Reimagining Study Performance Through Education

June 2021

Robert Geckeler
Product Director
ScienceMedia

Revising Outdated Training Approaches Can Help Sites Achieve More: Sites NOW June Session Tackles Reimagining Study Performance Through Education

Delivering effective study training is particularly important in today's clinical research climate, given the increasing complexity of study protocols and the trend toward utilizing more remote study elements adopted during the pandemic. This new environment provides the perfect opportunity for Sponsors to begin reimagining training as a way to improve study performance.

At a high level, study training provides the context for an investigational trial by explaining the underlying rationale for the study. It details the study drug, its mechanism of action, and its intended use in the population of interest. It also helps clarify the objectives and goals of the study by linking specific study requirements and assessments to those objectives. Ensuring that these requirements, measures, and assessments are clear is the best way to facilitate site performance. But it is equally important to update sites with any necessary clarifications or on changes to those requirements when amendments occur, and that is why it is vital to be able to provide ongoing training as a study progresses.

Recommendations on training from the Clinical Trials Transformation Initiative (CTTI) suggested goals like moving away from a one-size-fits-all approach to account for different roles and varying levels of experience of study staff. Study training systems that allow role-based lesson assignments and incorporate assessments go a long way toward meeting this objective. Likewise, rather than generic check-box training, study-specific educational programming tailored to the protocol and the needs of the site can empower sites and truly facilitate the conduct of a quality clinical trial. While CTTI recommendations discuss advance evaluation of a site's preparedness to conduct clinical research, that can reasonably be extended to mean applying some measure of comprehension and readiness for the trial based on study-specific knowledge. That means study training would ideally ensure, as part of the training process itself, that lessons had been effectively delivered and understood by all members of the study team.

Thorough and effective training primarily makes an impact by improving protocol compliance. Site staff who fully understand study requirements are more likely to adhere to them and avoid deviations and errors. Similarly, training works to support patient safety by ensuring that study staff and patients fully understand dosing schedules, expected risks, and the handling of

adverse reactions. Improved compliance will lead to reduced variance, thereby improving data quality. Together, these improvements should also result in less time spent by sites on resolving data discrepancies and other inefficiencies.

The risks of inadequate training are exacerbated in an environment characterized by increasing protocol complexity and reliance on decentralized approaches, further emphasizing the need for improved training in today's climate. For example, sites will vary in their prior experience using specific remote tools; adequate training can help level the field and reduce the burden on sites as they adopt these methods. Patient considerations like access to broadband Internet and technical ability come into play with the increasing use of remote approaches, and helping sites to account for and manage these in advance can save time and effort in the long run.

Many sites are bearing the burden of educating patients and implementing technology. Even though the technology aims to be more convenient to the patient, we are now asking patients to undertake activities that they would have experienced at the site. Study training that extends to providing instruction for patients lessons that effort for the site and may mean that sites are called upon less often to act as the 'help desk' when purely technical questions arise about the use of these tools.

However, many studies continue to rely on outdated training methods. After 30 years of having standard slide presentations serve as the primary tool for training, a change is clearly needed. Looking at CTTI's recommendations, educational programming for a study should look beyond traditional methods and apply adult learning best practices. The use of cutting-edge training technologies that employ these principles helps guarantee that study education is as engaging, interactive, and effective as possible. CTTI guidelines also call for focusing study training so that the time and attention given to the most critical aspects of the study are weighted in proportion to their relevance. Modern training approaches that take a risk-based focus to protocol education deliver on this goal by zeroing in on those aspects of the study that have the greatest impact. This is further achieved through the use of modular training focused on discrete topics, or microlearning.

Platforms that offer flexible delivery allow site staff who are pressed for time to benefit from the convenience of on-demand access to study training. And as staff turnover occurs, new team members have access to the same level of training as those who were on board at the outset of the study. Along the same lines, one-and-done training at the commencement of a study is insufficient. Lesson reinforcement through repetition is critical to ensuring that peak levels of knowledge are maintained throughout a trial, and approaches like the microlearning format are ideally suited for that. Support tools like quick reference guides also serve as a way to reinforce study requirements.

By reimagining study training, Sponsors and CROs have the opportunity to improve the support offered to sites, allowing them to better leverage site expertise by enhancing the efficiency and performance of study staff. A new approach to study education, which takes advantage of the latest standards for training content and delivery, has the potential to improve not only the site's experience and patient satisfaction, but the quality of the study overall.

Join the next SCRS Sites NOW meeting, convening every month. For details, visit https://myscrs.org/scrs-sites-now/.

June 2021 Sites NOW Panel:
Philip Bedrin, Director of Medical & Clinical Learning Strategy & Solutions, ScienceMedia
Doug Schantz, Vice President, Clinical Operations, Alexion
Michele Cameron, Director of Clinical Research, Clearwater Cardiovascular Consultants

Sources: Bechtel, J., Chuck, T., Forrest, A., Hildebrand, C., Panhuis, J., Pattee, S. R., . . . Swezey, T. (2020). Improving the quality conduct and efficiency of clinical trials with training: Recommendations for preparedness and qualification of investigators and delegates. Contemporary Clinical Trials, 89, 105918. doi:10.1016/j.cct.2019.105918

SCRS Sites NOW is a virtual discussion and content project created in response to the COVID-19 pandemic and focused on the changing landscape clinical research sites and industry partners now face. Each session is centered around a singular topic; in January, the topic was the Evolution of Patient Engagement. Attendees benefit from an opening presentation hosted by an industry leader who provides a unique perspective and meaningful metrics on the topic at hand, then break out into groups for a dynamic discussion guided by relevant queries designed to identify areas of opportunity for participants in the clinical research pipeline.

7250 Parkway Drive, Suite 405
Hanover, MD 21076

Phone: +1 410.696.5080
info@myscrs.org

SCRS
Society for Clinical Research Sites
Our Voice | Our Community | Your Success