AN INFORMED PATIENT IS A BETTER PATIENT

Explaining both the demands and potential rewards of a clinical trial can make patients more likely to participate fully in the protocol.

BY ARON SHAPIRO

A search on clinicaltrials.gov for the term retina yields well over 800 ongoing studies of alternative systems of drug delivery, gene therapy, stem cell treatments, imaging systems, and much more. Most retina specialists are fully prepared to implement such new techniques in the setting of a clinical trial, but these new, sometimes invasive protocols can seem daunting and scary to patients. To recruit individuals who will commit to participating in a long-term study, it is vital to take the time to discuss the details of the trial in order to appropriately manage patient expectations.

STARTING OFF RIGHT

Before the recruiting process begins, it is important for the investigator to buy in to the clinical rationale and approach for a clinical trial; that is, he or she must feel confident that the proposed intervention has meaningful potential in the treatment of the target disease. This belief can be based on preliminary studies, biologic plausibility, and the presence of a truly unmet need. Without the investigator’s commitment to the intervention at hand, it will be virtually impossible to recruit potential patients and come to an agreement with those patients that enrolling in a study is the most appropriate plan of action for their condition.

Identification of ideal patients starts by matching candidates with the particular diagnosis and then further determining if they would actually be eligible to carry out the study requirements. Often there are factors that will preclude someone’s participation in a study, so it is imperative to go over eligibility criteria with every potential candidate. It is also necessary to determine whether the patient would likely benefit from the treatment being investigated. Considerations should be made as to what treatments the patient is currently using and whether or not he or she is positively responding to these treatments. Determining how to transition a patient from a current therapy into the study protocol may be a significant factor due to any washout periods required before starting.

OPEN DIALOGUE

After the investigator has identified patients who may be a good fit for a clinical trial, an honest and open line of communication with those patients is essential. This is particularly important for studies involving invasive procedures, significant patient time commitments, and deferments of other therapeutic approaches. At this point, the ophthalmologist must convey his or her own confidence to the patient: the opinion that the experimental therapy is appropriate and that the clinician is well-qualified to deliver it.

It is not unusual for potential participants to feel uncertain or nervous about participating in a clinical trial. Although clinical trials are designed to improve the standard of care and in some cases provide a novel treatment for a disease, the idea of participation can frighten or overwhelm the patient. For this reason, it is important that investigators and study coordinators be able to adequately explain the study to patients during the consenting process.
Start with the basics. Outline the study protocol visit by visit, thoroughly explaining what tests and other procedures, including safety measures, will be conducted and how long each visit is expected to take. Letting patients know exactly what time requirements are involved allows them to assess whether they are able to commit to participation.

Be sure that any very technical procedures are explained in ways that the patient can understand, and avoid using medical jargon or terms that may make something sound worse than it actually is. Take the time to thoroughly explain how the investigational product will be administered, whether there are special instructions for the patient to follow on treatment days, and which doctor the patient may see on the day of treatment.

**EXPLAIN THE TREATMENT**

Often, the investigational product itself is the factor that is most unfamiliar to patients, so education on how they will be treated is very important. Potential patients are likely to have many questions, so explaining why they are being taken off their current treatments, what will happen during the washout period (if required), and how they will be monitored throughout the study is a great way to establish a comfort level. Sometimes the consenting process includes time for the patient to discuss the trial with a family member or friend before making a final decision on participation.

Sites with enthusiastic and well-informed investigators and coordinators are more likely to successfully recruit patients than sites whose staff members appear indifferent or are lacking specific treatment and study details. It is often easier to recruit patients for a clinical trial that involves a novel drug delivery system but utilizes a drug that already has regulatory approval. If the study is of an unapproved drug in phase 2 or 3 clinical development, background must be provided on previous studies. If a site has done previous studies with a particular drug, as is often the case, the study staff is likely familiar with the protocol and procedures, and this fact can be reassuring to potential participants. It should be pointed out that the clinical trial will be carefully monitored and controlled, with medical staff and personnel on board overseeing the study for its entirety. If applicable, highlight the number of nurses and doctors on staff.

**HIGHLIGHT POTENTIAL BENEFITS**

Many retina studies do not offer monetary incentives other than travel expense reimbursement, so be sure to highlight the qualities of the trial that patients may benefit from. Explain the pivotal role that clinical trial volunteers play in helping to better understand the disease in question and that the trial may make unprecedented scientific discoveries and potential breakthroughs in treatment options. Knowing that participation in scientific research may change the treatment landscape for a disease may be an influential factor for a patient’s involvement.

It is also helpful to emphasize that, as a participant in a clinical trial, the patient may receive access to cutting-edge experimental therapies. For some patients, the cost-free follow-up visits alone can often be motivation to participate. Patients with sight-threatening conditions may be particularly interested in the opportunity to receive a novel investigational treatment, especially if current treatment options are limited.

Another potential patient benefit is that involvement in a trial can introduce participants to others who are dealing with similar ailments. These patients can use each other as resources on their condition and find comfort and support from others who are going through the same treatments.

Equipping patients with the appropriate knowledge before a trial begins will allow them to make fully informed decisions on whether to participate. Full cooperation and participation are needed if investigators are to collect the information necessary for a successful study. Patients should understand that follow-up visits, though they may be frequent or time-consuming, are important for monitoring safety.

Although patients must be reminded of the importance of their commitment to the trial, it is also vital to acknowledge that their participation is voluntary. Ultimately, the decision to participate, or to continue to participate, in a clinical trial is entirely up to the patient.

**CONCLUSION**

Clinical trials can be intimidating for patients. Some may have received their diagnosis only recently, and even longstanding patients may have a host of concerns. It is important to provide them with details to help them make informed decisions regarding trial participation and to commit to fulfilling the demands of the trial protocol. Maintaining an open, honest dialogue and helping patients to understand their disease, treatment options, and the intervention under investigation will ensure the best outcomes for both your patients and the trial.

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