Clinical Trials in Your Office: Payoffs and Pitfalls

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MAUI, HAWAII — Clinical trial participation can be a moneymaker for an office practice with some realistic planning and savvy negotiations, according to Dr. Roy Fleischmann and Dr. Alvin Wells.

"If you're looking to make a profit, you've got to get a profit," Dr. Fleischmann said. "If I'm getting paid double what I'd get paid for seeing the patient, I have a feeling I'm OK." That extra in reimbursement provides a cushion to cover the unexpected, said Dr. Fleischmann of the University of Texas Southwestern Medical Center at Dallas.

Dr. Fleischmann explained, "You've got to figure out what your real charges are," and that includes allocating a reasonable portion of overhead to cover the share of phone and utility costs incurred because of the project. He said he calculates the average amount of overhead attributable to a patient visit and incorporates that in his cost estimate.

"You do have to think about your time," as well, in determining the costs of doing a trial, Dr. Fleischmann added. "You have to go to the investigative meeting—it costs you a day. You have to do the site opening—that costs you an hour. You have to fill out the case report form. You have to sign all those lab reports when they come in."

Once you know your real costs, he recommends negotiating a minimum of 30% profit, which can act as a cushion to protect against unforeseen expenses. Amendments to the protocol and deadline extensions can increase associated expenses.

The key is to have someone other than the physician negotiate the contract with the company running the research. Dr. Fleischmann, who is in a large group, has an accountant do the negotiating. It's important to find someone you trust "to have the wherewithal to say, 'This is what we really need.' " It has to be fair, he added. "You're not getting rich on this, but it's a fair value," he said, "and they need to understand that."

Dr. Wells noted that costs and the bottom line cannot be ignored in the decision of whether to participate in a clinical trial. In estimating what he needs to be paid for a study, Dr. Wells, director of the Rheumatology and Immunotherapy Center in Oak Creek, Wisc., explained that he works with his billing staff to see what he is being paid for various patient visits, and then adjusts those numbers upward by 20%.

Dr. Wells, who is not part of a large practice, uses his coordinator to negotiate for him. "She does the dirty work," he said. "We play good cop, bad cop."

Both Dr. Wells and Dr. Fleischmann made their remarks during a symposium sponsored by Excellence in Rheumatology Education.

Beyond planning for a profit, physicians should pick their research projects carefully. Dr. Fleischmann noted that it's important to pick studies for which you have the patients. And be realistic about how many patients you can deliver, he added. His own large group practice is participating in two studies involving patients who have not responded to anti–tumor necrosis factor (TNF) agents. Because only a few of his patients have not responded to TNF blockers, he has committed to providing "1 or 2 patients; we're not going to do 12 of them," Dr. Fleischmann said.

Although physicians always have the option of advertising for patients to meet recruitment goals, Dr. Fleischman advised against this. Work with patients from your own practice, he urged. "Patient recruitment is a killer," he observed. "Nobody does it well." If you don't have the patients in your practice who are willing to participate in a trial, he said, "you're not going to be able to do it."

Dr. Wells noted convincing your patients to be in a trial can be tough. He reported finding it difficult to enroll patients in the current trial of celecoxib (Celebrex). Bad publicity about increased risk for heart attacks and strokes with cyclo-oxygenase-2 inhibitors gave his patients pause.

In considering whether to participate in a trial, "many times the patient will do it because of [their loyalty to] you," Dr. Wells noted.

Dr. Fleischmann urged audience members to "be your own center" when doing a study. Or join up with a group of physicians with whom you are an equal partner. Avoid going through contract research organizations when doing trials, he said.

Contracts should include clauses to provide for renegotiation if the company makes a change during the course of a trial. "Sometimes companies will listen to it, and sometimes companies won't," he said. "But if you've got the study," he pointed out, and "you have patients in the study, you actually have a hook." For instance, your patients can be withdrawn from the study.

Dr. Wells observed that there are bound to be differences in perspective between someone who has done "tons of clinical trials in a huge research group and somebody who is just essentially starting."

Noting that he has done fewer trials than Dr. Fleischmann, Dr. Wells said he "might be willing to break even to get my foot in the door on a trial." And, he said, "You get to answer some interesting questions."

Dr. Fleischmann agreed that sometimes there are reasons to do a trial other than for money. "There are trials where we don't make money," he said, "because there's an answer that we want to get."

There is no correct answer on how long to keep records after a trial. "A lot of companies will say 15 years. That's the usual," Dr. Fleischmann said. However, the Food and Drug Administration has the ability to go back and look at the data from a study at any point in time, he said.

"We keep them forever," he said. He stores his records from clinical trials at Iron Mountain, and "the storage fee is actually part of the budget."

He referred to a case from his own practice, in which the FDA performed an audit on a study 18 years after its completion. Dr. Fleischmann asked what would have happened if he had not had the data. "We could send you to jail," he was told.

Dr. Fleischmann disclosed the following relationships with Abbott Laboratories, Amgen Inc., Centocor Inc., Genentech Inc., and Wyeth: speakers bureau, consultant/adviser, and research grants. He also is on the speakers bureau for Hoffmann-La Roche Inc.

Dr. Wells disclosed that he is a consultant/adviser for Abbott, Amgen, Bristol-Myers Squibb Co., Centocor, Genentech, and TAP Pharmaceutical Products Inc. ■