A Breath of Fresh Air

For the majority of clinical research professionals, the mere mention of the words 'investigator meeting' causes many to cringe. Let's face it, most investigator meetings are painful; painful for the participants as well as those who are charged with developing content and facilitating meetings. PowerPoint presentations have become 'the norm' in our industry for training sites - be it in-person or through virtual training sessions. At the end of the day, once training is over, sponsors and training sites breathe a sigh of relief and then get back to the business of conducting the clinical trial. Inevitably, the result is that key study challenges were not addressed and sponsors spend hours troubleshooting enrollment, study implementation and data related issues.

Post-training sites are now discouraged and frustrated, enrollment lags behind, and teams resort to holding rejuvenation meetings as a way to reinvigorate the study. Reconnecting with the sites in these live sessions presents a great opportunity to address the challenges, share best practices, and re-establish or strengthen relationships. However, if the rejuvenation meeting involves classroom style seating, dark rooms and the same one-way information exchange through endless slide presentations, the sites are still not better prepared than from the initial site training efforts.

Frankly, we need to breathe new life into our site training programs if we ever hope to solve some of the perpetual challenges we experience when conducting clinical trials. As a consultant who has helped develop and facilitate over 300 interactive meetings and workshops in the last 15 years, or so, I'd like to challenge you to take a few steps out of the conventional approach and try to transform your site training programs from "bore and snore" to engaging and effective. You'll be surprised how the sites appreciate and value the fresh approach, and how much more confident they are in implementing your studies.

Clearly understand and articulate what you want the sites to take away from the training. Often, teams start with a standard agenda with a laundry list of topics to cover, but what's the real intent and purpose of the training? What do you need to share and convey to the sites that can't be learned from just reading the protocol? The effectiveness of the meetings can be improved ten-fold if you can spend a few minutes outlining your goals and objectives for the training.

Specifically, study teams should ask the following:

- What are our top three learning objectives?
  Defining learning objectives in behavioral terms can help focus and prioritize the content for the meeting. The more specific you can be the better. For example, at the end of the session, sites should be able to:
  - List three new tactics for recruiting patients.
  - Describe the key process steps involved in navigating a patient through the baseline labs.
  - Explain the rationale for the selected drug dosages.

If you are planning an interim or rejuvenation meeting, teams should consider these questions:

- What are your top three challenges in the implementation of the study?
- What issues are you facing?
- What has prompted you to set up the interim rejuvenation meetings?

Finally, teams should ask:

- What will determine the success of the meeting?
  For example, the training will be deemed successful if we see a two-fold increase in screening efforts within six weeks from the training, or we see a reduction in the number of queries related to specimen processing, and so on.

Clearly understand what the sites need to get from the training. Site training programs are most effective when sponsors ask the sites what their training needs are. Often sponsors don't want to discuss the anticipated

Beth Harper, President, **Clinical Performance Partners, Inc.,** explains why Investigative Site training must move beyond PowerPoint slides and passive learning techniques.

challenges for fear that it will discourage the sites or reduce their enthusiasm. Sites would much rather learn about and address the expected challenges upfront and in the safety of the training program, than practice the protocol with real patients and products only to find they have made errors. Use pre-training surveys, teleconferences or discussions with the Clinical Research Associates (CRAs) to ask the sites what their top priorities are for the training. This may help you identify the information that can be shared via newsletters, web-training and on-site training versus those topics that are best suited to addressing in a live forum where sites can take advantage of peer-to-peer learning and clarification of important nuances and interpretations that can't be gleaned from reading the protocol alone.

Create an environment conducive to learning. If I could change one thing to make site training more effective, I would banish classroom style seating. Depending on the size of the group, U-shaped, round tables or other seating formats that allow for interaction can have a dramatic effect on the tone, energy and dynamics of the training session. This alone can reduce the intimidation factor often associated with the "old school" lecture hall approach where many questions go unasked because no one wants to appear "dumb" in front of their peers. Mixing and matching sponsor and site personnel, as well as experienced and inexperienced sites together at tables, sends the message that this is an environment where asking questions and sharing information and experiences is encouraged.

Help sites to make the important connections between 'the what', 'the why' and 'the how' of your protocol. You have a lot of information to cover, but as the saying goes, "telling ain't training." Although you have told the sites the information, it doesn't mean they have processed it or can apply it. There are endless and excellent resources that provide ideas on how to apply adult learning principles to appeal to different learning styles and how to validate that transfer of knowledge. A discussion of these techniques is beyond the scope of this article. That said, as you develop your site training, try to help the sites "see and experience" the protocol. What will it be like to navigate a patient through the study? What are the potential roadblocks and hurdles? How can these be overcome?

Lastly, don't forget to focus on the rationale. By the time you do your site training, you've been living and breathing the protocol for months and you understand what's behind some of the decisions that may not be obvious to the sites. Spend a proportionate amount of time in your site training explaining your thought process, and remember that sites who understand 'the why' are much more likely to comply. **FP**

BETH HARPER is the President of Clinical Performance Partners, Inc., a clinical research consulting firm focused on preventing, diagnosing and treating site and enrollment performance problems. In addition to her 25 years of clinical research experience, Harper is also an adjunct Assistant Professor, School of Medicine and Health Care Sciences – George Washington University Graduate Program in Clinical Research Administration. Beth earned a bachelor's degree in Occupational Therapy from the University of Wisconsin and an M.B.A. from the University of Texas.