CLINICAL TRIALS ADMINISTRATOR

An essential resource for managers of clinical trials

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Billing compliance: Big bucks require more CT staff buy-in

"If you're in an environment where the research staff says, 'That's a billing issue,' then you've got a problem."

It's good timing to improve your research compliance program now that billions more dollars in federal funding from the health care reform and stimulus package continue to be pumped into the research economy. Such money brings increased regulatory scrutiny, and this means clinical trial (CT) sites will need to make certain they are following all rules.

Billing compliance and tracking regulatory data are good places to start.

Everyone at a CT site needs to be accountable for the billing compliance process, says **Rachel Garman**, LPN, CCRC, a research manager in oncology at Cancer Care Northwest of Spokane, WA.

"The big question as you struggle when dealing with a billing office is getting everyone to buy-in and work together in compliance," Garman says. "If you're in an environment where the research staff says, 'That's a billing issue,' then you've got a problem."

Regulatory compliance and tracking also require research staff buy-in and cooperation.

Often federally-funded studies have multiple investigators and institutions involved, and each study has its own story and its own number of different groups that have to track what's going on, says **Pam Schwingl**, PhD, a senior epidemiologist and National Institute of Environmental Health Sciences (NIEHS) support services project manager. Schwingl is with Social & Scientific Systems, an NIEHS contractor, in Durham, NC.

"That's why it's really important to create a database to track study information and streamline this effort," Schwingl says.

The NIEHS projects involve clinical epidemiology.

"We have studies that are done in clinics, but they're more observational studies," Schwingl says. "We prepare data and have some analytic programmers do data analysis for principal investigators."

The database keeps historical information about past IRB and regulatory submissions and their approvals, she says.

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Deadline reminders

It helps study coordinators better manage their time by sending them reminders of deadlines.

"We determined the standard routine by polling study managers on how frequently they want reminders on particular due dates," says **Elizabeth O'Connell**, RN, BSN, senior study manager with Social & Scientific Systems.

"So we developed algorithm runs weekly, and every Thursday it sends out reminders on predetermined intervals, which could be six weeks, four weeks, or two weeks," she says.

When a manager submits a form, he or she has to put the submission date in the system.

"We have monthly reporting obligations, and that makes it easy for me to capture all of the information from one place to include in a written report," O'Connell says. "It gives us a tool to use to chase down the study managers and make sure they haven't just forgotten something."

If study managers don't document it, then it's not in the database, she adds.

Documentation also is integral to billing compliance.

Cancer Care Northwest has made this a consistent process by using various billing compliance tools, including a reimbursement billing distribution list, a billing guide, an audit form, and a reimbursement alert, Garman says. *(See story about using billing compliance tools, p. 63.)*

"We designate one person to do all of the research billing," Garman says.

Also, once a month Garman meets with a billing specialist and verifies that each charge was billed correctly.

This was a huge undertaking initially.

"We decided to make sure we were very compliant and catch anything that's billed incorrectly," Garman says. "We wanted to make sure we were catching [mistakes] in a timely manner and identifying refunds as needed."

Regulatory mistakes also need to be caught and corrected as quickly as possible.

Usually researchers have been good at getting their documentation submitted on time, but it's important to have a back-up system for when a problem occurs, Schwingl says.

The NIEHS-funded tracking tool gives research coordinators reassurance that if they happen to forget about an upcoming regulatory deadline, they'll receive an automatic reminder.

Here are some of the tool's attributes:

• **Database can handle multiple institutions:** "We looked around and found some packages out there of databases that can do similar things," O'Connell says. "But we have to deal with multiple institutions, so having a database that has it all in one place has been extremely helpful."

For example, one study might have a site at a North Carolina university, and that institution's

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IRB will have its own database, but it won't be linked with Social & Scientific Systems, where much of the study work is being done.

"We need to document all that information here so we can access it more easily," O'Connell says.

"For us to be study managers and make sure all approvals are still active and that we have captured it in one place is something we didn't have before," O'Connell says. "To have the information centrally-located so that anybody can access it here within the company has been very helpful."

• **Use system smart tags:** "We put in smart tags within the system so if a study manager is looking at her particular protocol and needs to quickly look at an IRB meeting calendar, then there's a link," O'Connell says.

There also are links built into the project's Intranet that would navigate someone to the submission or approval documents that are needed.

"While this database captures all dates, it also links you to the actual history and forms," O'Connell says.

The smart tags make it easier for study managers to review their own protocols and find dates for all of the institutional deadlines during any given month, Schwingl notes.

"Each study manager can access reports by their own name so they can see their due dates, rather than have to sift through each project," O'Connell says.

• **Limit access for changes and add visual cues:** Everyone involved in the research project has access to the regulatory tracking tool and database, but only the programmer, O'Connell, and select others have the ability to make updates and edits within the database, O'Connell says.

"We color code things within the pages, so if something is blue, it means it's an upcoming deadline," she says. "If it's red, then it means it's past due."

This gives viewers a quick visual cue as to what is due and how soon.

• **Encompass all regulatory issues:** The tracking tool tracks all IRB information, material transfer agreements, investigators on project, Office of Management and Budget (OMB) reviews and submissions, and other details.

"It looks at the burden of participants for anything that has to do with the government," O'Connell says. "It stores the OMB registration number if you have to go through the OMB, and it tracks whether the project has gotten clinical exemptions from the OMB."

• **Maintenance is minimal:** "It's really easy to use, and in terms of maintenance it depends on how many protocols you've got," Schwingl says. "But in terms of updates, we have a research assistant-level person who handles it."

For instance, when NIEHS changed its algorithm for when packages were due, the research assistant went into the database and reprogrammed it with the new information.

[Editor's note: The NIEHS regulatory tracking database/tool was developed with federal funds, so it is available at no charge to anyone who would like to use it. For more information, contact Elizabeth O'Connell at oconnelle@niehs.nih.gov.] ■

Need better billing compliance tools? Here are some examples

CR site is small, but compliance is mighty

Cancer Care Northwest of Spokane, WI, is proof that a clinical research site doesn't need to be large to have a successful billing compliance program.

"We do some extra things that large academic centers don't do," says **Rachel Garman**, LPN, CCRC, a research manager in oncology.

There are systems to prevent billing mistakes, but all the billing reviews are done retrospectively, she says.

"Everything in our practice goes out in 24 to 48 hours after the patient was seen," she adds.

For instance, if a study requires an EKG that cannot be done in-house, then Garman will create a separate account that is research specific.

Those invoices first go to Garman so she can verify the amount before she sends them to accounts payable.

"If I don't get an invoice from the vendor, I'll call the vendor to make sure they didn't send it to the patient," Garman says.

It takes a little time to get everyone aware and actively implementing the correct billing process, she says.

"I noticed once we started providing our billing people with more education on billing compliance that things got a lot better," she adds.

Garman describes some of the compliance program's billing tools and how these assist with improving compliance:

• **Research patient billing guide:** For example, the research site has created a simple billing guide that details precisely what a clinical trial will pay for, what should be billed to the patient's insurance, and how these study procedures apply to ICD-9 and CPT codes.

"It's a guide that says, 'This is what the trial pays for, and when you get these items, they should not be billed to a third-party payer,'" Garman says.

The billing guide lists the patient's name, date consented, the doctor's name, the study number, an account number, and research start date, as well as a description of details.

It also includes a table that lists the CPT/J codes, procedure, DOS, and when it was performed. The main sections are for lab procedures, chemotherapy, radiology, office visits, markers, and anti-emetics.

At the bottom of the form it clearly states, "Any items marked on this sheet are not to be billed to patient insurance. Any questions, please call the study coordinator."

• **Billing guide distribution list:** The billing compliance program also has a billing guide distribution list that includes the people who need to be notified when a patient begins a clinical trial. These would include the research staff, billing staff, pharmacy staff, and financial counselors who do pre-authorization, etc., Garman says.

"We don't notify the clinical staff until the patient is on the trial, but then the clinical staff isn't involved in billing the patient on the clinical research trial," she adds.

• **Reimbursement alert and log:** Another tool is the site's reimbursement alert, which was created for each study patient.

"Before billing for a research patient's visit, the biller will look at that alert to see what should not be billed to a third-party payer," Garman says.

"Our internal billing person who is looking at all of those charges knows which charges to scrub on the back-end, which drug administration needs to be taken out and not billed to the patient," she says.

The reimbursement log is a Microsoft Excel spreadsheet that has 13 columns. The first column lists the patient's name. It also lists the patient's initials, identification number, cycle of data, data registered, dollar amount received, date received, J code/CPT/NSOC procedure, DOS, performed by date, money received by cancer center, contract dollar amount, and insurance audit verified.

"We keep track of all patients on the reimbursement log, so I know exactly what day the patient got treatment, what was billed to insurance, and what was scrubbed on the back end," Garman says. "I use that as a guide to meet with my billing contact, and we look at every one of those patients to see if it was billed correctly."

Compliance specialists can review this log more quickly after they have some experience with it, she notes.

"The first time we sat down with it, we spent a good eight hours reviewing it," Garman recalls. "Now it takes us one to two hours to look at all of the patients."

When they discover problems, they designate the person responsible for fixing it, and later record the date it was fixed, she adds.

"We have a list that determines any issues, and we send it to a billing person and the director of finance," Garman says. "We tell everyone what the issues are, and the form gets sent back to me once they've corrected it."

They also make a note to follow-up on the problem.

"If the issue is that someone was billed incorrectly, then we contact the person who does refund to make sure it's taken care of," Garman says.

• **Track and trend:** "It's all about tracking and trending," Garman says. "If we notice one trial or one person who has a chronic issue, then we'll dig deeper and analyze the root cause."

Garman will look at the whole process to find the cause.

For example, Garman once put incorrect information in the electronic medical record.

"It was a simple mistake where I said this is paid for by the study when it wasn't," she explains. "So the breakdown was on my part."

She went back to change the electronic medical record's alert and the communication in the billing guide.

"I sent a notice to the billing manager and manager of research to say the information was put into the electronic medical record incorrectly," Garman says.

Other times, mistakes can occur when there's a hand-off between billing specialists, such as when the main person is on vacation.

The CR site provides training to all involved staff, but it's also important to provide billing staff

with contact information for the research manager. This way they can always call if a question arises when one biller is filling in for another one.

"When you take a good look at billing issues it becomes clear where you've had downfalls and where your risk categories are and how to fix them," Garman says. ■

BEST PRACTICES SPOTLIGHT

Take steps to prepare for up-and-down business cycle

Expert offers best practice tips

The current economy should be enough to convince clinical research (CR) sites that they need better strategies to handle the rollercoaster ride of the research business cycle if they want to survive and thrive for the long term.

"The bottom line is learning how to prepare for the crunch," says **Kathy Jones Beals**, chief operating officer and vice president of business development for NeuroTrials Research in Atlanta, GA. NeuroTrials has 17 years of experience in clinical research, and Beals was a scheduled speaker about CR site financial management nationally at the 2010 MAGI Clinical Research Conference - East, held May 23-26, in Boston, MA.

"We're seeing the business cycle crunch to a greater extent now than in previous years, but it's always there," Beals says. "We're at the mercy of the pharmaceutical and device companies' cycle."

However, there are some smart strategies CR sites can take to better manage their finances in the lean times and avoid overspending during the busy times. Beals offers these suggestions:

- **Try smart staff strategies:** "At our site we have our core staff that is there all the time, and we have PRN staffing in the wings when a busier time arrives due to the research cycle," Beals says. "These are people we've brought in and trained in our procedures and philosophy."

A clinical trial site has to prepare for the busy times by hiring as-needed staff before they're truly needed.

"We've utilized these PRN employees sporadically over a period of time so when we get very busy we can bring in someone who is familiar with the organization," Beals says. "We make sure they stay trained and ready."

Sites can find professionals interested in this occasional work by seeking out mothers of school-aged children. These women sometimes do not want fulltime or even part-time work. But they are open to the occasional project for bringing in extra income, she suggests.

Also, retired research professionals and research interns are other sources for building a temporary workforce.

"Usually people come to us through a referral organization," Beals notes.

For example, a local college might call to say there's a bright student in their research program who is looking for an internship.

"We might have that person come in and intern with us so we can evaluate him or her and find out whether they could serve as PRN or a part-time staff member down the road," Beals says. "Many internships are at no or low cost to a company."

The key to training these temporary workers is to have an experienced and dedicated core staff that takes on the mentoring and training roles, she adds.

- **Use only a little more than the space you need:** It's important to have adequate and comfortable space for meeting research participants. But it's not necessary to rent or purchase much more site than a site needs.

When Beals looked at NeuroTrials' current facility several years ago, she decided to lease what the CR site needed to fit current staffing and exam room needs plus only 15% for expansion.

"It's exciting to develop these huge, state-of-the-art sites, but when business slacks off, you're supporting that space while waiting for healthier times," she says.

However, sites still can prepare for the cyclical busy times by making certain there is additional space available for temporary expansion or use.

For instance, NeuroTrials has an agreement with medical clinic tenant in the multistory building the two organizations share: when NeuroTrials needs some additional space, they can rent space from their neighbor during off-hours, Beals says.

"We put in place a contingency plan for bearing a greater study load, but to not bear permanent

costs," she explains. "You need to be creative with your needs."

Another strategy is to open the CR office on weekends when a fast-enrolling trial makes the office very busy in the short term.

- **Avoid the latest, most expensive models:** "With our phone systems and software programs, and other technology, we wanted state-of-the-art, but we didn't need to be cutting edge," Beals says. "You should go for what truly meets your needs, but don't be swayed by the bells and whistles that aren't necessary for your operation."

Occasionally, the organization will buy second-hand equipment. But the chief cost-cutting strategy is to buy new equipment that is discounted because a newer, more expensive model has just hit the market, she says.

"You can get a much better deal on last-year's model," she adds. "So if everything else remains the same with the technology and quality, don't be shy about buying last year's model."

- **Cross-train staff:** "We heavily cross-train all of our staff, and the reason is because when we're really busy, we may need to have staff who can wear different hats," Beals says.

CR sites pay handsome salaries and benefits for experienced clinical trial coordinators, so it makes sense to train these professionals to do phlebotomy, package and ship supplies, and do other CR tasks as needed.

"It helps their job security, it helps the company with its cash burn rate," Beals says.

CR sites that have fulltime coordinators and fulltime phlebotomists will have an expensive staffing load to carry during lean times, she adds.

"If you have people cross-trained, then you can be a leaner group and get high quality procedures done," Beals says.

- **Negotiate optimal lease commitments:** CR sites often can negotiate much better leasing options than they're first offered by a vendor.

For instance, a copy machine company might say the machine has to be rented for three years, but the same monthly payment could be negotiated for a 24-month period instead, Beals says.

"The shorter your leasing commitment, the less financial commitment you have overall," she explains. "So being thoughtful on the front end when negotiating terms for leases can save you a whole lot of money on the back end."

In the case of renting space, CR sites should research their local market well before deciding whether to buy or rent. If the market is high-priced, leasing might be the less costly option.

If it's a down real estate market, then now might be the time to buy the property.

In a high-priced real estate market that appears to be heading up, then it's also a good idea to negotiate a long-term lease with a better rate because of the terms.

"We got a longer term rate because we know we'll be in business for the next five years," Beals says.

- **Keep a cash flow cushion:** CR sites should anticipate having cash flow issues. All research sites do, depending on the cycle, Beals says.

"There are bountiful times and some very lean times," she explains. "So we try to keep a three-to-six month operating cushion, with three being the minimum."

In addition, consider opening a banking line of credit.

"They might not use it, but it's there in case it takes the site more than six months to become profitable again," Beals says.

The key with all of these suggested strategies is for CR sites to have the plans in place before they need to use them, Beals adds. ■

New study: Feasibility should be top priority

Get feedback from all departments

Assessing a protocol's feasibility should be a top priority for clinical trial sites. And it's a good strategy to have a thorough feasibility process in place.

"When we are approached or thinking about doing a project here, it is imperative that we understand all facets of it so we can make an intelligent decision of whether we want to do the study here," says **Denise Dorman**, RN, CCRP, clinical research director for Coastal Orthopedics & Pain Management in Bradenton, FL. Dorman was scheduled to speak about protocol feasibility at the 2010 MAGI Conference - East, held May 23-26, in Boston, MA.

Coastal Orthopedics & Pain Management has 17 physicians, including 11 orthopedic surgeons, five offices, two surgery centers, and five physical therapy departments. The private practice has been

in clinical practice for 45 years. The organization has been involved in research for five years, Dorman says.

"It's important that I get the feedback from all of the different departments," she notes.

"We do a combination of drug and device studies, and we have a large amount of physician-initiated research," she says. "So there are a lot of determining factors to whether we're going to do a project."

The bottom line is finding a balance between the financial aspect of research trials and strategic self-interest.

Here are some ways a clinical trial site can ensure a feasibility process that will result in the best decisions about protocols:

• **Have investigators fill out research protocol sheet:** "If the study is a physician-initiated project, then I have a proposal sheet where they write down what they want to do, and I look for funding," Dorman explains.

"They answer basic questions about the study and treatment and patients," Dorman says.

The research protocol form is a simple chart with two columns. The second column is for answers, and the first asks for answers to a variety of items, including these:

- Name or short description;
- Type/study design;
- Initiating investigator;
- Project coordination;
- Device(s) to be utilized (if applicable)/indication;
- Background/history (what's in the literature);
- Objective;
- Patient population and sample size;
- Study population;
- Methods;
- Evaluation criteria;
- Follow-up assessments;
- Timelines;
- Data collection;
- Core labs/vendors;
- Statistical analysis, etc.

If a study is sponsor-driven, then Dorman sends the investigator a protocol feasibility form to review and complete.

• **Have all departments assess study feasibility:** "We want to know how much personnel it will take to do the trial, whether we'll need to work with other departments," Dorman says.

If a study, whether it's investigator-initiated or sent by a sponsor, will involve other departments in the organization, then each department will need to complete a protocol feasibility form.

"It's a one-page form that asks if their department can do this for us," Dorman explains. "Once I get all of those back, I look at them, and I have a grid I fill out."

The protocol feasibility checklist form has a table at the bottom for various clinical research groups to complete as "approve" or "reject."

It also has five sections to be completed, with these questions:

- Previous experience with sponsor and/or CRO (Good or Bad)?
- Enrollment goal realistic?
- Enrollment period realistic?
- Have we had similar trial and met enrollment?
- Inclusion/exclusion realistic, screen failure rate?

Protocol:

- Is it well designed?
- Are other departments involved; which ones?
- Extra equipment?
- Extra training?
- Long duration drop-out rate?
- Case report forms complex; what medium?
- Drug/device accountability complicated?

Procedures:

- Are there frequent procedures?
- Are procedures complicated?
- Are there subject diaries, electronic/paper?

Staff:

- Adequate staff for trial?
- Additional training?
- Are visits complex, requiring many staff members?

Budget:

- Is preliminary budget available?
- Is it adequate?
- Is budget line item?
- Up front costs non-refundable?
- Is payment schedule available and acceptable?
- Has cost been calculated?
- Is the project profitable?

Developing a thorough protocol feasibility checklist has been a learning process for Coastal Orthopedics & Pain Management, Dorman notes.

"You need to know what information they need to make the study successful," she says. "A lot of physicians might look at this and think they have these patients, but has a learning curve."

If the answer from everyone points to doing the study, then the next step is to complete a protocol feasibility report.

• **Dig deep to find essential information:** Dorman does a little research to find answers to some of her feasibility assessment questions. For instance, sponsors often do not let CR sites know what their screen failure rate has been in previous trials for the drug/product.

"Sponsor will know what the screen failure rate is, and that information can tell you how hard the trial will be to enroll," Dorman says. "If they have a screen failure rate of 50 to 60%, then you know you'll only get a few patients."

But sponsors won't divulge this information unless sites request it.

Dorman also analyzes the study's inclusion/exclusion criteria and might ask physicians how many patients they see in their practice who might meet these criteria. She also has access to the patient database and can review the numbers of patients who have any particular diagnosis.

"I look at the trial itself to see how it's going to be reimbursed," she says.

Sometimes if patients have to bill their insurance for the study procedures, they might be less willing to participate in the study.

And if the study is going to be a long-term one with four or five years of follow-up visits, then it might be difficult to recruit many patients.

"Are your patients snowbirds or long-term residents," Dorman says.

"You figure you'll have a certain amount of drop-off," she adds. "I look to see if the study will be detrimental to us if we do lose 20% to 30% of patients after the initial visits, and I want to know how we'll get paid for this."

Also, if a study is longer, it's important to know if the sponsor is providing incentives to keep people enrolled. These incentives could be gift cards and other small tokens of appreciation.

It's also essential to understand precisely what types of procedures will be needed for a trial.

"We once did a phase II trial that would require many exams and labs, and my staff was not adequately trained on the physical and neurological exams that would have to be done on these patients," Dorman recalls. "So I went back to the sponsor and said, 'I don't think we know how to do this, and we're worried about the study time limit for completing them."

The sponsor agreed to provide training for the CR site staff, and that made the difference between the site rejecting the study and agreeing to do it, Dorman adds.

• **Sign-off on research protocol feasibility report:** "Assessing feasibility is a continuous process up until we actually start the trial," Dorman says. "We have many procedures we go through, including having our research board look at it, and then I have another one-page sheet I send in, and it's signed by the physician, our corporate chief executive officer, and myself."

The feasibility report also is a simple, two-column table with one column for answers, and one column for these items:

- Name of trial/#/sponsor;
- Investigator coordinator;
- Start date/length of trial;
- Number of subjects;
- Physician involvement;
- Procedures;
- Equipment needed;
- Total hours/visits per subject;
- Other costs;
- Total cost by trial;
- Advertisement;
- Total budget;
- Contract attached;
- Other information.

To conduct a suitable feasibility assessment, it takes everyone's involvement at the CR site, as well as several feasibility forms, Dorman says.

"It's our job as sites to get information about studies to make sure we can do the protocol," she explains. "It's only fair to the sponsor that we can make an intelligent decision and do the trial well at our site." ■

CT directors should take steps to manage risk

Think of subjects' financial risk as well

Clinical trials directors should take reasonable steps to manage their organization's risk in human subjects research. It's not wise to assume that someone else is taking care of this issue, an expert advises.

"Keep in mind that subjects don't understand all this legal stuff, and it's up to us [to handle it] at the site level," says **Barbara M. Longmire**, MSN, director of the office of clinical trials at the University of North Carolina at Chapel Hill in Chapel Hill, NC. Longmire was a scheduled

speaker about managing risk at the 2010 MAGI Clinical Research Conference - East, held May 23-26, in Boston, MA.

"We have a reputation to uphold, and we have moral and ethical obligations, as well," Longmire adds. "So keep this in mind when you're negotiating a contract with a sponsor."

Longmire offers these suggestions for managing a CT site's risk:

- **Make certain sponsor is insured sufficiently:** CT directors should make certain sponsors have insurance that will cover problems with the drug, biologic, or device, Longmire suggests.

"Be sure the contract shows that they have sufficient insurance to meet their obligations, and that they can provide proof of it," she says.

"We've had contracts with companies that filed [Bankruptcy] Chapter 7 or 11, and were left owing money," Longmire says. "So be sure the company is solvent."

- **Understand indemnification:** Clinical research contracts include language regarding indemnification.

"Indemnification is a contractual obligation assumed by or legally imposed on one party to protect the other party against losses or damages from specific liabilities," Longmire says.

This basically is the terminology used to explain who is responsible for what when something goes wrong, Longmire says.

"The wording could say, 'We'll indemnify you for our own negligence,'" she adds.

A CT site could indemnify the sponsor for any negligence on its part, such as if the CT site did not follow the protocol properly, and a subject was injured because of that negligence.

There are two main ways for a company to reimburse for a subject's injury: one is to have a completely separate contract provision that is not part of the indemnification clause, and the other is to have them indemnify a site for a subject's injury that is related to a study product or procedures, Longmire says.

"If the sponsor will agree to a separate contract provision for subject injury then they agree to reimburse however it's defined -- upon receipt of documentation or invoice -- and the lawyers can stay out of it," she explains. "We try to get a separate subject injury provision that is not part of indemnification because sometimes going through the indemnification process takes a long time, and the subject's medical bills will build up."

- **Check contract language and informed consent document for inconsistencies:** "Make sure there is consistency between the contract subject injury section and the injury section in the informed consent document," Longmire advises.

If the contract clearly states that no subject injury costs will be reimbursed, then it would be a mistake to have an informed consent form that says any treatment for injuries suffered because of the research will be covered by the sponsor, she adds.

"Patients have to be able to trust that what is in the informed consent is accurate, and the contract backs that up," Longmire says. "There's a huge gap usually between the research subject's knowledge of this whole process and what is in the contract."

- **Keep in mind that PI-initiated trials are handled differently:** Trials initiated by principal investigators typically have no subject injury provision by the drug or device sponsor, Longmire says.

"And there's very little indemnification, because it's not the sponsor's protocol," she adds. "So even if the research organization receives $500,000 in funding from the pharmaceutical company, if it's a PI-initiated protocol, then the pharmaceutical company will say it's not the sponsor."

CT sites need to make certain the informed consent conveys this message.

- **Think of subjects' financial risk, as well:** "Most people think of the risk-benefits section of informed consent as only addressing physical risk or benefits to participating," Longmire says. "But in my opinion, I think there is a financial risk to the subject for participating in the research, and it's seldom disclosed in detail."

For example, the subject may be responsible for insurance co-pays and deductibles resulting from procedures done during the study.

And there is even a bigger financial risk in some device trials.

"I saw a contract one time for a device trial that said the cost of the device will be billed to the subject or to the subject's insurance company," Longmire says. "But what they didn't say was that if the insurance company rejected the claim, then the device would cost the person $28,000."

For most people, the prospect of having to pay $28,000 out-of-pocket is a potential risk, she adds.

- **Watch for contract carve-outs:** Sometimes contract language will say that the sponsor will pay for treatment injury so long as the injury doesn't fall into one of the common categories, such as an adverse event that is related to a pre-

existing disease or condition, Longmire says.

"I've seen contracts that say they won't pay for treatment if the subject fails to follow instructions, and that's open to a lot of different interpretations and meanings," she adds.

For example, a subject could live a couple of hours away from the research site. Then on the day of one scheduled visit, the subject's car breaks down, and the subject misses the appointment, showing up a couple of days later. If the subject later has an adverse event, the sponsor could say that injury treatment is not covered because the subject didn't follow instructions when he failed to make the visit at the appointed time, Longmire says.

"I would negotiate to have this carve-out language taken out of the contract," she says.

Some universities have written policies stating they will not enter into a contract with a sponsor unless the sponsor contractually agrees to cover all the costs related to the adverse event, she adds.

"We at UNC probably spend as much time negotiating the subject injury section of the contract as we do anything else in it," Longmire says. "We feel strongly that if a subject is volunteering in a research study and he's injured, then the cost of treating the injury should be covered by the sponsor, who stands to benefit if the product is approved."

- **Consider CR site's own risks:** If research organizations are not careful when negotiating the risk part of contracts, then they might find themselves in great risk of harm financially and to their reputation.

"In university hospitals and teaching hospitals, your research subjects come from your clinical population," Longmire says. "So that's an additional reason to pay really close attention to what you do."

Also, sites often say that subjects are not waiving any of their rights when they sign an informed consent form. But sponsors might want the site to include IC language that basically says the sponsor will cover treatment costs for injuries related to the trial, but that they will not cover loss of wages, pain and suffering costs, Longmire says.

This conflict has to be worked out, or it will create some risk for the CR site.

The key is to keep in mind that people involved in clinical research should be treated fairly, particularly when they're at risk of injury.

"Sponsors are looking for ways to limit their potential liability, and I understand why they're doing it, and I don't disagree that they need to limit their costs," Longmire says. "But it shouldn't be at the risk of research subjects." ■

Market your clinical research site to potential new sponsors

Finding a match between site's assets, trial protocol

It's the rare clinical trial site that stays consistently busy with research. Most sites need to do at least a little marketing. Only they might not call it that, or even have a business strategy for recruiting and maintaining a steady business stream.

It's a mistake to leave a research organization's business plan to chance, an expert says.

Research sites need to have a business plan for approaching sponsors and clinical research organizations (CROs) and delivering the site's value to a particular sponsor or study, says **Kevin Ketels**, MS, chief executive officer of KMED Research in St. Clair Shores, MI. KMED is a clinical research site and consulting firm that manages phase II through phase IV trials.

"I think the two most important things you have to go through are to first figure out what your business strategies and goals are as an organization, and then you have to think about what is your value proposition," Ketels says.

For instance, what is the site's capability and expertise, and what can it offer to a potential client, such as a sponsor or CRO?

The goal always should center on finding a good match between a site's assets and a clinical trial protocol. But this might mean that a site has to be proactive in seeking clinical trials that would fit in with its mission.

Ketels offers these suggestions for how to find and recruit the most suitable studies:

1. Develop your CR site's pitch.

"What my staff and I have done is create a value proposition," Ketels says. "The first two paragraphs talk about us, our site, our capabilities, and what we call key differentiators."

Key differentiators include a site's expertise, knowledge, capabilities, and appearance.

"This tells why we're special," Ketels says. "So you put that information in an email or conversation and say, 'I'll send you some follow-up infor-

mation."

Ketels introduces himself in the email message, saying that he would like to offer the sponsor his site's services.

"I keep it short, concise, and to the point," he says. "When a person reads the email he knows who we are and what we have to offer."

When a potential sponsor requests more details, here are some items to include in the pitch:

- The site's medical director and staffing;
- A chart that describes the site's subject database, including aggregate numbers and populations represented;
- A description of the site's clinical population and numbers of patients seen each month;
- A list of clinical trials completed, past subject recruitment history, clinical trial trends.

"We give them an idea of what it would be like if they had a site like ours," Ketels says.

This information should be concise, brief enough to send out in emails, he adds.

Charts and more precise details can be sent as an email attachment.

"We provide sponsors with more information so they can follow through and see if our value proposition matches their needs," Ketels says.

"If you have a good match then sponsors and CROs are always looking for good sites, but the match has to go both ways," he adds.

2. Identify right person to contact.

"Sometimes it takes a little detective work," Ketels says. "And you have to be assertive about this."

When a CT site is targeting a particular sponsor it helps to use salesforce.com, an inexpensive resource for names and contact information, he suggests.

"Salesforce.com shows you relationships that exist between organizations, who reports to who, and you can send out emails directly from that software," Ketels says. "So I can create a report and see how many contacts they've made, how many times they've sent out site questionnaires or emails or made calls."

However a CT site identifies the key people to contact, the goal is to send out emails and information about the site's research attributes.

This contact information needs to be filed electronically so multiple people at a CT site have access to it, Ketels notes.

"If you have some staff turnover you'll need to have all of those contacts and phone numbers available," he says. "You need to be able to look at it any time and see a particular sponsor that you've been trying to acquire as a client and see when this client has been called."

3. Follow-up the introductory pitch.

Sites should follow-up with emails and telephone calls.

"If you know someone at the sponsor, and you know their name and phone number, then you should just call them," Ketels says.

"It's a little more powerful if you can do the follow-up by telephone," he adds. ■

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

■ Big pharma is catching on with better payment terms

■ Financial conflicts of interest policy advice given

■ Expert offers advice on obtaining payment terms that work

■ Learn more about continuous outcome measures in CTs

■ Site's good clinical practice methods work

CNE/CME QUESTIONS

21. A research protocol form designed to help assess a protocol's feasibility for a site should include which of the following?
    A. Study design, initiating investigator
    B. Project coordination, devices to be utilized, background of study
    C. Objective, patient population and sample size
    D. All of the above

22. Which strategy would be useful and a best practice in managing a clinical research site's risk?
    A. Make certain sponsor is insured sufficiently
    B. Check protocol contract language and informed consent document for inconsistencies
    C. Watch for sponsor contract carve-outs
    D All of the above

23. When a giving a brief marketing pitch to attract a new study, it's best to omit any reference to past subject recruitment history and clinical trial trends.
    A. true
    B. false

24. What is the purpose of a research patient billing guide?
    A. The guide details precisely what a clinical trial will pay for, what should be billed to the patient's insurance, and how these study procedures apply to ICD-9 and CPT codes
    B. The billing guide provides documentation that the site has standard operating procedures in place for identifying billing mistakes
    C. The guide meets accreditation approval
    D. None of the above

Answer: 21. D; 22. D; 23. B; 24. A.