Recruiting for Invasive Clinical Trials

BY ARON SHAPIRO AND ASHLEY LAFOND

The difficulty of delivering effective treatment to the posterior segment has prompted many clinical trials to focus on evaluating alternative forms of drug delivery systems, gene therapy, and stem cell treatments. At times, these new, sometimes invasive, protocols can seem daunting and scary to patients. Although retina specialists are in-tune and on board with new techniques being examined in emerging clinical trials, many patients may be grappling with a recent diagnosis or are nervous at the thought of a more invasive procedure. In order to recruit subjects to commit to a long study, it is important to take the time to discuss the details of the trial, treatment arms, procedures, and risks to appropriately manage the patients' expectations.

STARTING OFF RIGHT

Before the recruiting process begins, the investigator must believe that the intervention under investigation could potentially be of value to the management of the disease based on preliminary studies, biologic plausibility, and the presence of a true unmet need. If he or she does not fully believe in the intervention at hand, it will be virtually impossible to recruit potential patients and come to an agreement with the patient that enrolling in a study is the most appropriate plan of action. If the investigator is enthusiastic about the potential of the therapy, the next step is deciding which patients are the most suitable candidates. Some considerations may be whether the patient is already on a treatment, his or her response to the current treatment, how to transition a patient from current therapy into the study, and the effect of any washout periods before starting.

OPEN DIALOGUE

After the investigator has identified patients who may be a good fit for any clinical trial, but particularly one that may utilize more invasive procedures, an honest and open line of communication is absolutely essential. 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 the first approved treatment for a disease, they can be invasive and overwhelming for the patient. For that reason, it is important that the investigators and study coordinators be able to adequately explain the study to the subjects during the screening process.

Start with the basics: Outline the study visit-by-visit, thoroughly explaining what tests or procedures, including safety measures, will be conducted. Be sure that any technical procedures are explained in a way that the patient can understand, and avoid using terms that may sound worse than they actually are. Potential participants will likely have many questions, so explaining why they are being taken off the current treatment, what will happen during the washout period, and how they will be monitored throughout the study is a great way to establish a comfort level. 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 all of the treatment and study specific details. Providing background information and particulars about the study will also help to fully inform patients. For example, if the clinical trial involves a novel drug delivery system but utilizes an already US Food and Drug Administration-approved drug, this can also help to set a patient at ease. If the study is in phase 2 or 3, provide background on previous studies. If the site has done consecutive studies, the study staff is likely familiar with the protocol and procedures, which can be reassuring to a potential participant. Point out that the clinical trial will be carefully monitored and well-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.

Because many retina studies do not offer monetary incentives other than travel expense reimbursement to patients, be sure to highlight the qualities of the trial that may be appealing to patients. It is important to explain the pivotal role that clinical trial volunteers play in helping to better understand the disease, making unprecedented scientific discoveries, and creating potential breakthrough treatment options. Additionally, emphasize that as a participant in a retina clinical trial, they may be receiving access to cutting-edge experimental therapies and will be closely monitored by trained medical staff throughout the duration of the trial at each visit. For some patients, cost-

free follow-up alone can often be motivation to participate. Patients with sight-threatening conditions may also be interested in the opportunity to receive novel investigational treatments, particularly if the current treatment options are limited.

Patients must also be reminded of their commitment to the trial. Full cooperation and participation is needed if the investigators are to collect the information necessary for a successful study. Equipping patients with the appropriate knowledge before the trial begins will allow them to make fully informed decisions on whether to participate. Finally, remind patients that participation is voluntary. Ultimately, deciding whether to participate or to continue to participate in a clinical trial is entirely up to the patient.

PUBLIC FORUMS

In the information age, it is inevitable that potential trial participants will research the disease, site, and sponsor online. Embrace this as a chance to generate positive and informative messages about the purpose of the trial, what patients can expect, the risks and benefits, and the impact of clinical trials. This can be easily accomplished by making information regarding your trial and drug or device available for public research through online forums. Social media networks such as Facebook and Twitter allow interested patients to access more information on their own. These public forums afford an opportunity for patients to discuss with each other why they should participate, why the study is interesting, and why the trial or device is important, and to receive feedback from others in the same position. Be sure that any information being advertised or publicized related to a clinical trial has been approved by the relevant institutional review board (IRB). Also encourage investigators to get sponsor approval even prior to submitting anything to the IRB, as it is possible that a sponsor may consider certain study-related information confidential and not appropriate for inclusion in recruiting materials.

CONCLUSION

Clinical trials can be intimidating for patients. In addition to a recent diagnosis for some, your patients will likely have a host of concerns, and it is important to guide them in making the best decision, possible regarding treatment. Maintaining an open, honest dialogue and helping patients to understand their disease, treatment options, and the interventions under investigation will garner the best outcomes for both your patients and the trial. ■

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