ENHANCING PATIENT RECRUITMENT IN CLINICAL TRIALS

Pearls from a private practitioner.

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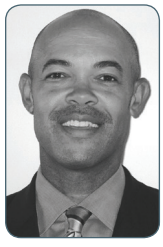

Participating in clinical trials puts you at the cutting edge of emerging treatments. To succeed in this endeavor, however, you must learn how to transform patients into study subjects. This article shares what I have learned after performing clinical trials in a private practice environment for the past 15 years.

CHOOSE THE RIGHT STUDY

Your practice's population should match the type of patients that the study is trying to recruit. For example, if your practice is largely tertiary and you perform few cataract procedures, signing onto a study of microinvasive glaucoma surgery is likely to be a disappointment for you and the sponsor.

It is also important to carefully examine the inclusion/exclusion criteria for issues that might trip you up. For instance, some recent drug and surgical studies list previous selective laser trabeculoplasty as an exclusion. Even if you have a very large patient population, few of these individuals will likely be eligible for a study of this type if you advocate selective laser trabeculoplasty as an early treatment option.

Most important is only choosing studies in which you truly believe. Foremost is your belief that the intervention will be safe, followed by your strong feeling that the patient in question will receive some benefit from the intervention and that he or she will not be unduly inconvenienced by participating. If you do not think that it is in patients' interest to participate, they will ultimately realize it and will be less likely to enter the trial.

SELECT APPROPRIATE PATIENTS

Once you have chosen a suitable trial, you must identify appropriate patients and then discuss the merits of the trial with them. There are two ways of identifying patients for a trial. If the criteria are broad, I will typically recruit subjects as I go through my normal clinical day. If I perceive that it will be difficult to find patients who meet the study criteria, I will have my research coordinator look through the schedule for weeks or months in advance in an effort to identify potential candidates. It can also be handy to keep a list of potential study candidates, perhaps those who have participated in trials in the past, to help enroll a new study quickly.

If you are in a group practice, your partners can be a source of study patients. Because recruiting for clinical trials is likely to be low on their list of priorities, it is important to remind them frequently of your ongoing trials and their criteria. Often, it is necessary to offer some incentive, financial or otherwise, to stoke your partners' enthusiasm.

Many research sponsors will provide resources to help you comb through your upcoming appointments for candidates. Sponsors may also offer support for advertising and outreach to referring ophthalmologists and optometrists in the community.

TALK TO YOUR PATIENTS

Prepare yourself to discuss participating in the trial with your patients. I like to think through the potential benefits

to the study population in general—and to the patient in front of me in particular—before I engage him or her in conversation. This is a critical exercise. For example, a drug trial might allow participants to reduce their quantity of daily medication. A surgical trial might allow patients to receive multiple microinvasive glaucoma surgery implants instead of one, which might improve IOP control. Initially, it can be awkward developing your "sales pitch." Your ability will improve with practice and the more experience you have in a particular trial to learn the drug's or device's unique benefits.

As you begin the conversation, it is important to point out enthusiastically that the person qualifies for something unique. Most likely, only a few people per week will meet the entry criteria. You will quickly get a sense of whether a patient's perception of this unique opportunity matches yours. Most patients have a high level of trust in their physician, and many are far more altruistic than you might imagine. It is your responsibility as a physician not to betray that trust. Be certain that the patient in front of you has a clear understanding of what he or she may be agreeing to as well as of its unique benefits and risks to him or her.

Pointing out indirect benefits to a given patient may be helpful as well. For example, a particular glaucoma patient may be happy with his or her current drop regimen and question the benefit of entering a clinical trial to try a new medication. In such cases, it can be helpful to point out that the time may come when the current medication may cease to control his or her IOP or when he or she may become intolerant of it. Helping to get a new medication approved may become useful to such patients if they themselves need to change or advance their therapy in the future.

Nearly all trials cover the cost of medication and study visits as well as provide financial payments for most study visits. Theoretically, these financial payments are not meant to be inducements to participate, but in reality, they serve as positive incentives for many patients.

AT A GLANCE

- Your practice's population should match the type of patients that the study is trying to recruit.
- Identify appropriate patients, and prepare yourself to discuss participating in the trial with them.
- The importance of a skillful study coordinator cannot be overstated.

> **"In addition to being fairly meticulous and having strong organizational skills, a study coordinator must have effective people skills."**

HIRE OR APPOINT AN EFFECTIVE STUDY COORDINATOR

The importance of a skillful study coordinator cannot be overstated. I have had two coordinators over the years. Both were ophthalmic technicians who showed an interest in clinical trials. Initially, they were handling studies part time, but when the volume of study patients became sufficient, these employees converted to being full-time coordinators.

In addition to being fairly meticulous and having strong organizational skills, a study coordinator must have effective people skills. In the middle of a busy clinical day, after I have introduced the study and reviewed the important points with a potential subject, I ask the study coordinator to come into the examination room to answer the patient's inevitable follow-up questions, explain the study visit schedule, and initiate the informed consent process. In many instances, patients' enthusiasm for participating in the study relates to their enjoyment of the extra attention they receive and to spending time with my coordinator.

CONCLUSION

Participating in clinical trials has been an extremely positive experience for me. I believe it has allowed me to offer novel treatments to patients that have benefitted them. The experience has also broadened and improved my surgical skills, which benefits my other patients. In addition, participating in clinical trials has engaged my passion for teaching.

Advances in the field of glaucoma require more physicians who can effectively enroll future clinical trials. ■

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