JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 10, No. 1, January 2014 "Happy Trials to You"

Choose to Succeed in Clinical Research

By Suzanne J. Rose

Since the Danbury Hospital Office of Clinical Trials was created five years ago, we've grown to a staff of one director (the author) and six certified study coordinators. The hospital is now part of a health system, consisting of two hospitals and a 75-physician outpatient network, for which we are responsible. Along the way, we've learned some important lessons.

Lesson 1. Choose the Right Investigators

Successful investigators share many common characteristics. Unsuccessful investigators need have only one problem characteristic.

For example, one new investigator said "yes" to everything we asked of her. However, she apparently meant "no," since there was no follow-through. She did not attend scheduled meetings and was very difficult to track down. Another new investigator was overconfident in his clinical research capabilities, to put it mildly. Education and monitoring were ineffective. Our IRB eventually put his study, the first and also the last, on hold, to get his attention.

Today, we would have declined to work with these investigators, or at least, addressed the issues much more quickly. We are now better at selecting and developing capable investigators. We have now have 20 principal investigators and 40 sub-investigators.

- **Listen to the investigator's peers.** Do colleagues have reservations (usually subtle) about a physician's ability to perform research?
- **Sign a contract.** Sign "contracts" with investigators that clearly state their responsibilities and those of the central clinical trials office. Link their compensation to performance.
- **Watch for the warning signs.** For example: Does the investigator not review lab reports in a timely manner? Does he or she miss educational programs? Does he or she ignore helpful suggestions? Does he or she not return messages?
- **Take timely corrective action.** If an investigator is struggling, don't be shy about asking respectful but pointed questions, such as: "How can we help you avoid future protocol violations?", "Moving forward, how can we best communicate?", and "Do you still want to do research?"
- **Create a "Naughty and Nice List."** Create a list of investigators with whom you will or will not work. If a naughty investigator wants to get back in your good graces, set stringent requirements and don't forget why he or she is on the list.

Lesson 2. Choose the Right Sponsors and CROs

In January 2012, a contract research organization (CRO) contacted us about conducting a study. We returned the confidential disclosure agreement within 48 hours. On the regulatory side, we received the regulatory package a week later and returned it to their "clinical trial specialist" in early February. The CRO approved it (without questions or changes) in April. We received IRB approval in May. On the contract and budget side, we received the clinical trial agreement and budget template in March, submitted our changes in April, heard back from the CRO in July, received signature documents in August, and signed a week later. We

had already attended the investigator's meeting four months previously. During this seven-month period, contacting the clinical trial specialist was very difficult, achieving little or nothing. Attempts to escalate were unsuccessful.

In August, a new clinical trial specialist replaced the first one and re-reviewed all of our regulatory documents. She required changes to the informed consent form (ICF) that the first clinical trial specialist had approved, so we had to resubmit it to the IRB for approval.

In October, the CRO turned our site over to the study sponsor to obtain study drug, supplies and the regulatory binder, which we received in December 2012. At that time, the sponsor authorized us to start enrolling subjects. In January, the sponsor closed our site for lack of enrollment. If our performance during the 12-month startup phase had been inadequate, neither the sponsor nor the CRO had said so.

We obviously would not have started work on this study if we had known what was in store for us. To avoid similar problems, we have learned how to better select and work with sponsors and CROs:

- **Establish effective channels of communication.** We identify contacts that will communicate with us and follow up on our behalf, with clear rules for escalation.
- **Track progress.** At weekly staff meetings, we discuss open studies, paying special attention to those that are stalled or otherwise problematic.
- **Take action.** When we identify a problem, we do something about it and actively follow up until it is resolved.
- **Create a "Naughty and Nice List."** We seek out studies from good sponsors and CROs and not from bad ones. There are some sponsors and CROs with which we will not work. However, sometimes an opportunity is too good to refuse, so we pursue it, but very, very carefully.

Lesson 3. Choose the Right Trials

In 2010, we agreed to conduct an NIH-sponsored trial because the investigator considered it a good fit for our site and an opportunity to build our prestige, given the many academic medical centers participating. The study team screened more than 300 patients, of which 10 passed and none agreed to participate. We later learned that hospital physicians were uncomfortable with the study and had not been referring their eligible patients. After two years of hard, frustrating work, we closed the study, hoping our prestige had not been damaged.

To avoid similar problems, we have learned how to better select studies that fit our site's goals and capabilities:

- **Take feasibility assessment seriously.** If a study is not a good fit, it's not a good fit. You will waste a lot less time in a thorough feasibility assessment process than in a misconceived study.
- **Talk to the right people.** Include multiple people in the discussion, especially the study coordinator(s) who will have to do the work and the physicians who will have to refer patients. Obtain commitment from every department that will participate in the study. Ask them pointed questions, such as: "Do you want to be involved in this type of research?", "Do you have time for this study?" and "Will you give it your full support?"
- **Ask the sponsor and/or CRO questions.** Don't just guess when the sponsor or CRO might already know the answer to an important question.

- **Don’t be shy about saying “no.**” Sponsors and CROs respect sites that decline their studies for valid reasons. They do not respect sites that make promises they can’t keep.

Lesson 4. Choose to Make the Right Choices

The most important lesson we’ve learned is that we are the master of our own fate. Our site is successful and growing because we have the discipline to make the right choices. That is not to say we never make bad choices, but we use them to learn how to make better choices.

Author

Dr. Suzanne J. Rose, MS, PhD, CCRC is the Director of Clinical Research for the Danbury Hospital Office of Clinical Trials. Contact her at 1.203.739.8074 or suzanne.rose@wchn.org.

