Choosing the Right Trials for Your Practice

Many factors contribute to the success of clinical trial research. Establishing an efficient research team, identifying eligible patients, developing outreach strategies, and securing funding are all integral to success. But perhaps the most important step toward success is choosing the right trials to open—selecting trials that will ensure the ability to accrue patients. Not every practice will have the same success with the same trials because of differences in practice size, resources, and patient populations. How do community oncologists determine the “right trials” for their practice? Asking the right questions is essential.

“There are so many areas to cover when deciding to open a new trial,” says Marge Good, RN, BSN, MPH, OCN, manager of the Wichita Community Clinical Oncology Program (CCOP; Wichita, Kansas). “We used to open [nearly] everything that came to us. We are now much more selective, and we don’t hesitate not opening a trial that we think will not result in accrual or that has minimal funding to support the accrual and data collection work attached to it.”

The Wichita CCOP is one of the 12 clinical trial research teams that received a 2006 ASCO Clinical Trial Participation Award (CTPA) in recognition of their high-quality research program and high accrual rates over the previous 3 years. Despite having similar success in improving patient accrual to clinical trials, the award-winning practices varied with respect to the types and number of trials they offered, pointing to the need to assess the feasibility of a trial in terms of the characteristics of an individual practice. Most research teams follow a similar approach to choosing trials that begins with the evaluation of potential protocols by a multidisciplinary team. Steps within that approach may vary according to the unique features of the practice.

The number of protocols evaluated and trials opened vary according to the size of the practice and the resources devoted to clinical trial research. Some of the CTPA recipients, such as Wichita CCOP, Green Bay Oncology (Green Bay, Wisconsin), and Marshfield Clinic (Marshfield, Wisconsin), review 10 to 12 protocols and open three to four trials each month, whereas other recipients, such as St Joseph Mercy Hospital Cancer Program (Ann Arbor, Michigan), review 40 to 50 protocols each month and open 10 to 13 trials. The research team at St Joseph uses technology to help meet the challenge of reviewing the high number of protocols. When the practice was funded as a CCOP 13 years ago, it had a database developed to gather information on potential trials. “There are so many factors to consider,” says Beth LaVasseur, RN, MS, Oncology Research Manager at St Joseph. “The database enables us to create lists of trials to help set priorities. And we are constantly refining fields in the database so that

we can generate reports that help us select suitable trials. Without something like this database, our process would be unmanageable.”

Once information on protocols is gathered, discussion about the various aspects of the trials is needed to determine which trials can be carried out by the practice. “The interactive process of debating is important,” says Thomas Saphner, MD, of Green Bay Oncology. But the framework for the discussion of potential trials varies across practices, and there is no one “right” way to select trials to open.

Many practices have formed committees to discuss the wide range of issues pertaining to potential trials. These multidisciplinary committees typically meet once or twice a month to review available protocols, and most of the CTPA recipients report increased accrual after establishing a committee process. The members of these committees include such individuals as practice physicians, oncology research managers, research nurses and coordinators, data managers, investigational drug pharmacists, laboratory personnel, radiology and nuclear medicine staff, and oncologists in other specialties. Engaging physicians from outside the practice in the review process can add to the success of a practice’s clinical research.¹

Some practices involve fewer people in the decision-making process. “We do not have a large committee to review studies,” says Good. “Most of the decisions are made by our principal investigator, perhaps one other physician, a CCOP nurse, and me. The fewer people involved, the quicker the process and the faster we can get a study we want open and activated.” Tennessee Oncology (Nashville, Tennessee) follows a similar process. Anthony Greco, MD, notes that at this practice, which is involved primarily in investigator-initiated trials, eight scientific directors “decide what trials we want to be involved in.” He adds, “There’s much less bureaucracy that way.”

Despite differences in the number of people involved in the decision, all practices seek the answers to core questions that help them determine what trials will be right. The CTPA recipients agree that evaluating the scientific merit of the study is the first step, and they ask such questions as the following:

- Is the science sound?
- Does the study design make sense?
- Is the question being asked by the study a valid one? Is it worth the investment of our time and efforts to answer?

It is also important, note the CTPA recipients, to determine if the proposed protocol competes with other open studies.

“You need to know if you can have patients enrolled on a concomitant protocol, such as a quality-of-life study,” says Robin Zon, MD, member of the ASCO Cancer Research Committee and oncologist at the Michiana Hematology-Oncology, PC, which provides leadership for the Northern Indiana Cancer Research Consortium CCOP (South Bend, Indiana).

Issues concerning patients and the investigational treatment are paramount. Such questions as the following can help a practice determine how a specific trial protocol will affect their patients:

- Is this a good treatment option for our patients? Does it add benefit for them?
- Does it add to our menu of care options?
- Will patients need testing that may be outside the realm of so-called normal? health care?
- Can the trial be carried out in the community setting?

Joni Richman, RN, BSN, OCN, Director of Research Operations at the Rocky Mountain Cancer Center (Greenwood Village, Colorado), points out that another critical question is whether the treatment patterns for the disease being studied are expected to change within the timeframe of the trial. “Often, as new drugs are approved, treatment patterns will change and make a study that was written before that obsolete,” she explains.

Most research teams use a template assessment form to help them evaluate a protocol and determine if the practice has the patient population, resources, and staff to carry out the trial (Table 1). These forms provide guidance for evaluating the various aspects of research protocols, including general eligibility; accrual plans; clinical details; drug ordering; laboratory, pathology, and radiography issues; need for special equipment; informed consent; data management; financial aspects; and regulatory issues.

Many of the CTPA recipients emphasize the importance of specific considerations. James Lockhart, MD, of Warren Cancer Research Foundation (Tulsa, Oklahoma), notes that it is important to evaluate how easy—or difficult—it will be for the protocol to be approved by the institutional review board (IRB). “Trials with small numbers for accrual might be completed before you can get the trial through the IRB,” says Dr Lockhart. Regulatory issues should also be evaluated, according to LaVasseur. “We found that regulatory issues could impede the trial if we opened it before assessing these issues,” she says. Kendrith Rowland, MD, of Carle Cancer Center (Urbana, Illinois), adds that his team’s evaluation of protocols includes a review of “audit traps” or “nuances that will likely be missed,” he explains. “The goal is to educate our entire staff about the detail needed to perform such trials and minimize the infractions at audits.”

Another factor that can have a significant impact is the time needed to complete the data. “Complex data requirements

Table 1. Questions to Ask to Determine if a Clinical Trial Is Right for Your Practice

Do we have the patient population?
How many patients are needed?
How many patients do we have with this disease entity?
Are the entry and eligibility criteria too restrictive?
When does the enrollment phase end?
Do we have the necessary resources at our facility?
What is the mode of treatment? Is it done easily in an outpatient setting?
Are the medications routine?
Are any nonstandard devices needed to deliver the medications?
What laboratory tests are required and at what frequency?
Is there a central laboratory?
Do laboratory specimens need to be shipped? If so, shipped in batches, or individually?
Does the laboratory testing require special equipment (eg, refrigerated centrifuge)?
Do the findings of any testing need to be centrally reviewed?
Will special support of local pathologists be needed?
Is any special equipment or equipment that needs to be credentialed required?
What kind of radiographic measurements are needed?
Are evaluable radiographic criteria needed?
Is the compensation sufficient to cover the costs?
Is there funding to pay for non-standard testing?
Will the medications be covered by insurance?
Do we have the staff necessary to carry out the trial?
Will education for staff or patients be needed?
Does the required process for data collection differ from that normally used?
How are the data collected and submitted? By hard copy CRFs or by electronic methods?
What do the forms ask for?
How many data forms are there?
Are informed consent forms available? Are they HIPAA-compatible?
Will additional staff be needed to perform laboratory tests?

may require more staff hours than a practice can handle,” adds Dr Zon. Lastly, Tarit Banerjee, MD, of Marshfield Clinic, notes, “We also evaluate whether we need to develop electronic orders or need to work with local hospitals and other departments, such as surgery, radiation therapy, dermatology, and so on. In addition, we evaluate the staffing required for the protocol and whether staff needs any additional education to run the protocol, such as how to perform an ECG.”

Practices also must consider their specific situations carefully when reviewing protocols. Jane Harris, RN, MS, Clinical Research Manager at St Luke's Mountain States Tumor Institute (Boise, Idaho), notes that because the institute is an outpatient facility with regular hours, requirements such as pharmacokinetic sampling or a very rigid dosing schedule may not be feasible. She adds, "The demands of a rigid schedule that requires several visits a week are difficult for many of our patients who have to travel several hours for treatment. If the protocol requires a visit two or three times a week for many weeks, it's just too hard for already sick patients."

LaVasseur sums up the complex selection process in simple terms. "For us, it's a constant balance of what's available, what types of patients are being seen, and what treatments are already available. All of our decisions are based on overall assessment, patient need, and doability—we assess protocols carefully to make sure they can be done in a community setting."

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Reference

1. Increasing clinical trial accrual: Collaboration and physician-to-physician contact. *J Oncol Pract* 3:152-153, 2007

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