Enhancing Oncologist Participation in Research

This article is the eighth in a series describing the qualities of exemplary research programs in clinical settings. The goal of this series is to describe supplemental attributes of high-quality research programs already in compliance with Good Clinical Practice guidelines. Participation in the clinical trial development process, a cited attribute, will be discussed in this article, the aim of which is to share suggestions from experienced clinical investigators with oncologists wishing to become more involved in the research process.

Create a Research-Centered Culture

Successfully initiating and developing a successful research program requires a commitment to making research a foundation of the culture of a practice. "To me, the development of a full research program reflects a doctor's desire to create a culture where people are developing their own faculties through education and stimulation. I don't see it as a way to do something that the hospital can market or as a new revenue source," says Alan Lyss, MD, of the Missouri Baptist Cancer Center (St Louis, MO).

"You really have to be committed to the whole concept of doing clinical trials to make it work," says Richard L. Schilsky, MD, chair of the Cancer and Leukemia Group B cooperative group and immediate past president of ASCO. However, promoting a culture of research is dependent, in part, on clinical trials that are easily implemented within the research program of a practice. Investigator and research staff involvement in the clinical trial process can help ensure that clinical trials remain relevant and executable.

Attend Meetings and Speak Up

Participating actively in cooperative groups or pharmaceutical meetings is a key step an oncologist must take to become more involved in trials. "Many oncologists enroll patients in cooperative group studies, but if they want a deeper involvement in developing studies and in analysis, it boils down to attending the group meetings," emphasizes Schilsky. "Show up. Ask questions. Get to know the committee leadership. That way, you learn more about the group's work, and its leaders get to know you as an interested individual."

Lyss agrees: "The meetings give a community oncologist the chance to interact with national leaders. By virtue of those interactions, by raising one's hand and volunteering or speaking up at the microphone to give the community physician's perspective, one can get recognized and have opportunities thrust in one's direction." Furthermore, Lyss emphasizes the necessity for community investigators to provide feedback on experiences in treating patients, which in turn encourages study sponsors to design protocols that can be practically implemented in the clinical setting.

Schilsky maintains that "the only real way to become involved in cooperative groups trials is to get appointed to one of the group committees." He says that community-based members provide a "reality check" during development of a study. They help the committee understand whether the questions asked are of interest to physicians and patients and whether the execution of the study in the community is feasible. "Often the people designing studies are not the ones enrolling patients," Schilsky adds. "They need feedback from people on the front line." A forthcoming individual might be invited to join an ad hoc group to help design or modify a study. "Before you know it, after doing one or two of these things, you're invited to be a standing member of a committee," Lyss explains.

To participate in the final analytic stages of research, says Schilsky, a physician must join in the planning stages. "Those two things go hand in hand. The main thing is to get onto those committees." Several sources say once physicians establish themselves as reliable participants, research projects will find them.

Join a Cooperative Group

Many community oncologists are active members of cooperative groups or other research bases. To become a member investigator, an oncologist must meet certain criteria, submit an application, and be accepted. These groups present an ideal opportunity for community physicians to become deeply involved in many stages of research. Schilsky observes

ASCO Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites

The ASCO statement addresses the minimum requirements for sites conducting quality clinical trials as well as the attributes of exemplary sites.[3-5] Both minimum requirements and exemplary attributes were determined on the basis of a review of the literature, current regulatory requirements, and consensus among community and academic clinical researchers. To conduct quality clinical research, sites should meet the minimum requirements. It should be noted, however, that the exemplary attributes are voluntary and suggested as goals, not requirements. Not all attributes will apply to all clinical trial sites, and many sites may be able to conduct high-quality clinical trials without accomplishing all attributes.

that although industry-sponsored studies enlist community physicians to enroll patients, because of concerns about intellectual property, community investigators generally do not design the trials or analyze results. He describes a 2001 ASCO survey investigating how oncologists felt about working on cooperative group versus pharmaceutical-sponsored trials: "Oncologists clearly felt that the cooperative groups asked more interesting questions and addressed more important issues for patients. They considered the cooperative group studies more reliable and more carefully reviewed and approved. Although the drug companies pay a lot more to support research expenses, the ASCO members strongly preferred putting patients on cooperative group studies."[1,2]

Another Option: Work With a Private Research Network

The Sarah Cannon Research Institute (SCRI; Nashville, TN) is one of several private research networks. SCRI enrolls 2,200 patients onto clinical trials annually, working predominantly with community-based practices seriously committed to research. SCRI does not participate in federally funded studies. Dee Anna Smith, chief executive officer of SCRI, says, "We have a no-dabbling rule. Dabbling means research never becomes a part of your group's culture, so you make more mistakes. Everyone is at risk, the patients and also the company that owns the compounds." Smith notes it is possible to reap financial rewards as a member of SCRI, "but it takes years and a critical mass of patients. This isn't a get-rich-quick scheme. You need to do this because it's the right thing to do for patients." Joining a private research network allows a community practice to offer patients a varied menu of trials. The network frees the physician to concentrate on caring for patients and producing quality data by managing research-related administrative tasks in the regulatory, quality assurance, budgeting, and financing areas. When the process goes smoothly at a practice, says Smith, "industry comes to see you as a consistent, reliable network. You build a reputation, and your opportunities expand."

One Key to Success: Careful Self-Analysis

In developing a practice research program, reflection is critical. "A group has to ask itself, what do we want to accomplish? How big is our appetite? How important is not losing money?" advises Smith. Physicians must also carefully analyze each protocol with which they may become involved. They and their staff need to understand it in depth. Which patient population is eligible, and do they have the demographics to support enrollment? What is the treatment plan, and how does it compare with the community standard? Can they administer the treatment themselves, or will they need to engage physicians in other disciplines? Are there specimen or unique imaging test requirements? There are even more questions: Is staffing equal to the administrative tasks required? Is there appropriate staff support for more sophisticated protocols? If physicians work on federally sponsored trials, can they maintain a full accounting of research expenditures? If a practice receives funding from both industry and government, is it able to create separate cost centers verifying that the federal money was used for intended purposes only?

Such careful analysis supported the gradual growth of the research effort at the Wichita Community Clinical Oncology Program (CCOP; Wichita, KS), explains its manager, Marge Good, RN, BSN, MPH, OCN. It was one of the first CCOPs created by the National Cancer Institute. The Wichita CCOP started with phase III trials in the 1980s, moving gradually into phase II work. Currently, says Good, "we are just getting our feet wet with the earliest stages of phase I work. These tests are pretty intense, with frequent blood tests and close monitoring. They're challenging in a community setting."

Another Key to Success: Careful Partnering

Physicians should proceed methodically when choosing research partners as well. If considering working with an academic cancer center, physicians should be certain the types of trials at the center fit their patient population. Smith suggests, "Ask yourself: 'What do I have, and what can they offer me? And how much am I willing to invest? How much can this potential partner help me?'"

Lyss observes that many institutions and physicians choose partners without serious analysis. He advises being careful. "Ask yourself if the partner can add materially to your program. You want to develop a complementary team, where people in the other program have expertise your group lacks and vice versa. Choose a partner that shares your vision of what you are trying to build." For instance, his group collaborated with another group that shared its vision of winning a CCOP grant. After working closely for 2 years, they achieved it.

Multidisciplinary Trials Pose Special Challenges

The simplest trials for a community oncologist to join—and a good starting place—are ones in which access to the patient population is easy, and treatment consists entirely of chemotherapy. "But more and more, many trials have requirements that mean you have to interact with other kinds of specialists," says Schilsky. For instance, treatment may involve a biopsy and molecular tests on the specimen before the patient enrolls. Some studies require specific imaging tests or mandate that a test be done in a protocol-specified way, which may not be the way the test is generally performed by the imaging center the oncologist uses. These requirements add complexity. "They can create the need for a whole set of communications you wouldn't ordinarily have to do if you were just ordering a routine scan," explains Schilsky.

Take It Step by Step

The process of building a solid research program is gradual, requiring long-term vision and commitment. Good advises treating it as "a day-by-day process. Don't become frustrated. Take one thing at a time; work on it, and learn from it." Although no one denies the challenges associated with clinical research, the benefits to physicians and patients are numerous. Enhancing participation in the clinical trial process assists in minimizing the barriers to protocol implementation and accrual. Physicians in all practice settings have the opportunity to become more actively involved by making the right connections and taking advice from experts such as those listed here.

Upcoming Events

The next article in this series, to be published in the January 2010 issue of *Journal of Oncology Practice*, will provide suggestions for novice researchers in the initial stages of clinical trial development. During fall 2009, ASCO will also be holding conference calls in which content providers will discuss the topics in this series and be available for discussion. The entire exemplary attributes series can be found online on the *JOP* Web site under the Clinical Research section of previous issues: http://jop.ascopubs.org. Information about the upcoming conference calls is available on ASCO's Web site: www.asco.org/ClinicalTrialResources.

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References

1. Finn R: Surveys identify barriers to participation in clinical trials. J Natl Cancer Inst 92:1556-1558, 2000
2. Finn R: Oncologist's role critical to clinical trial enrollment. Natl Cancer Inst 92:1632-1634, 2000
3. Zon R, Metropol NJ, Catalano RB, et al: American Society of Clinical Oncology statement on minimum standards and exemplary attributes of clinical trial sites. J Clin Oncol 26:1-8, 2008
4. ASCO outlines minimum standards and exemplary attributes for research sites: Previews tools to be provided. J Oncol Pract 4:185-186, 2008
5. Zon R: Guidance for quality research. J Oncol Pract 4:186-187, 2008