Including Clinical Trials at Your Practice

First-time investigators should consider several matters when preparing for a clinical trial.

BY ARON SHAPIRO

Whether you are new to the field or an experienced retina specialist, the decision to include clinical trials at your practice is one that should be arrived at after careful consideration and planning. Conducting research is quite different from traditional practice: There are contracts, recruiting strategies, forms, protocols, and regulatory documents that will require very specific procedures for proper trial execution, and the investigational medications and/or devices used in the study will likely be subject to stringent usage guidelines. Clinical trials require time, effort, and attention to detail, and there is no room for shortcuts. Despite these added challenges, clinical trials are frequently fulfilling for practitioners and beneficial to their practices.

WHY BECOME AN INVESTIGATOR?

Clinical trials offer access to new innovations in retina therapy, cutting-edge technologies (such as new imaging and surgical tools), and novel therapeutic options. Additionally, clinicians and their staffs have the opportunity to learn about new technologies before they are available on the market. Participating in clinical trials provides first-hand knowledge of safety concerns and treatment efficacy, which should raise one's confidence level when treating patients.

Access to cutting-edge therapies and treatment strategies available via clinical trials may also serve as a marketing tool: It may bring attention to a practice and increase the number of patients on the roster. If run efficiently, a clinical trial is an additional source of revenue. As the staff becomes familiar with the process of conducting a trial, it may be possible to simultaneously conduct multiple trials, potentially increasing the sources of revenue for the practice.

Most important, though, clinical trials help advance the practice of medicine. Participation should instill pride, because even unexpected results from a study will add to the knowledge base of the subspecialty.

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PATIENT BENEFITS

Clinical trials can benefit current and newly added patients. Patients who are eligible to participate in the study may benefit from new treatment options in a controlled environment. Participants may also have access to novel diagnostic techniques, technologies, and equipment throughout the study at no additional cost. Patients who have not responded to the standard of care may respond positively to novel therapies or devices. Participants in clinical trials receive extra care and attention, as well as close follow-up: Instead of annual visits to monitor a current therapy or discuss additional treatment options, clinical trial participants visit more frequently to receive treatment and undergo extensive testing.

WHERE TO START?

In addition to regular practice duties, an investigator must supervise each trial, interact with the institutional review board, develop budgets, and manage audits and inspections. Basic introductory courses on the principles and practice of clinical research and courses targeting the ethical and regulatory aspects of human subjects are good resources for information on the spectrum of clinical research. Online courses are available for clinicians who cannot attend classroom courses.

Observance of good clinical practices (GCPs) is essential when conducting clinical research. It is recommended that clinicians and their staffs undergo GCP training to prepare for study participation. The Collaborative Institutional Training Initiative offers research ethics education to those participating in clinical research and

is the primary training program for GCPs (citiprogram.org). Initial training should be followed by biannual training in courses such as the National Institutes of Health Protecting Human Research Participants course, which highlights the obligations of those conducting clinical research to protect the rights and welfare of study subjects (phrp.nihtraining.com).

TIME AND STAFF

Conducting a successful clinical trial involves much coordination, recruitment, follow-up, and documentation. Conservatively, these administrative functions will require about 10% to 15% of the total time spent on clinical trial duties.

Many first-time investigators underestimate the time it takes to properly manage a clinical trial. Although it often does not take additional time to treat patients with investigational products, the amount of time spent on administrative duties associated with a trial may be substantial. A typical retina specialist is too busy to dedicate time to the tasks clinical trials require. Therefore, it is critical to have a designated study coordinator. The study coordinator should be an individual who wakes up every morning excited about the study, so it is important that he or she be fully invested. This person may be a technician or other staff member from the practice who is ready for a slight career change, or a staff member who is interested in gaining more responsibility. As the practice prepares to conduct additional clinical trials, the study coordinator can transition into this new role and grow with the practice. A staff member dedicated to the running and oversight of clinical trials will free clinicians' time, allowing them to dedicate time to patient care. One option is to balance clinical trial duties between 1 or 2 part-time staff members and a study coordinator; as the research end of the practice grows, more full-time staff members can be added.

Clinical trial participation might require travel, particularly if the practice is part of a multicenter study. As an investigator, your presence may be required at protocol development or institutional review board meetings. Although such travel is an extra responsibility that reduces the time spent in your the clinic, these meetings are opportunities to connect and network with other retina specialists who share similar interests.

ADAPTING THE PRACTICE

In addition to staff adjustments, the physical setup of the practice may need to be changed to prepare for a trial. A study's sponsor will typically inspect a study site before it is approved and again immediately prior to the study start. Sponsors will want to know that a practice is well equipped and is prepared to execute the trial effectively and efficiently. Areas and examination rooms where the study participants will be seen should be clean, accommodating, and well organized.

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Every study is different, so the changes to the physical setup will depend on the investigational drug or device. Almost every study requires a secured room with a locking door, set aside specifically for the investigational product. Be sure the practice's normal drugs are separate from clinical trial drugs. When rearranging the office, consider that some products may need a refrigerator, freezer, or additional shelving for storage. Additionally, ensure that any equipment being used has been serviced according to the manufacturer's requirements. It will also be beneficial to dedicate space for storage of research data and study supplies. It is likely that there will be several monitoring visits from the trial sponsor to review data throughout the study, and it is wise to earmark space for monitors to comb through data.

CONCLUSION

For many retina specialists, participating in clinical trials is rewarding and provides a welcome revenue stream, and a practice may grow as a result of participating in a clinical trial. All clinical trials require protocols to ensure they are run safely, responsibly, and according to accepted standards of practice, all of which will mean extra time and resources dedicated by study coordinators and their staffs. Clinicians, however, should strive to maintain a "business as usual" atmosphere with non-study patients while providing excellent care for those who are participating in the study. ■

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