Prepare and Plan for Financial Constraints on Clinical Trials

Many leaders in the oncology clinical trials movement are quick to say that participating in clinical trials is one of the most satisfying parts of their careers. “You get to be at the forefront of scientific development and see what works and doesn’t work,” said Shaker Dahkil, MD, who is president of the Cancer Center of Kansas (Wichita, Kansas). Dr Dahkil is proud of his ability to offer patients state-of-the-art care through his practice’s participation in the clinical trials process. His institution’s research portfolio has spread state-of-the-art care to patients in rural Kansas who would not otherwise have access to clinical trials. It has also proven invaluable in marketing services to patients throughout Kansas. “When [patients] see you can do [clinical trials], they come to you. It means that people don’t have to travel to centers out of state, but can get quality care right here.”

Yet, if you ask Dr Dahkil how he envisions the future of clinical trials, he is far from enthusiastic. In particular, he is concerned that decreased funding for the National Cancer Institute (NCI) Cooperative Group clinical trials could jeopardize his group’s participation. These Cooperative Group trials have been the cornerstone of bringing the highest standards of evidence to oncology practice. However, shrinking budgets are forcing his institution and many others to reassess their participation in the Cooperative Group trials. “Our NCI budget [for clinical trials] is down by \$100,000,” he says. “That is a substantial cut.”

Facing the budget reduction and anticipating more, Dr Dahkil questions whether enrollment targets will still be feasible. Kansas’ interest in clinical trials has not been motivated by dollars. In fact, the center has been subsidizing clinical trials for a long time. However, Dahkil said that no matter how strongly interested one is in doing good science, “there reaches a point where you can’t subsidize it any more. You need nursing staff, data managers, and you have to subsidize your [institutional review board].” Currently, approximately 20% to 25% of the center’s trials are sponsored by the pharmaceutical industry.

John M. Rainey, MD

John M. Rainey, MD, founder of Louisiana Oncology Associates, expressed similar reservations about participating in NCI trials, saying that he has found the requirements so onerous that he has stopped performing them almost entirely. The paperwork, institutional review board expenses, and data management are quite costly. “Even if you hire a CRO [contract research

organization], it costs \$1,500 per protocol per year.” He also is troubled by the regulatory burden imposed on physician investigators, which has also impacted his ability to conduct clinical trials.

Laurence H. Baker, DO

Clinical trial proponents worry that these trends—insufficient funding to cover the costs of Cooperative Group trials that require subsidy from other sources—are threatening the future of the Cooperative Groups. As an example, the University of California at Los Angeles (UCLA) recently withdrew its participation in the NCI-funded Southwest Oncology Group (SWOG). This is a decision that clearly troubles

SWOG chair Laurence H. Baker, DO. “I am not being critical of UCLA,” he said. “This is a reflection of reality.” Baker faults NCI budget cuts, the costs of labor and housing in Southern California, and other factors. For the record, UCLA Jonsson Cancer Center spokesperson Kim Irwin said that UCLA continues to participate in other Cooperative Group trials, including the Gynecology Oncology Group (GOG), Children’s Oncology Group, and National Surgical Adjuvant Breast and Bowel Project. As far as SWOG withdrawal, Irwin said that the university decided to invest its own resources into translational research and early-phase trials. In other words, UCLA decision makers choose to stop subsidizing the SWOG clinical trials.

According to Dr Baker, funds available to SWOG from NCI’s Cancer Treatment Evaluation Program (CTEP) could be reduced by 10% for fiscal year 2006. “We are getting \$9 for every patient enrolled in clinical trials” to cover the overhead and other expenses associated with SWOG central operations. Faced with shrinking budgets, Baker said that SWOG’s 10 disease committees will engage in a systematic scientific review of its entire portfolio to see where they can make cuts. “It will be a very strategic and transparent process. . . . What it could mean is that funding for two rare disease categories will have to be eliminated. Yet no matter how transparent the process is, I anticipate that there will be significant disappointment.”

In October, SWOG celebrated its 50th anniversary. Given the current fiscal climate, what will the Cooperative Groups look like in the years ahead? “This is going to change who does clinical trials in a dramatic way. It has put NCI into competition with pharmaceutical-sponsored clinical trials.”

Financial Planning Key for Successful Clinical Trials Participation

If financial issues related to participating in trials seem insurmountable, you can adopt strategies that help, according to Sharon Jameson, RN, MBA, senior director of clinical research at the International Oncology Network, Houston, Texas. "The most important thing community oncologists can do is to plan before they jump on board with clinical trials. One of the biggest problems I see is that a lot of times there is no planning. No goals are set," she said.

Jameson identified several recommendations that can help make a practice's experience with clinical trials positive.

- At least once a year, make a budget for research.
- Set a goal of how many patients you plan to accrue into clinical trials. This is the only way to be able to estimate how much per patient the trial will cost.
- Figure out who in the practice is willing to participate.
- Recognize that being involved in research is a commitment.
- Keep the research part of the office totally separate.
- Hire dedicated staff, most importantly, study coordinators.
- Look to clinical trials research as a marketing tool that can bring more patients into your practice.

The NCI has responded to ongoing pressure by expanding CTEP's Clinical Trials Support Unit (CTSU) Independent Clinical Research Site. Through this initiative, the NCI hopes to increase the number of physicians taking part in clinical trials by connecting them with physicians who have the resources and staff needed to carry out rigorous clinical studies. Participating physicians are required to satisfy a

minimum annual patient enrollment quota to maintain their ability to participate in cooperative group trials. *[Editor's note: JOP will explore the Clinical Trial Support Unit in a future article in this series.]*

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