First Study Visit Success

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Over the past few months, we have sought to provide retina specialists and their staff members with an understanding of the world of retina clinical research, the site-selection process, and basic but effective strategies for recruiting subjects. In this month's column, we will provide an outline of simple steps that can be taken to ensure that your first study visit is a success.

PRE-STUDY LOGISTICS

With a thorough understanding of the study's protocol under your belt and quick-reference guides prepared, one must not lose sight of the importance of pre-study visit logistics. Simple precautions can be taken to avert troublesome situations. Ensure that all equipment, particularly imaging systems, is in working order prior to a study visit. Conducting a pre-study meeting or walking through a patient's visit is crucial to troubleshoot study flow challenges. Placing reminder telephone calls to patients a few days in advance of their study visit is also advised. In doing so, you not only help to build a rapport with your patients, but also learn of any late-breaking scheduling or transportation issues that the patient may raise during your discussion. If the patient's transportation to and from the study visit appears to be problematic, your office staff may be able to arrange transportation on the patient's behalf. Study sponsors may be willing to provide for patient travel cost reimbursement if this provision has been approved by your site's governing institutional review board (IRB). Thus, taking even simple steps, such as proactively checking your site's equipment and ensuring that patients will come in at their scheduled times, can contribute to a smooth and successful study visit.

PROPER PREPARATION

Once you are comfortable with the protocol's structure and contents, it is advisable to place study quick-reference guides in your research space. These tools usually distill most of the critical elements of the study's design into compact, laminated manuals. If your study's sponsor or clinical research organization (CRO) has not provided you with guides, we recommend that your staff create them de novo; these accessories will not only be valuable in answering common study-related questions, but your site's creation of its own set of study-specific reference tools shows initiative and attention to detail to sponsor or CRO representatives. Quick-reference guides commonly include lists of key inclusion and exclusion criteria, schedules of procedures for each study visit, visual acuity requirements, and study-specific instructions for ophthalmic photographers to ensure that imaging data is collected per protocol. Having a set of well-designed and accurate quick-reference tools will likely pay dividends on busy clinic days, when consulting a dense clinical protocol for answers to basic questions may be too time-consuming.

FIRST PATIENT FIRST VISIT

As is the case with most aspects of running a busy clinical practice, proper preparation in advance of a study patient's first visit is critical to the visit's success. If you are unfamiliar with clinical research, this event might seem daunting at first. However, even if you and your staff members are experienced clinical researchers, making adequate preparations for your site's first patient first visit (FPFV) in a new study will help your team approach this milestone with confidence. Creating and maintaining a checklist of the items discussed within this column to help track your site's preparations for your FPFV is one way to assure that all necessary tasks have been fulfilled. Although you and your study coordination staff should have previously reviewed the study's protocol, we recommend thoroughly rereading the document to gain a deeper understanding of exactly what will be required of you, your staff, and your patient at Visit 1.

With the pearls that we have provided in hand and the suggestions of your peers to guide you, your FPFV will hopefully prove to be problem free. Your preparations will undoubtedly prove to be valuable and, with your first study visit behind you, you will have the confi-

KEY CONSIDERATIONS

Prior to the study visit:

- Make a checklist of important steps throughout the day.
- Review the protocol.
- Create and/or review study quick-reference guides.
- Ensure that all study-related equipment is functioning properly.
- Place reminder calls to subjects.
- Have subject contact numbers and names of CRO or sponsor handy for questions.

During the visit:

- Complete all source documents accurately and thoroughly.
- Call your CRO or sponsor with any questions. They are there to support you!

After the visit:

- Assess what worked and what did not work. Are there parts of the visit that could have gone more smoothly?
- Transcribe source data into case report forms.
- Follow-up with subjects, if necessary.

dence and experience to tackle future study visits with finesse. Remember, however, that once your first study patient has left your clinic for the day, your job is not yet complete. Promptly transcribe source data into the study's electronic case report forms (eCRFs) and address any automated edit checks that may appear; rapid and accurate data entry following a study visit is critical, as these CRFs are the physical records of your findings. Once these data have been successfully entered into the eCRF, it is worthwhile to schedule a time to speak with your staff and debrief. You will want to collectively assess what worked or did not work during the study visit and come up with solutions to problems that were encountered.

CONCLUSION

Pat yourself and your staff on the back for a FPFV job well done. With the lessons learned from this experience, preparation and execution of future study visits should come as second nature. In next month's column, we will discuss proper documentation practices in a clinical research setting. ■

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