Identifying and Selecting a Clinical Trial for Your Practice

John Kugler, MD

A successful practice-based clinical trials program maximizes the practice's use of its patient, personnel, and financial resources. Practices must identify and select the most appropriate trials, based on the patient population served by the practice, the type and phase of the trial, or the trial sponsor. The patient pool determines, in part, the potential for maximum accrual. Representatives of three practices recognized

by presentation of the ASCO 2007 Clinical Trials Participation Awards discussed how they identify and select clinical trials for their practices. John Kugler, MD, is with the Oncology Hematology Associates of Central Illinois—Illinois Oncology Research Association Community Clinical Oncology Program, in Peoria, Illinois. This practice has 14 physicians and seven midlevel providers serving about a million individuals in the Peoria and Bloomington, Illinois, areas via 15 clinics. Douglas Weckstein, MD, practices at New Hampshire Oncology-Hematology, PA, in Hooksett, New Hampshire. They have 11 physicians and five full-time midlevel providers that cover five practice sites. Ronald Korn, MD, PhD, is with Scottsdale Medical Imaging, Ltd (SMIL), Scottsdale, Arizona, a large private radiology practice with 10 sites in the greater Scottsdale area.

Patient Population

The Oncology Hematology Associates of Central Illinois serves a mixed rural, small town, and urban (Peoria and Bloomington) population, most of whom are white and non-Hispanic. New Hampshire Oncology-Hematology also serves several small rural towns and cities with a population that is mostly white, half of whom are older than 60 years. "The population that our practice serves is not large enough to support clinical trials for uncommon cancers. We focus our trials on lung, colon, breast, and prostate cancer, and lymphoma," says Weckstein. Kugler says that they also cannot consider trials for very rare cancers.

Weckstein says they attempt to identify trials they believe offer patients a reasonable chance of benefit, based on promising data for the study treatment as determined in smaller trials or other settings. "We also try to select trials that will answer important questions that will ultimately improve patient care," he explains. "For instance, we might select a randomized phase III trial that we believe will ultimately answer a question, rather than a phase II trial for the same indication." SMIL serves a 90% white population, with the remaining 10% being African American, Hispanic/Latino, Asian, and Native American. More than half the patients are age 65 years or older.

Douglas Weckstein, MD

Selecting the Trial

Because of their patient population demographics, SMIL is not able to support studies determining correlations between disease, treatment, and race. Otherwise, they look at the inclusion/exclusion criteria of a trial to determine the population limitations, then look for parameters that may affect participant appeal, including whether the procedures are or close

to standard of care, how many visits are involved, the level of invasiveness, and reimbursement for study procedures or study participation. Finally, they determine if they have a strong referral base to support trial enrollment. Nearby centers, including Scottsdale Healthcare Hospital, the Virginia G. Piper Cancer Center and its Research Institute partnered with T Gen, and private oncology practices provide them with patient referrals for trial enrollment. Research department review by coordinators and potential principal investigators (PIs) uses a feasibility checklist that takes into account the overall interests of the PIs, and includes a review of trial timelines and the procedures required, Korn explains. The checklist also compares the study to standard of care imaging and SMIL imaging protocols, and assesses physician involvement and interpretation methods, technologist involvement, scanner time, number and location of participant visits, and the overall burden to the imaging center.

Ronald Korn, MD, PhD

SMIL conducts device/treatment trials involving interventional radiology (eg, trials of vertebroplasty devices and phase III and IV contrast agent studies for use in computed tomography or magnetic resonance imaging). The research department provides a designated staff of clinical research coordinators trained on good clinical practices who can obtain clinical history,

medication history, vital signs, perform phlebotomy, and process laboratory tests, so that staff at each site do not have to bear the burden of performing these functions in addition to collecting information for rapid radiologist review. "Equipment requirements are a limiting factor," Korn adds. "If a protocol requires equipment or software that is not already at our sites or provided for by the study, then the protocol would not be considered."

Kugler says, “We don’t select trials based on our population. Our goal is to make as many trials available to our patients as possible.” We are active in all of the [National Cancer Institute (NCI)] cooperative groups except SWOG (Southwest Oncology Group).” The practices conduct prevention, treatment, and symptom management trials, a majority of which are cooperative group trials. Kugler says that although they do not conduct phase I trials, they have the staff to handle all other types of trials, and the infrastructure to participate in tissue procurement and translational trials. They make every trial available at all of their clinic sites, so patients who do not require hospitalization can be treated in their local communities.

The New Hampshire group conducts observation and psychosocial trials in addition to prevention, treatment, and symptom management trials, which are primarily cooperative group trials. Weckstein says that the PI and research director, a clinical research nurse, identify trials for which they will be able to accrue sufficient patients. The research director often uses registry data to “ground our idealistic hopes by showing that there aren’t as many eligible patients as we think.” Weckstein says in addition to assessing accrual expectations, feasibility also depends on the availability of laboratory, pathology, and other support services, as determined by their research director. This ensures that they will be able to fulfill the requirements of the protocol before opening a trial.

Weckstein adds that the practice selects trials they believe will answer valuable questions or provide important information. For example, there are two competing large international trials for premenopausal patients with hormone receptor–positive breast cancer. The Tamoxifen and Exemestane Trial (TEXT) trial compares ovarian ablation plus tamoxifen versus ovarian ablation plus an aromatase inhibitor. The Suppression of Ovarian Function Trial (SOFT) trial compares tamoxifen alone versus ovarian ablation plus tamoxifen versus ovarian ablation plus an aromatase inhibitor. The TEXT trial will reinforce the findings of the SOFT trial, but only the SOFT trial will answer the question of the value of ovarian ablation in these women. “The TEXT trial is an easier sell, and, in fact, has accrued patients twice as fast as the SOFT trial,” Weckstein observes. “We chose the SOFT trial for just that reason. We believe it answers the most important question and we want to contribute to completing this critical trial.” In addition, they will not open a new trial if it would compete with one already open in their practice for a similar study population.

Choosing a Sponsor

Korn says, “We rarely have to make a decision based on industry versus private sponsors. We look at the whole picture as far as the scientific merit of the study, the possibility of gaining future studies with the sponsor, whether industry or private, and if we feel that we can do an exceptional job on the protocol.”

Weckstein says that they select trials based on their perception of the quality of the trial, and how those trials fulfill their selection criteria, so the specific sponsor has little if any bearing on

selection. Reimbursement is a minor consideration. “We would choose a modestly remunerated trial that fulfilled our selection criteria and would decline a high-paying trial that was of little interest to our physicians,” he says.

Although most of the protocols they have open are NCI cooperative group–sponsored, Kugler says his practice also offers some pharmaceutical company–sponsored trials. “The decision is based first and foremost on whether there is good, solid science behind the study,” he says, as well as whether the trial will offer patients access to treatments they would not otherwise be able to obtain. “We made some costly mistakes in the past,” he notes. Now, with NCI funding declining, they sometimes consider industry-sponsored trials as a way of offsetting deficits and maintaining their infrastructure, although they will not select a trial that would compete with one from a cooperative group.

Resource Management

As New Hampshire Oncology-Hematology has grown, they have developed a research committee comprising the PI, two other physicians, the research director, a nurse leader, and a social worker who leads the psychosocial studies. This committee serves as the ultimate arbiter in trial selection. The PI regularly reviews the Cancer and Leukemia Group B and Cancer Trials Support Unit menu of active trials to search for newly opened studies. The PI will refer new trials that seem to fulfill the group’s selection criteria to the research director, who then analyzes feasibility. When a trial is deemed feasible, group and research committee consensus is sought via e-mail.

The SMIL research department is responsible for identifying and selecting trials based on a research feasibility checklist. Once a study has been identified and approved by the research department, it is brought to the group’s leadership committee, then to the executive committee for final approval.

Kugler’s practice plans to adopt Varian Medical Systems (Palo Alto, CA) electronic medical records (EMR) by the end of 2007. (*Editor’s Note:* This article was written in November 2007.) The EMR will be used by clinical research associates (CRAs) to screen all new patients in the practice and determine potential eligibility for protocols. This will replace the reliance on physicians to recruit new patients, and will involve nurses and CRAs in the process. The EMR will allow primary physicians to determine what other treatments might be available for their patients. “I’m hoping with EMR and tracking, we will have better electronic staging, which has been mandated by the Center for Clinical Effectiveness,” Kugler says. “This will allow us to bring up research protocols in the practice based on the stage of a patient’s cancer, as well as to determine patient eligibility. This should make trials more accessible and readily apparent.” This will replace the physicians having to call the CRAs to ask what trials are available for a given patient’s disease. The CRAs will be able to look for protocols actually available in the practice, rather than having to search through a national database of all open trials.

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