Developing and Managing a Healthy Clinical Trials Program in a Community-based Cancer Center

Passion for research leads to success

by Steve Smith

Clinical trials are essential in the advancement of cancer care. Not too long ago, most research occurred in academic institutions, where oncologists who wanted to be involved in the development of new therapies chose to practice. Patients who were qualified for clinical trials and who were willing to participate and able to make the commitment were required to travel—often great distances—to the site of the trial.

Fortunately, times have changed. Today, more cancer patients are being treated in community-based settings. And various research organizations and networks offer multiple opportunities for community-based oncologists to incorporate clinical trials into their practices. Extending the reach of research into communities across the nation has enormous benefits for everyone in the cancer care continuum. Most important, patients have easy access to the latest cancer-fighting therapies. Improved access to clinical trials has helped reduce the time it takes to accrue the required numbers of enrolled patients to statistically support results, speeding up the approval time for new therapies to become available for use by other patients.

Many oncologists choose private practice because of a deep-rooted belief in the value of bringing advanced treatment to patients in their communities, close to where people who are battling cancer live and work. By bringing research to the "private practice" and serving as investigators in ongoing studies, oncologists fulfill their desire to provide high-quality care to patients in their communities, while also gaining great professional satisfaction by playing a key role in the development of new therapies. Now, oncologists can have the best of both worlds.

Create the Right Culture

Developing a clinical trials program requires a significant commitment of time, effort, and resources. While most oncology practices already have much of the infrastructure in place to conduct trials—conference room, infusion room, files storage, locked drug storage unit—some start-up capital is required to cover additional personnel, training of existing personnel, possible extra workspace, a computer for data management, other office expenses, and marketing.

Without a doubt the biggest investment in developing a clinical trials program is time. Oncologists who are considering adding clinical trials to their practice need to be prepared to spend hours reviewing potential studies, understanding the Good Clinical Practice (GCP) requirements and protocols, educating and supervising staff, and recruiting and consulting with patients. Even after months of developing the right processes and internal structures, once the initial learning curve is over, the time commitment remains. Oncologists must continually communicate with co-investigators in the practice. And staff will require weekly meetings for training, revision of processes, and communication and education about amendments to protocols.

Given the need for such commitment, it stands to reason that the most critical component of a successful clinical trials program is creating a culture in the practice where there is passion for research. From the oncologists who serve as investigators and nursing staff who help administer the protocols to the insurance specialists and receptionists, everyone in the practice must embrace research and be willing to devote whatever it takes to making research happen.

The Research Team

In addition to involving the entire practice in the research program, multi-physician practices usually find having one of the oncologists serve as the director of research or "research champion" helps provide the necessary leadership and direction for the program. In addition to creating the right culture, the research champion is responsible for supervising each trial that the practice participates in, ensuring that:

- Staff is properly trained
- Protocols are managed
- Data are collected
- Patients are actively accrued
- Compliance and informed consent regulations are met.

Most practices hire a clinical research coordinator, or redefine the job description of one of the oncology nurses, to take on these responsibilities. An effective clinical research coordinator serves as the "right hand" of the research champion. He or she will work with the physicians in the practice to:

- Implement and manage the protocols
- Help educate other staff about protocols
- Screen patients and assist with recruitment by working with referring physicians
- Educate patients and their families about studies
- Organize the informed consent process
- Manage participating patients' care by scheduling tests and monitoring results
- Collect and organize data.

Depending on the size of the research program and the number of trials oncologists participate in, some practices may also invest in a data manager who manages the clinical trials data and prepares the data for the trial sponsors and agencies that monitor the trials. Often, however, when a practice initially begins a research program, current staff takes on additional responsibilities. For example, a staff nurse may serve as the data manager, and all nurses will administer therapies to patients, record the required data, and provide

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important education to the patient about the treatment.

Insurance specialists must understand the reimbursement issues associated with each clinical trial. In most cases, costs for care that is required whether or not a patient is participating in a trial (referred to as "standard of care" services), including routine doctor's visits, hospital stays, or diagnostic tests, are covered by third-party payers. Costs for extra care due to participation in the trial, such as additional tests to monitor the study, may or may not be covered by the sponsors of the trials. It is important to anticipate and identify these extra costs and who will pay for them prior to beginning the trial. The insurance (or claims) specialist will be responsible for researching these situations and clearly communicating findings and options with the oncologist and the patient.

Staff Education

A big part of creating the right culture in the practice revolves around educating staff about clinical research. Not only must each person understand the reasons for participation and the benefits to patients and the practice, each staff member must be open to learning new skills. Training can be broken down into two categories: 1) general education about clinical trials and the practice's program and 2) specific training about each protocol.

General training paints a big picture view of the program for everyone in the practice:

- Laying out guidelines for the responsibilities of each team member
- Training on new skills required to conduct research
- Discussing new processes that need to be implemented throughout the practice.

Typically, the research director and clinical research coordinator work together to devise a training plan and schedule. Working with a strong research network that has helped other physicians begin research programs can offer significant benefits compared to creating a training plan from the ground up.

Before participation in each new trial, the research director and clinical research coordinator must train all office staff on the trial's specific protocol, providing step-by-step instructions for conducting the trial. The training should include:

- Rationale for the protocol and its objectives.
- Explanation of the requirements of the protocol, including relevant regulations and guidelines.
- Explanation of new skills needed to conduct the specific study.
- Specific dose and administration of the therapy.
- Details about the testing required by the study.
- A review of potential side effects.
- Procedures for managing side effects.
- A review of all materials provided by the study sponsor. These include forms, logs for recording data, drug information sheets, and procedures for reporting adverse effects.

A common pitfall of practices first beginning research programs is to only train oncology nurses and oncologists who serve as co-investigators. To have a successful program and comply with the protocols of each study, however, everyone in the office must work in concert. For example, scheduling personnel must understand the requirements of each treatment protocol to ensure patients are scheduled at the right times. The staff member responsible for data management must understand reporting requirements to ensure that appropriate information is collected and entered. The bottom line is that good communication with, and coordination of, the entire practice team is imperative for a successful program.

Marketing: It's Not the Big Ugly

Many oncologists have been dragged kicking and screaming into the realm of marketing. As patients have become savvier, looking for differentiators that make one practice stand out from another when choosing where to receive their care, oncologists have come to understand how vital marketing is to their success. Though for most, it remains a less than favorite activity on which to spend time or money.

Adding a research program gives a private practice a golden opportunity to strengthen its brand and reputation. It helps establish the practice as being on the leading edge of cancer care, and can open many doors for establishing new relationships with referring physicians. When developing a research program, oncologists must include a marketing plan. Generally, the clinical research coordinator is responsible for implementing the marketing plan and its initial two objectives: 1) to establish awareness of the practice as a research site and 2) to recruit patients for specific trials.

The first step to creating a marketing plan is to understand the main sources for potential participants—current patients, physician referrals, and patients who learn about the trials from other sources, such as advertisements, the Internet, friends, and family. Targeting these audiences need not be costly. In fact, many simple, yet effective tactics will reach each audience, including:

- Sending a letter to referring physicians explain-

ing the reason the practice made the commitment to participate in clinical trials and how research benefits patients in the community. Conclude the letter with gratitude for their support and referrals, and an invitation to discuss the program in more depth.

- Sending a follow-up letter [to referring physicians] each time the practice begins a new clinical trial. The letter should outline the criteria for the trial and ask for referrals.
- Distributing a press release announcing the new research program to local newspapers. Each new trial presents another opportunity to make an announcement and provide specific details about eligibility requirements.
- Creating counter cards or posters for the patient waiting area and infusion room. The message can be simple, such as "Ask us about our clinical trials program."
- Developing an inexpensive, tri-fold brochure outlining the valuable opportunities that clinical trials offer patients. The brochure can be added to your literature rack.
- Educating patients about the research program. Don't be shy! Tell all current patients about the program, even patients who aren't candidates for a study.
- Adding information about the research program on the practice's website.

Certainly, many other marketing tools can be used to get the word out. Print advertisements, radio spots, even television spots and billboards are all examples, but these strategies require a much larger financial commitment. If the practice is already using these tools, then revising the creative piece to include a message about the new research program will not be too costly.

Accruing Patients

Once a patient has been identified as a potential candidate for a trial, he or she must undergo a comprehensive screening. This screening ensures that the patient meets all of the eligibility requirements as defined in the protocol and that the patient understands all of the treatment options. The screening also makes certain that the patient is able to meet the scheduling requirements of the study, and fully understands the informed consent and the dangers or risks involved with the study.

Talking to patients and their families about participating in a study may be delicate. For many patients who are candidates for trials, the standard treatment protocol has not worked, and patients are often very emotional. It most likely will require multiple discussions to answer questions and absolutely ensure patients understand all of their options and the details of the study before obtaining an informed consent. Often, patients seek information about the clinical trial from their primary care or referring physician, as well. For this, and many other reasons, oncologists should thoroughly communicate with referring physicians about treatment options so they can help patients better understand the information and make decisions.

Patient participation in trials is always voluntary. At any time and for any (or even no) reason, a patient may decide to stop participating. There are also times when oncologists recommend patients stop the experimental treatment. As such, practices must have a plan in place that helps transition patients who stop participating in a clinical trial back into mainstream care. This scenario includes having an appropriate process in place to absorb patients from clinical trials back into care after their trial has ended.

Make the Commitment

Participating in clinical trials can be extremely rewarding for oncologists and both clinical and non-clinical practice staff. With new therapies being developed at an extraordinary rate, the opportunity for advancing the way cancer care is delivered and offering new options to patients is happening more quickly than ever before. While developing a clinical trials program may seem like an overwhelming task, many research organizations are available that can help provide the necessary tools and support.

Remember, managing a research program is complex and requires contributions from everyone in the practice. The keys are creating a culture where everyone is excited about the opportunity, staff is willing to take on additional work, and the site has a plan that identifies who will perform each responsibility to ensure that each person understands his or her assignments, and the process for continually reviewing assignments and procedures. Aligning with a research network experienced in developing a team and implementing the right processes can help ensure the practice research program gets off to a strong start.

Steve Smith is the vice president and general manager, Research and Personalized Science for US Oncology.

The US Oncology Solution

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In addition, US Oncology Research negotiates single contracts and budgets on behalf of the research network, provides investigator-initiated trial support, including data management, biostatistics, and medical writing, and offers central financial management for both registration and investigator-initiated clinical trials, central Institutional Review Boards, Radiation Therapy Oncology Group (RTOG) studies, and access to scientific and clinical thought leadership.

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