Clinical Trials: What Young Practitioners Need to Know

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This installment of "Residents and Fellows" focuses on the ever-daunting topic of embarking into the realm of research while trying to balance clinical practice. Involvement in clinical trials can be a very exciting way to become more involved in ophthalmology while simultaneously bringing new and potentially cutting-edge treatments and products to patients. A common theme emphasized by all of our participants this month is organization. Having had the opportunity to be involved in a few clinical trials myself, I wholeheartedly agree that organizational skills are key to successful and meaningful research.

—Sumit "Sam" Garg, MD, section editor

DANIEL H. CHANG, MD

Participation in clinical trials in a private practice setting is a significant commitment that can have a variety of benefits, including intellectual stimulation, exposure to the latest technology, and access to some of industry's best talent. Building a strong clinical practice, both in terms of quantity of patients and quality of care, is essential. A steady volume of patients is needed to enroll enough subjects who meet the selective entry criteria. If enrollment is not completed in a timely fashion, there is simply nothing to study. Volume alone, however, is not enough; a commitment to quality outcomes is necessary to provide clear data regarding the performance of any index to be measured. In a practice that is already devoted to best outcomes, a clinical study would require little additional improvement in clinical care. The increased burden would primarily be administrative.

Identifying a great study coordinator to manage the administrative rigors of clinical trials is critical. Clinicians rarely have time to complete all of the documentation and paperwork required. A reliable study coordinator is needed to keep everything organized. Although experience is helpful, companies provide significant guidance, so even a seasoned technician without specific research experience could be a good coordinator. He or she should be interested in research and independently motivated to achieve excellence. Because the rigors and demands of clinical trials can be significant, both the investigator and the research coordinator must tackle the extra work required to attain the rewards of answering a clinical question or bringing a new product to market.

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—Daniel H. Chang, MD

JEFF GRIJALVA, COT, CCRA

I am the clinical research coordinator (CRC) at the University of California, Irvine. Based on my experience, the key to succeeding in clinical research is organization. The principal investigator (PI) is responsible for the conduct of the study, in its entirety, at his or her site. He or she must fully understand the obligations associated with being a PI as well as the study's protocol.

Clinical research involves a tremendous amount of regulatory documents and paperwork that must be completed

in a timely fashion and submitted to the study's sponsor. The PI must complete all necessary training required for the study and ensure that all members of the study's team have done so as well. Records regarding training for the study must be kept up to date.

An experienced CRC takes most of the burden off the PI's shoulders. The CRC handles all of the regulatory requirements for the study, which means that he or she needs to fully understand the study's protocol. The CRC will guide the PI throughout the study and will know what study-specific tests and/or procedures need to be conducted at each study visit. The CRC is also responsible for scheduling all of the study's subjects within his or her study visit window and ensuring compliance.

MALIK Y. KAHOOK, MD

I have had the good fortune to participate in many clinical and surgical trials at the University of Colorado over the past 8 years. The benefits and drawbacks of involvement in single and multicenter trials are numerous, but I will focus on the big picture. Physicians early in their careers, whether in private practice or an academic setting, must consider a few questions early in the process of setting up a research center or joining an existing research infrastructure, including

- Will my practice be able to recruit patients for any given specialty?
- Will my practice have the infrastructure (staff, space) to properly manage and complete studies?
- How will the research funds be managed once the contract is signed?
- How will I finance such studies if single-center, non-sponsored research is desirable?
- Will I receive any start-up funds to establish a particular line of research if sponsored research is not included?

Unfortunately, many clinicians answer these questions on the job and learn by making mistakes. The best advice that I can offer to a young investigator is to seek mentorship (either within or outside his or her practice) from individuals with established research programs similar to what he or she would like to pursue. There are many unique obstacles in private practice versus academic settings. Advice from those who have navigated a similar setting would be of great value.

It is also extremely important to lead by example and to establish open lines of communication with team members so that they feel comfortable approaching you with suggestions and concerns. It is good practice to frequently review the progress of ongoing studies and to ensure that proper scientific and ethical standards are maintained. The investigator is ultimately responsible for the research taking place within his or her center. Finally, pursuing a career in ophthalmology that includes research of any kind will benefit patients as well as enrich the lives of the investigators and their staff members, resulting in greater career satisfaction for all. Participating in research has enriched my career, and I would recommend that all young physicians consider the pursuit of new knowledge in any form that they find most compelling.

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—Malik Y. Kahook, MD

MARTIN KRUPA, MD, AND NATALIE A. AFSHARI, MD

One of the most daunting tasks a young investigator faces is organizing data. Haphazardly organized data make statistical analysis cumbersome and require tedious manipulation, which in turn can lead to errors. Our experience with clinical research projects has shown that errors can be greatly reduced and that statistical analyses can be sped up through the use of a structured, centralized format for storing patients' data and outcomes such as structured query language (SQL) databases.

SQL databases work very well in both small and large multicenter clinical research projects. They enable users to model data as tables, much like a spreadsheet would. Unlike with a traditional spreadsheet, however, tables in a SQL database can have links such that one table contains data that are located in another table. The SQL database takes care of all the links behind the scenes, thus allowing users to focus on designing the structure of their database to best represent their data. In addition, SQL databases provide an intuitive and powerful query language and adaptors to third-party applications, and they are available as free distributions such as MySQL (www.mysql.com). The greatest advantage of the SQL database is its ability to create web-based front-ends that allow users to enter data using a web browser. Using a scripting language like Hypertext Preprocessor (originally Personal Home Page, commonly referred to as PHP), simple web-based front-ends can be created to interface with the database and programmed to perform input validation. Similarly, web pages that query the database and display result sets can be made.

Several applications exist to help users organize, manipulate, and query their database, including the free web-based project software tool phpMyAdmin (www.phpmyadmin.net). Perhaps the only downside of using an SQL database is the steep initial learning curve involved, but this effort should quickly be rewarded with cleaner and more consistent data that are easy to analyze. ■

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