Running a Tight Ship: Pearls for Conducting a Clinical Trial

BY ARON SHAPIRO

There is much to consider when conducting a clinical trial, and there is not much wiggle room to change parameters once the trial has been initiated. The high number of procedures that are performed during a study visit requires that everything run as smoothly as possible to ensure a successful trial. This article discusses tips for running clinical trials, including the importance of maintaining efficient practices and the management of study participants' needs.

STAFF TRAINING

Conducting clinical trials in your practice is a huge undertaking. During any given study your staff will conduct many procedures and tests and use many different technologies. It is likely that the same test will be repeated on each participant. As the lead investigator, you must fully understand the study protocol and carefully vet all available resources to judge whether your clinic is an appropriate site for the trial. Early-stage studies often require an extensive battery of tests, imaging, and patient evaluations, which can be time-consuming and logistically challenging for the study staff. You must ensure that all procedures are performed according to the protocol so that the participants are not overwhelmed by the need to repeat tests or exams because they were not conducted correctly. Before incorporating clinical trials into your practice, prepare everyone involved for the challenges to follow.

Once you have decided that a study is of value to your practice, you should next ensure that your clinical trial staff is adequately trained. A consistent, cohesive training plan on all procedures specific to the study should be set in place prior to the beginning of the trial. This training plan should include standard operating procedures and provide continuity. Once your staff has been trained, they will be prepared to conduct the study and to train future staff. You should also place quick-reference guides in your research space, including any useful tips for equipment operating methods, procedure checklists, and the order of events. Should a staff member have a question, he or she can quickly reference the guide rather than waste time flipping through study protocol or procedure manuals.

Before incorporating clinical trials into your practice, prepare everyone involved for the challenges to follow.

Trials examining new frontiers will utilize cutting-edge, exciting technologies, but if your staff does not know how to use such technologies, these devices will not be used to their full potential. The same can be said for the plethora of exams and procedures conducted in most trials. If you ensure that your staff is familiar with all the study procedures, you will likely benefit from more efficient execution of all aspects of the protocol. It is no secret that standardized training takes time and money, but your site will profit by having a staff that is well-informed and prepared for the challenges of trial operation. Finally, give your staff plenty of time to become acquainted with the study protocol so that when the site visits begin they will feel comfortable and confident.

TAKE CARE OF STUDY PARTICIPANTS

The complex nature of clinical trials requires special attention to the well-being of study participants. Timing requirements of the procedures conducted during trials might dictate that you shuffle participants from 1 procedure to the next. No one wants to feel as if he or she is a guinea pig, so it is important to make participants feel as comfortable as possible during the study. A high number of exams can be unsettling for anyone, even for those

(Continued on page 30)

(Continued from page 26)

When participants feel more like an individual and less like a number in a trial, they are likely to feel more at ease amid all the hustle and bustle.

who have participated in previous studies. Although your staff is on a strict timeline, be sure that they do not neglect the needs of participants. Simple gestures, such as offering a glass of water or hot coffee, can make all the difference.

It is also advisable to carefully outline for study participants all procedures that will be performed, particularly safety issues and the measures in the protocol to address these. Additionally, expect to spend a significant amount of time documenting participants' medical histories. When participants feel more like an individual and less like a number in a trial, they are likely to feel more at ease amid all the hustle and bustle.

Although clinical trials are designed to improve the standard of care and are structured to be as safe as possible for study participants, spending a day outside of their normal routine can overwhelm participants. Potential participants are sure to have many questions, so it is important to come prepared with answers. Sites with well-informed investigators and coordinators will be able to ease the minds of potential participants. Trial investigators who are prepared to answer potential participants' questions will more successfully recruit participants than those investigators who do not understand study-specific details.

PREPARATION AND PRACTICE ARE KEY

The process of conducting clinical trials will become easier as your practice conducts more of them. Make things easy for yourself and your staff by setting up your site for success from the start. Do not take on something that your practice cannot to handle, and start by enrolling 1 or 2 patients to get a feel for the study before trying to meet your enrollment goals. Know that there may be hiccups along the way, but that, if you have the proper plans in place, you and your staff can work through them. Finally, take care of your study participants—they are, after all, the backbone of your study. ■

Aron Shapiro is Vice President of Retina at Ora Inc., in Andover, MA.