveland says.

Cleveland shared her personal profile with the team and encouraged joking and advice. One member said the behavior attributed to Cleveland was right on target and even gave an example of when she had behaved exactly that way.

"I was able to show everyone that this was an issue I have and they could call me on it," she adds.

Goodwill isn't the most important trait on a team or in leadership, but it should be a part of a team dynamic, Sprouse notes.

"It's the human way of doing things, showing you care more about the individual than what they produced for you in the last five minutes," Sprouse says. "You'll react much better to me if I take some interest in you; it's human nature."

It's also wiser: "By knowing a team member better, you know when it's appropriate to push and when it's not appropriate," he says.

"These subtleties are lost on many of these teams, especially in heavily scientific and technical groups that are driven by numbers, facts, and are heavily analytic," Sprouse says. "I've had a lead scientist on research and development programs tell me it doesn't matter what these people are like; it only matters that they know science." ■

Experts' strategies for CR team performance improvement

Analyze, seek individual improvements

Individual research institutions and companies can turn their low-performing teams into high-performing teams by addressing behavioral and personality problems.

Experts offer these suggestions for how to turn a low-performing team into a high-performing team:

• **Analyze teams and their members for internal motivation**: "We think internal motivation is genetically pre-disposed," says **Ross Giombetti**, MBA, vice president of Giombetti Associates in Hampden, MA. Giombetti uses a behavioral/personality assessment process called Performance Dynamics with research teams to identify their obstacles to success.

"If your team and culture are highly-motivated, meaning your company moves very quickly and you bring on board somebody who does not possess the areas that drive motivation, then they'll be a mismatch with your team and culture," Giombetti says.

Mismatched team members cause conflict and stress on teams.

Also, born leaders tend to be competitive, high energy, disciplined, and have strong internal motivation.

"Natural-born leaders are naturally able to influence people, and they typically have an ability to think and strategize effectively," says **Curtis Sprouse**, president and chief executive officer of EurekaConnect and Boston Market Strategies of Ipswich, MA.

"They manage authority well and don't hammer people, but handle things appropriately," Sprouse adds.

These personalities are desirable on teams, but they can be rare and should be nurtured and given the opportunity to meet their potential, Sprouse says.

Unfortunately, the research industry often has such talent hidden away in labs or backrooms cranking out statistics, and no one realizes they have strong interpersonal skills and can inspire and lead, Sprouse says.

Or, worse, such leaders might be suppressed on a team that is dysfunctional.

For instance, team members might be resistant to improving their leadership skills and qualities, says **Kara Cleveland**, principal of Colby Management Group, a San Antonio, TX, biotech/pharma/IT consulting company.

"I was working with a team and tried to invite people to a global leadership group, and they looked at me like I had three heads," Cleveland recalls.

Cleveland also encouraged team members to join local networking and leadership groups, but one person on her team sought to derail this idea.

"This person said there was a leadership group within the company, and that was the route they take," she says.

Cleveland eventually succeeded in obtaining buy-in for the behavioral/personality assessments by presenting these as tools that would help people develop their leadership skills. Once the first group of people went through the assessment process, they were sold on it and talked about it with their colleagues.

• **Address team members' attitude**: "The biggest detractor of team performance is attitude," Giombetti says. "You can hire somebody who has all the talent in the world and all the technical ability to solve any problem that comes their way, but if they have a terrible attitude they'll be a terrible detriment to your team and single-handedly bring it down."

Some people with bad attitudes can change. In other cases, it might be better to fire the person who disrupts the team.

"We saw one team of 12 people in which four were naturally-born leaders, and that's highly unusual," Sprouse says. "But the team had one toxic personality, a person who was likely to disrupt or destroy the project."

The bad apple's behavior involved exerting control over all aspects of the project regardless of whether other members of the team had more expertise and experience.

"This type of person comes to a meeting and says, 'I don't agree with you,' but offers no solutions," Sprouse explains. "Or the person might say to the boss, 'I don't know what I'm supposed to be doing,' giving the team the perception that the leader hasn't communicated clearly."

Cleveland handled an incident like this by addressing the person's bad attitude in front of the team.

"I said, 'Help me understand. You've been here six months, and you mean to say you don't know

what your role is?'" she explains.

In Sprouse's example, this one bad apple was bringing down the entire team. The disruptive team member admitted to the bad behavior, but said it would change. Unfortunately, this change never occurred, leaving management to make a decision about whether to save the team by taking this one person off of it or letting the unsatisfactory status quo continue.

On the other side, team members with positive attitudes often are people who have good interpersonal skills. They care about people and care about the team, Giombetti says.

"The biggest asset and contributor to any team is interpersonal skills," he says. "One trait that measures attitude is compromise; it's a personality trait that measures one's ability to be open-minded, flexible, and adaptive to the ideas and opinions of others."

On one side you have people who will search for the best possible decision for the team. On the other side, you have someone who is strong-willed, opinionated, cynical, and inflexible, and who wants it done his way, he adds.

• **Help turn-around passive-aggressive behavior:** In the research industry, passive-aggressive behavior is prevalent and contributes to the industry's indecisiveness and problems, Giombetti, Cleveland, and Sprouse say.

Team leaders and management should take quick note of these behaviors and address them.

For example, Cleveland was leading a team meeting that was attended by consultants she had brought in to expedite a project's completion. One member of her team questioned why one of the consultants was spending time at a meeting instead of working on assigned tasks. Only this passive-aggressive team member did not ask Cleveland this question. Instead, he emailed the question to a supervisor who was not present, including Cleveland in the email. And he did this while sitting one foot away from Cleveland in the meeting.

During a break, Cleveland saw his email and the supervisor's response and she was flabbergasted. She decided to address the situation in two ways:

— First, she asked the team member why he emailed his question and didn't just ask her about it at the meeting. He replied that he didn't want the consultant to hear the question, and Cleveland's response was that the consultant was a big girl who could handle this type of question. When Cleveland pointed out that his behavior was passive-aggressive, he denied it.

— Secondly, Cleveland opened the next day's meeting by saying, "We're putting a lot of money and time into these meetings, and it's not just a waste of your time, although I get the sense some people think it is."

She asked team members to come speak with her that afternoon if they had any questions and concerns, but to focus on the meeting topics while they were there.

"I said, 'If I see you on the phone, I'm going to take it away,'" she says.

Unfortunately, the one team member's passive-aggressive behavior continued, causing interpersonal problems, and it had to be re-addressed, she adds.

• **Forget about situations that cannot be controlled:** One cause of decision-making paralysis in the research industry is that teams tend to require too much accuracy before deciding on a course of action.

"We'd encourage these folks to think about the decisions that require an accuracy that you can't control," Giombetti says. "They should forget about them, not worry about them."

This saves time to focus on the decisions that are feasible and will make a team faster, he adds.

"The general rule of thumb we would encourage these people to go by is when they are making a decision they should have 40% to 70% of the data," he says. "

If they have less than 40% then they probably made a rash decision, and if they have more than 70%, it's almost always too late, he adds.

Dysfunctional research teams often wait until they have 70% to 90% of the data, Sprouse observes.

"We see teams that need a lot of data and spend significant amounts of time working on it," he says. ■

Major research organization fine-tunes the site start-up process

Study start-up time dropped whopping 41%

Duke Clinical Research Institute (DCRI) in Durham, NC, has implemented a site start-up team process that quickly shaved 77 days off the amount of time between when the regulatory packet is sent to the trial's activation.

Pre-2008, the start-up time was 186 days. After the DCRI began its site start-up team process, this dropped to 108 days. The 41% decrease in time occurred within a year of DCRI's launch of the new process, greatly exceeding the team's goal of a 10% decrease, says **Jennifer L. Peterson**, clinical trial manager, site start-up, DCRI.

The site start-up team makes the new study a priority at sites and assists them with a coordinated effort.

"You can shave off time if you concentrate on identifying hurdles and seeing what you can do to streamline the process, Peterson says.

As the world's largest academic research organization, DCRI's success likely will catch other research institution's attention and show sponsors that increased resources at the site start-up process can result in huge benefits.

"The study start-up phase is key," Peterson says. "It's important to streamline it from the beginning because it sets the pulse for the study."

Here's how DCRI implemented the process and achieved the positive outcomes:

• **Form a study start-up team**: The study start-up team's role is to communicate with trial sites about the timeline for submissions and meeting regulatory requirements.

The team also builds trust with study coordinators and investigators and makes expectations and deadlines clear to everyone. The team establishes accountability and improves communication.

"We knew this process would increase efficiency at the site," Peterson says. "We wanted to make sure our faculty principal investigators were comfortable with this new model, which is the reason why we put together the site communication plan."

• **Customize a communication start-up plan**: "One thing we found that worked well is having a customized communication plan with the site, especially with study coordinators," Peterson says. "It's always easy to say the staff at the site is 100% dedicated to the study, but in reality study coordinators might be doing clinical rounds and have other studies and priorities."

The customized start-up communication plan asks coordinators how they wish to be contacted, whether by telephone or email. It also asks these questions:

— When will you be able to respond to the study start-up team's requests?

— When is it a good time to call coordinators to discuss the study?

— What is your schedule?

"We ask for a commitment of how much time each week they can spend on this study," Peterson says. "Then we work closely with that particular site, respecting the study coordinator's time."

The communication plan is customized for each study with information from the site specialist, who puts in protocol information. Sponsors can see the plan upon request.

It's a part of the standard process, and it's created from a one-page template. *(See sample communication start-up plan, p. 31.)*

The purpose of the plan is to establish a collaborative relationship with study coordinators, while making certain that the study remains a key priority and deadlines are met.

All of the communication questions answered by coordinators will be documented in the plan along with deadlines. This way the study start-up team knows when to call and check on reports and data.

• **Put escalations in place**: If a site doesn't meet its deadline or isn't responsive to sending in documentations, then the case is escalated. The study start-up team will find out what is causing the hold-up and address the problem.

For instance, it could be the study coordinator just had his or her work hours cut to part-time due to the organization's budget cuts.

The solution would be to re-establish the site's communication plan to accommodate the coordinator's new schedule, Peterson says.

"As long as we have reasons for why the site is not being responsive, then we can resolve it," Peterson says. "It could be the site has just gotten another study and we need to help them prioritize effectively."

• **Make seamless transfer to monitoring**: The study start-up team's work is done with the site has begun enrolling subjects. But rather than stop contacting the site abruptly, the team helps the site make a seamless transition to the clinical research associate's monitoring process.

"We hand over the site communication plan because it's important, historic information the monitors can use as well," Peterson says.

The monitor will call the site coordinator to confirm the plan's details, saying, "Hi, I see you worked with Jennifer in start-up. Does it still work best to call you on Wednesday from 10 to 2 p.m.?" Peterson says.

"This keeps the site from feeling like the process is compartmentalized, and now they'll have to start over," she adds. ■

Study start-up site communication plan

DCRI shares template

The Duke Clinical Research Institute (DCRI) of Durham, NC, has developed a site start-up team communication plan that is customized for each study. The plan's goal is to improve communication between study coordinators, principal investigators, and the site start-up team.

Each communication plan is developed from a brief template that asks for basic information from the site. DCRI's site communication plan includes these items:

- **Site Regulatory Contact**
  - — Name
  - — Phone number
  - — Email address
  - — Work schedule
  - — Preferred communication method: email or phone
  - — Response expectation: same day or next business day
- **Regulatory**
  - — IRB: central or local
  - — If local: next (3) submission dates; next (3) meeting dates
  - — IRB approval turnaround
  - — IRB approval contingent on contact: yes or no
  - — Other sub-committee approvals: yes or no
- **Site legal document contact**
  - — Name
  - — Phone number
  - — Email address
  - — Work schedule
  - — Preferred communication method: email or phone
  - — email preferred for red-lined documents, no fax
  - — Response expectation: same day or next business day
- **Legal documents**
  - — Legal entity name
  - — Site signatory(ies)
  - — Estimated timeline for site contract review
  - — Contract execution dependent on IRB approval: yes or no
  - — 3rd party requirement: yes or no
  - — Other ■

FDA discourages use of memos, looks for more CAPA responses

Watch for documentation sloppiness

The U.S. Food and Drug Administration (FDA) wants clinical trial sites to prove their compliance with regulations through better documentation of corrective actions, an expert says.

"Right now the FDA is not fond of memos to file," says **Kathy Valasek,** JD, a quality assurance and regulatory compliance consultant with cQA Solutions in San Diego, CA. Valasek speaks about FDA audits and quality assurance at national clinical trial conferences, including the MAGI Conferences.

"The FDA is looking at CAPA-type responses," she adds. "This means they want somebody at the site to have identified a problem, do a root-cause analysis, and then fix the specific problem."

This corrective and preventive action (CAPA) strategy is familiar to most clinical trial professionals, but it may not be systematically applied at every research site.

"Some clinical trials (CT) people are starting to do it, and some are doing pieces of it," Valasek says. "The FDA is expecting to see the CT site following this because it's a good program, and it works."

When attempting to solve a problem at a CT site, one could do a quick, shallow fix or get to the bottom of what's wrong and find a solution that will prevent the problem from recurring. This is the strategy the FDA wants to see sites take, she adds.

"Sometimes the right answer is not the one that's popular with management, Valasek says. "Because sometimes it really is that staffing levels are low and people have too much work to do when you get down to it."

The FDA's increased vigilance comes at a time when the agency has been under a great deal of public scrutiny. As a result, the FDA has hired more staff to conduct inspections, and the agency has changed the way sites are selected for audits, she explains.

"The FDA used to select high enrollers," she says. "Now they've developed more of a risk-based management approach."

This change can have a big impact on research

sites. For example, if the FDA audits a low-enrolling study that has four sites and two of those sites have significant issues, then the FDA will say that 50% of the sites have problems, Valasek says.

"The burden is put on the sponsor to go back and demonstrate to the FDA that these problems were not replicated at all of the clinical trial sites," she adds. "This is very expensive for sponsors, who have to assemble teams of independent auditors to ensure all sites and problems did not exist at other sites and that they can stand behind their data."

The FDA made another change by doing inspections in real time as studies are ongoing, which means that phase I and phase II studies might as easily be investigated as phase III studies.

Here are some suggestions for how clinical trial sites can prepare and handle FDA audits:

• **Learn and use CAPA**: Find resources online or in an institutional library about CAPA, which is part of Good Manufacturing Practice.

The Internet has resources, and there are courses available, as well.

Also, CT sites might check the FDA's guidance on the various responsibilities of clinical research investigators and personnel and explore how to conduct a root cause analysis and apply corrective actions, Valasek suggests.

• **Analyze problems**: When something occurs at a clinical trial site, the first step is for the compliance director or other leader to meet with the team and ask for opinions on what caused the problem, Valasek says.

They can ask these sorts of questions:

— What do we think is the cause of the problem?

— What contributed to it?

— What could we do to fix it to prevent them from occurring again?

"Initially, they say it's training, but that probably is not what it is," Valasek says. "Sometimes, it's just that we're too busy."

• **Present a good attitude**: "You can't fake your way through an inspection, but if you act properly and have things organized, and they appear to be in good control, then you often can get through some things that have sticky areas in it," Valasek says.

Sometimes this means an investigator will need to explain calmly why a particular new FDA regulation should not be applied to an old study, which had been initiated before the regulation went into effect, she adds.

"It might be the FDA expects you to have done something more to keep with the current standards," she says.

• **Keep documentation accurate, up-to-date, and logically organized**: "Make sure all documents are there and put them in an easy order," Valasek says. "This helps make the inspection much easier."

A recent trend with FDA audits involves auditors finding very sloppy documentation at sites, Valasek says.

Sometimes the results are so bad the site receives a warning letter, she adds.

For example, there have been incidences where a site documented that one staff member was working with two different subjects at the same time, which was obviously inaccurate, she says.

A solution to this is to purchase a radio-controlled clock that will make certain accurate times are recorded for procedures, she adds.

Also, sites might assign someone to be a coach to play-act the role of an auditor finding a problem.

"How would you respond to it?" Valasek says. "Work on your response a little bit and get them to explain what happened in clear and concise words, not giving too much detail."

The key is to give a brief explanation of what happened in a calm tone.

• **Improve source documents**: "Source documents often are inadequate from an auditor's perspective," Valasek says. "You need music and lyrics on the same page, meaning that when sites use sponsor-provided documents they need to have these incorporated into their own source documentation because that's what people follow."

The problem is that sites frequently don't include enough information in the source documentation, such as vital signs, diagnostic tests administered, etc.

Keep trial activity details in source documents, along with the correct order of doing these activities.

"If you do three EKGs in 10 minutes, include this, and document how many doses are given and whether or not you are collecting diaries," Valasek says.

• **Keep an up-to-date delegation log**: FDA auditors will want to see that all necessary signatures are on documentation. So this means research sites should keep up with obtaining signatures and making certain an auditor can find out who made that signature.

"Sometimes there is a problem of different handwriting, and you don't know who wrote that signature because you don't recognize the hand-

writing," Valasek says. "So you need to go back and check the delegation log to see that the person with XYZ initials is a nurse who was delegated that responsibility."

If the signature came from someone not listed in the delegation log, then there is a problem, she adds.

"The FDA could disqualify data," Valasek says. "You don't want an auditor saying this person was not qualified doing the medical history or obtaining informed consent, so you need to close those loops." ■

CT organizations could learn a lot from practices of brand-new sites

Focus on staffing, SOPs, equipment

Starting new clinical trial (CT) sites requires adequate staffing and equipment, proactive standard operating procedures (SOPs), and budgeting skills.

An expert who has experience in starting new clinical trial offices says organizations also need to know how to network and market the new site to be put on sponsors' radar.

"Sit down with your principal investigators to find out what kind of studies you want and are equipped to handle," suggests **Cindy Mendenhall**, CCTA, clinical research coordinator at Evergreen Healthcare in Kirkland, WA. Mendenhall has spoken about the logistics of starting new CT sites at national MAGI research conferences.

"I took one medical center's studies from zero to 14 in six months," she says. "The site did everything from pulmonary, oncology, cardiology, epilepsy, and diabetes studies."

Here is how the site achieved this success:

• **Don't skimp on staffing:** New CT sites need to make research staffing a priority if they want to succeed. While one very energetic and talented clinical research coordinator could handle a large caseload of studies, what will the site do when that person is sick or on vacation? Plus, overloading one individual likely will result in burnout and the site's greatest asset quitting for a better job.

"You can't run the program with one person," Mendenhall says.

"You need at least two people at a site," she suggests. "You need one person who knows all the regulations and research and another who doesn't know everything, but can learn."

If a site is conducting cancer research then at least one of the CT employees should be a nurse with experience in oncology. But in most other CT sites, the main study coordinator does not necessarily need a medical degree background, she adds.

CT sites that struggle with funding issues should find creative ways to staff adequately, but affordably.

For instance, a CT site near or affiliated with an academic institution could create an internship for students in nursing and other medical programs, Mendenhall says.

"An intern could come in and work in research for a few months, which would help the student, as well as the research site," she adds.

Sites also could find volunteers who could handle some of the duties that clog up a study coordinator's time, such as running documentation to principal investigators for signatures.

"That's a big help and time saver since you have to sit around waiting for the PI to sign the papers," Mendenhall notes.

• **Write and follow basic SOPs:** "I recommend using basic SOPs that include study feasibility, monitoring visits, informed consent, and drug accountability," Mendenhall says.

"It's important to have SOPs in place because if regulators come in, you'll need them," she adds. "Also, in research it's very important things are done in a standardized way."

For instance, an SOP might state how informed consent is performed. And the SOPs could include references to specific Food and Drug Administration (FDA) regulations. *(See table with SOPs template, p. 34.)*

"I pick up my federal regulations book and go through it to make an SOP from every regulation," Mendenhall says.

• **Install or ask for necessary equipment and space:** It helps if a site coordinator and investigator have decided which kinds of studies they will take. Once they make this decision, they can assess the site's available space and equipment to see what additional items or space are needed.

"If you're doing a pulmonary study, make sure you are in place to have the equipment you need," Mendenhall says. "If you are doing diabetes studies, then invest in glucose monitors, blood pressure cuffs."

Studies often provide ECG/EKG machines, but a site could have one on hand, as well, she says.

CT sites can purchase the necessary equipment for very little, sometimes even obtaining used medical devices at no charge.

"It's good to save money every chance you get," Mendenhall says.

"With one study, we needed a refrigerated centrifuge machine, and I told the sponsor that we didn't have one of these and if they wanted us to do the study we'd have to have one," she says.

When the study ends, the site can then ask the sponsor if they'll sell the used machine at a greatly reduced rate. They often agree to this arrangement, she adds.

"Check your space to see if you have enough space to store all binders and files," Mendenhall says. "At the beginning of a study you might have 10 to 20 lab boxes, so where do you put those?"

• **Market your site to sponsors**: New sites and any CT site that wishes to expand its research needs someone on staff who likes to network.

A study coordinator who works in a doctor's office or medical center could make business cards for the CT site with the coordinator's contact information. Then when pharmaceutical representatives visit the office or department, the coordinator could hand the rep a couple of cards and ask that these be passed on to the right individuals, Mendenhall suggests.

"Normally when I get the pharmaceutical representative's card I write on the back the name of the medical liaison and follow-up with the drug rep that next afternoon, " she says. "I thank the person for taking my cards and ask for emails of people to call about protocols."

The federal government's drug trial registry at clinicaltrials.gov might also prove to be a useful resource.

"You can call a company listed on the registry and ask if they are doing add-on sites for that particular study or if they have any other studies like that," Mendenhall says.

Sites could market themselves by showing sponsors that they have the necessary study population.

"The PI should make a de-identified list of patients who might qualify for the study," she says.

"This can help in negotiations too," she adds. "You can say, 'If we get your study, we have these patients who meet enrollment criteria.'"

CT sites that impress sponsors and clinical research organizations will get more studies and can quickly build on their success.

• **Develop a good budget**: CT coordinators should learn how to develop a good budget.

"Talk with other centers and say, 'We're trying to get started, so what is your average budget for something like this?'" Mendenhall suggests.

"You want to be in the middle — don't underprice or overprice your site," she adds. "Make sure that everything you do is good for the company."

• **Pay attention to details**: Successful sites meet deadlines and attend to all necessary details.

"Make sure you're quick to fill in your case report forms or electronic documentation," Mendenhall suggests. "Make sure data are clean when the monitor comes out to visit, and make sure you don't have big holes in documentation."

Mendenhall creates a packet of necessary information for site monitors. The packet includes investigators and staff curriculum vitae's, licenses, human subjects protection certificates, and a note about the research site.

She also lists the site's equipment that would correspond with what the study requires.

CT sites also should check to see what certification they need for their studies, such as lab certification or phlebotomy certification when state or local laws require it, Mendenhall suggests.

"Make sure you have all of those things in place," she adds. "Talk with local research organizations to find out what you need."

Finally, new CT sites should have an outside audit or research consulting contractor audit them before they begin a research project, Mendenhall advises.

"It's always nice to have a second set of eyes," she says.

"An outside company can look over the SOPs, drug storage, equipment, training certificates, etc.," she adds. "This will assure you that you are ready to start your business and that you can concentrate on giving sponsors what they want: accurate, clean data." ■

Expert provides list of basic SOPs for CT sites

Put SOPs in place early-on

Clinical trial (CT) sites should have a basic list of standard operating procedures (SOPs) written and in place before research is initiated, an expert suggests.

"It is always best to have many SOPs in place before starting your program," suggests **Cindy**

Mendenhall, CCTA, clinical research coordinator at Evergreen Healthcare in Kirkland, WA.

"That way if anything arises you can say, 'This is the way we have to handle this situation — it's in our SOPs," she says.

Here is Mendenhall's list of suggested SOPs for CT sites:

- Contract and budget negotiations
- Site selection visits
- Site initiation visits
- Interim monitor visits
- Informed consent process
- Selection of IRB
- Procedure for assignment of central IRB
- Communication with the IRB
- IRB audits
- Adverse event reporting (in-house and IRB)
- Serious adverse event reporting (in-house and IRB)
- FDA audits (include how to respond to infractions, as well as how to conduct the audit from the site's perspective)
- Procedure for obtaining confidentiality agreements
- Study feasibility questionnaire completion
- Release of patient information to third parties
- Recruitment and retention (include pre-screening, pre-approval of media materials, internet advertising, and approaching another physicians' patient)
- Communication with subjects (email, postal mail, telephone calls, etc.)
- Privacy and protection of health information
- Drug accountability
- Storing investigational product (before, during, and after the study)
- Temperature logs
- Dispensing investigational product
- Lab processes (include, IATA certification, will you require — or does your state require — a phlebotomy license, disposal of hazardous waste, courier methods, etc.)
- Medical records search (include electronic, paper, and obtaining information from other facilities)
- Source documentation
- Protocol violations
- CRF completion
- Research training (when do you re-train staff on SOPs, new FDA regulations, protocols, amendments, etc.)
- Archiving and storing a study after it is closed. ■

BINDERS AVAILABLE

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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

■ Strategies to support research at community teaching hospitals

■ Best practices in a subject injury compensation program

■ Practice FDA-friendly documentation

■ Here is the latest in clinical trial agreements

CNE/CME QUESTIONS

9. Team dynamics and behavioral experts say the clinical research industry has a widespread problem of dysfunctional teams, due mainly to one particular personality trait. What is it?
A. Passive-aggressiveness
B. Indecisiveness
C. Low good will
D. Poor people skills

10. A customized start-up communication plan for research site coordinators typically would not ask which of the following questions?
A. When will you be able to respond to the study start-up team's requests?
B. When is it a good time to call coordinators to discuss the study?
C. Will you drop your other priorities to answer questions when the call comes in?
D. What is your schedule?

11. Which of the following is an important item to include in a clinical research site's standard operating procedures (SOPs)?
A. Interim monitor visits
B. Selection of IRB
C. Temperature logs
D. All of the above

12. A new clinical trial site can easily handle all clinical trial work with one study staff member.
A. True
B. False

Answers: 9. A; 10. C; 11. D; 12. B