Online Investigator Training in Clinical Trials: A ROADMAP FOR SUCCESS

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Successfully implementing online investigator training for clinical research sites requires technology and processes developed specifically for this purpose. As readers of this article are aware, research sites operate in a highly regulated and scrutinized environment. Sites also have a wide range of technical infrastructure and capabilities from study to study and region to region. To work effectively with small primary care physicians and large academic research institutions alike, Sponsors must select and implement online training solutions that scale to meet this range of needs.

When selecting a training solution, the initial challenge facing many sponsor organizations is defining project governance for the teams charged with this task. Often these teams are comprised of stakeholders from various functional areas within the sponsor. These include IT, procurement, training, clinical operations, quality assurance, regulatory affairs, and sometimes meeting planning. Many of these stakeholders are not directly involved in the day-to-day conduct of clinical trials at the site level. They may have limited exposure to the realities of training for a study at a busy research site. As such, their priorities primarily reflect the work most closely related to their functional area.

Vendor Selection:

When these teams consider vendor criteria, advocacy for the specific needs of site personnel can be inconsistently emphasized throughout the selection process. Often, there is not a clear understanding of the specific environment in which the sites will use the training platform. The value placed on features and aspects of a solution can be disproportionately weighted by these internal teams, at odds with how the application will actually be used at the sites. Generally, sites want solutions that require a minimal learning curve while providing the fastest access to study information.

A Shotgun Approach

As each internal stakeholder focuses on their specific area of expertise, the scope of the RFP can become overly broad. While clinical operations representatives contribute criteria based on site and study team needs, the sheer volume of additional requested information can dilute the information to be provided on this critical area. When vendors are asked to focus on areas outside the scope of the primary goals of the study and operational team, responses are difficult to evaluate and compare. An initial RFP that requests vital information about specific, site-facing capabilities and vendor experience should be used to narrow the field of competitors prior to requesting more general information.

Overcoming Challenges

Fortunately, there are companies that have overcome these difficulties and may serve as examples to organizations. These companies were willing to take a hard look at what was and was not working and aggressively pursue innovative yet practical solutions that improve investigative site training and performance across the enterprise.

Independent Advocate: One of the first actions taken was to nominate independent resources that served as the primary advocates for the sites. These resources reported directly to senior management and evaluated existing practices by gathering input from internal and external stakeholders.

Gathering Investigative Site Feedback: These independent resources conducted a comprehensive assessment and analysis of investigative site feedback. Most importantly, the results of this analysis were embraced by stakeholders at all levels of the sponsor organizations. This consensus enabled the sponsors to filter out divergent perspectives, allowing them to focus on dramatically improving the quality of their online clinical training programs.

Results

With a commitment to this vision and a disciplined approach, a strong base of subject matter expertise was created within the sponsor organization. Study teams were encouraged to apply their in-depth knowledge of the system to support an environment of continuous improvement.

A wide range of ideas and innovations flourished within these organizations. Even large organizations were able to quickly adopt technologies such as an enterprise-wide compliance and certification directory and a centrally-managed standardized clinical library. In one organization alone, investigators were able to receive credit for over 4,600 training modules which would have been taken as redundant training using traditional training processes. This same organization also realized a 200% improvement in site startup speed. PV

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Online Training — What Investigators Want

1. **Easy to Use.** "I shouldn't need training on how to do my training."
2. **Always Available.** "I can take the training when it's convenient for me, at my own pace and in my own time zone."
3. **Eliminates Redundant Training.** "I took this on the last study. Why do I have to take it again?"
4. **Sends Consistent Message.** "Everyone I talk to says something different."
5. **Robustly Supported.** "If something is wrong I want it to be fixed right away…by a real person… who knows what they are talking about."
6. **Becomes Useful Reference.** "It should be easy to refer back to my training for specific information when I need it."
7. **Easily Shared.** "Everyone at my office can access the same training I received."
8. **Respects Professional Experience.** "Anyone could pass this quiz. I've been doing clinical research for years!"
9. **Tailored to My Role.** "Why should I have to take EDC training when I don't do data entry?"
10. **Provides Channel of Communication.** "If I need clarification on something, it should be easy for me to get it."

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