Structuring an eClinical Training Program TO IMPROVE EMPLOYEE AND SITE PERFORMANCE

Contributed by

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Clinical trials have the potential to represent the costliest and most time-consuming phase of product development. One study can include hundreds of patients and multiple sites, therefore sponsors, as well as CROs, must consider methods that improve site efficiency and data accuracy.

Training employees and site personnel on GCP fundamentals, study protocols, and even EDC (electronic data capture) technology has been often conducted using an in-person approach. However, this can be costly, as employees and sites become more dispersed.

In recent years, eClinical solutions have introduced Web-based training management, and in most cases, e-learning has been combined with some form of instructor-led training. For example, sponsors and CROs are increasingly relying on secure Web-based systems that enable sponsors and CROs to conduct and manage clinical and GCP training, including policies and protocols. Companies using these types of systems are reporting on average a 40% or more reduction in site initiation training costs. At the same time, these same companies are reporting that both employees and site personnel have demonstrated improved proficiency within studies. Sponsors and CROs have linked eClinical training to several stated business metrics, including the ability to:

1. Provide timely and consistent updates of critical study information to project teams as well as external study teams;
2. Gain assurances that the study and product information was received and understood by the responsible person;
3. Start or complete post-marketing commitments on time.

Four Guiding Rules for Structuring an eClinical Training Solution

The eClinical training solution must be structured in such a way so it enables companies to meet their regulatory obligations, improve patient safety, streamline the approval process, and reduce administrative time and effort. Based on our experience with our compliance training platform, we recommend four rules for structuring an eClinical training framework.

1. Align Training Requirements with Clinical Roles

Ensuring training compliance requires accurate, timely distribution of protocols, GCP content, and other areas (such as use of EDC applications) to all responsible parties, and consistent naming conventions ensure the administrator has the ability to easily locate the right document for reporting and modification reasons. The learning management system should provide the administrator with the ability to:

- Organize each study by geography, sponsor, product, etc.
- Build User Groups by role or title (PI, CRA, CRC, etc.).
- Identify training that will be conducted via classroom versus training that can be delivered electronically.

2. Build a Training Hierarchy that Accommodates Growth

In many cases, the system is expected to grow as more trials are conducted around the world. It is critical that each investigator and clinical research associate within each study, and in each location, receive just the training that matters to his or her role within the study. The eClinical training solution must be flexible enough to accommodate a company's unique training structure. This eliminates training content overlap and reduces maintenance of training assignments as new site personnel are added to specific user groups.

3. Develop a Process for Maintaining Site Personnel Data

To organize site personnel and align them into defined training requirements, the clinical training management team must define and maintain meaningful user data attributes. Data integrity and the ability to view real-time information are critical. Sponsors or the CRO must define user data management policies to ensure that any changes to end-user data, such as turnover among site personnel, are captured and the training modified for that user.

4. Provide Management Visibility

The delivery and tracking of training for audit purposes addresses the regulatory compliance burden. In addition, senior managers need meaningful data to adapt and scale for future growth, and to get a sense of the overall compliance and employee performance health of the organization.

Conclusion

By using technology to manage both employee training as well as investigator training, sponsors and CROs are improving employee and clinical site personnel performance, as well as demonstrating a commitment to a well-trained staff during sponsor audits. What's more, the eClinical training solution can improve clinical data accuracy while reducing overall training costs. PV

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