Making Research Dollars Stretch for Community Practices

Obtaining funding for clinical trials is a challenge most practices face. Representatives of practices recognized by the presentation of American Society of Clinical Oncology 2007 Clinical Trials Participation Awards (CTPAs) discussed how they address clinical trial funding issues.

Covering Support Services

Like many community oncology practices, Oncology Hematology Associates of Central Illinois, located in Peoria, participates in the National Cancer Institute's (NCI's) Community Clinical Oncology Program (CCOP), and receives grant funding for this effort. But, according to clinical research coordinator Heather Burks, "this funding is always only a portion of our actual operating budget, and at this time, is funding only between 50% and 75% of our costs." Burks continued, "as a member of many of the national cooperative groups and as strong believers in that system, we try to open many of their trials covering as many tumor types as possible, while still maintaining a reasonable regulatory burden." As a result, the practice may open trials in which they do not ultimately enroll patients. There are a variety of reasons for this scenario, including changing patient mix, underestimation of a patient's willingness to participate in trials, and the rarity of the disease being studied. Accrual for a trial that appears feasible today may not be viable in 6 months. The practice, therefore, reassesses its open trials on an annual basis and closes studies that have failed to enroll patients during the year.

As Douglas Weckstein, MD, of New Hampshire Hematology-Oncology (Hooksett, New Hampshire) says, "in a nutshell, our practice loses money on clinical research. We have enrolled to both publicly funded cooperative group trials and pharmaceutical [industry] trials. Most of our trials are publicly funded and most of our patient enrollments are on these trials. Since reimbursement is lower for the publicly funded trials, we lose money. We have always felt that quality research is part of our practice mission, and therefore have been willing to subsidize the trials program. Unfortunately, as our program has become more successful and we have added research staff, we have lost more money than the practice is willing to bear."

Weckstein mentions two major approaches to address his practice's economic shortfall and acknowledges that there are problems inherent with these strategies. One approach is to increase revenue either by participating in higher paying pharmaceutical industry-supported trials or by gaining more public funding; another is to decrease costs by reducing either the number of research staff or the number of patients accrued to trials. They are, in fact, trying both of these strategies in order to reduce their research budget

deficit. They are seeking out more pharmaceutical industry-supported trials as well as seeking greater public funding via the CCOP. In addition, they have decreased the size of their research staff, though this has increased demands on their existing staff.

Cathy Berendts, MS, RN, of Duluth Clinic Cancer Center (Duluth, Minnesota), says that funding does not affect types of trials they conduct. "In our cancer center, we have separate cost centers for physician practices, the infusion center, oncology clinical trials, and other services, to keep track of where money is spent. At the same time, we don't get too hung up on costing exactly and may use people from other cost centers for clinical trials." About 2 years ago, because of decreasing government funding, they had to take two full-time equivalents from clinical trials and move them to the physician practice cost center. "The physicians are ultra-committed to research," she notes, and are not inclined to eliminate research because of decreased funding. The majority of their trials are in cooperative groups. Staff from the physician cost center can work on clinical trials, in part because their medical oncologists are part of a large, multispecialty group. "If they were in a free-standing practice and needed to hire two individuals for clinical trials, they might see a difference in their pocketbook," she says. Currently, however, they can get by with cost shifting, and they are truly committed to offering clinical trials to their patients. Additionally, like the Peoria Practice, the Duluth Clinic Cancer Center has increased the percentage of industry-sponsored clinical trials, which allows for some cost shifting. Berendts' colleague Anne Forsman, BSN, RN, OCN, notes that as trials become more difficult to conduct as new novel agents are added, the eligibility criteria are more difficult to meet, the costs of central laboratory and imaging increase, and "it means stretching dollars."

Burks agrees, saying that because they are only partially funded by a federal grant, they do look to other sources of revenue to fill that gaps in funding. "Doing quality research depends on having an extensive infrastructure in place," she says. "Adequate staff, staff with longevity and experience, and adequate space and equipment are essential, but also very costly."

Partnering Opportunities

When asked if the Duluth Clinic Cancer Center partners with industry, foundations, other practices, or disease or patient advocacy groups, Berendts responds, "'Partner' is not the right word; 'sponsor' is better." The percent of effort funded by industry is increasing, but they are not cutting back on the number of cooperative group or government trials. They have not applied at this point to foundations or patient advocacy groups for grants.

Weckstein explains that they have increased their participation in quality pharmaceutical industry trials. Although they are not a US Oncology practice, they have been a member of the US Oncology Research Network. "The network affiliation has allowed a streamlined process to gain access to multiple drug company trials," he explains. "We also participate in pharmaceutical trials via a partnership with the Dana-Farber Cancer Institute, an NCI-designated cancer center in Boston, Massachusetts. Although we have been successful in gaining access to more pharmaceutical trials, we will continue to emphasize publicly funded cooperative group trials as the core of our research program. We strongly believe in the mission of cooperative groups in cancer research. Therefore, we expect that we will continue to rely on publicly funded trials to support our research efforts." They are planning on applying for CCOP funding to allow their practice to maintain and grow their clinical trials program. Since federal funding for the CCOP is expected to decline in 2008, they expect it will be more difficult to obtain support.

"The Oncology Hematology Associates of Central Illinois is a main component of our CCOP," explains Burks, "and through that private practice group we partner with industry to participate in industry-sponsored trials." She observes that the world of industry trials differs from the world of cooperative group trials in that industry is much more selective about trial participants. "As we started to focus on implementing more industry-sponsored trials, we discovered that industry doesn't often immediately see the benefits of having community oncology participants in their trials," she says. Burks believes that industry tends to favor academic centers due to the volume of patients assumed to be seen, as well as the availability of multidisciplinary physicians in one location.

Burks feels that establishing a good track record with the industry sponsor makes it much more likely that their site will be recruited for the next study that comes along, and that they will get to the point where the sponsor comes to them instead of their having to seek out the sponsor. "We also participate in a national phase II consortium," she says. This provides studies and funds for each patient enrolled. Even with industry and private partnerships, their practice does not completely cover the costs of doing research at their institution. "Fortunately, as a private practice-based research organization, we are not at the mercy of a large hospital system's annual budget process." Their physician group is dedicated to providing research to their patients and does its best to recover as much of the cost as possible. However, having to pay the difference is just the cost of doing business, which for them, is providing state-of-the-art quality care to their patients, she notes.

Fundraising

Berendts says that the Duluth Clinic Cancer Center is part of a large integrated health system and has its own internal foundation. This foundation supports half of a full-time

equivalent clinical research assistant that the practice couldn't fund with any other sources. As clinicians, her group doesn't actively participate in fundraising. However, if a grateful patient wants to donate, they will pass the name on to the foundation. As part of community goodwill, staff may speak at functions like Rotary luncheons and other fund-raising functions, but it is not a significant part of the duties of the clinical trial staff. She notes that the Duluth Clinic Cancer Center has just completed a brochure featuring the need for fundraising and explaining how donors' money would go to clinical trials that could change the course of cancer treatment. "As an administrator," says Berendts, "I appreciate that funding is one of the greatest challenges in clinical trials."

Burks says that they had not in the past participated in any sort of fundraising to support research, but within the last 2 years began a patient advocacy program to provide clinical trials education to patients and the community. "We have solicited private and industry funds to support this program, and use those funds to purchase audio-visual equipment and provide educational programs to grassroots community organizations. In the very near future, fundraising will be a focus of our organization, and the funds raised will be used to supplement patient care costs, provide continuing education opportunities for the research staff, and promote research through advertising and marketing in our community." She emphasizes that the time it takes to promote research in the communities served by the Illinois Oncology Research Association CCOP is not a trivial issue. "Making presentations, setting up displays, and just being present at the many events and organizational meetings throughout our large CCOP catchment area is very time consuming and requires spending much after-hours time," she explains.

"We do not fundraise for our research program," Weckstein states. "When I met the representatives of the other practices who were selected for the CTPA this year, I asked them about their strategies for finding research. I heard that several practices were pushing their pharmaceutical [industry-sponsored] trial portfolios, but I also heard that some were subsidizing their programs as we do. I'd like to get that message across."

These ASCO 2007 CTPA-winning practices have adopted several strategies to cover shortfalls in the cost of clinical trial participation. The most common described strategy is pulling funds from another cost center—either industry sponsorship, physician take home, or other source. Other practices have developed philanthropic means of covering the shortfall, through local foundation fund raising. Another has developed an affiliation with a large group that increases the ease of trial activation and participation by spreading the work involved over a large number of participating practices, and that they imply lowers their cost of conducting the trial.

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