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Three Key Considerations for Risk-Based Study Training

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When you think about taking a risk-based approach to clinical trial training, what does that mean? A risk-based approach ensures the quality of a clinical trial by identifying, assessing, monitoring, and mitigating risks that could affect the quality or safety of a study. We use training to mitigate identifiable risks and decrease protocol deviations.

And there are plenty of risks to consider. Whether it's an investigator-initiated trial, a first-in-human PK study, a global phase three device, or a post-market registry study, you need to anticipate the risks of patient safety and data integrity as you develop protocols. Plus, different elements about the study determine the level of the potential risk. For example, the complexity of the study design and study population, the type of endpoints and the number of them, the types of patients you need to enroll, the site's experience with clinical studies and the geographic locations of sites—all of these factors influence potential risks for the study.

Using what you know about potential risks and sharing that information with your sites is the foundation of a solid risk-based approach. That's why training is such an important tool to help you anticipate and circumvent the risks.

Here are three things you need to know to help you develop and deliver training that will help you mitigate study risks with an effective risk-based approach:

1 CAPTIVATE YOUR AUDIENCE

One of the best ways to deliver great content is to make it relevant to your audience. Focus on concise messages covering potential study challenges. Don't let the most important things you want your sites to remember to get lost in repeating common sense content. Instead, cut to the chase with the most critical messages. Skip self-explanatory points and focus on the complex and more challenging parts of the protocol.

You also need to be mindful of your audience, their experiences and qualifications, and ultimately their time. The last thing you want to do is make your sites feel that training is burdensome. Sites are busy, and they have choices for clinical trials they choose to participate in. If you want to be a sponsor of a choice, then robust site training strategies are a way to stand out. Training that is customized for the site versus training that is thrown together last minute speaks volumes to those who are required to complete it.

Finally, great site training content should be an opportunity to provide information and knowledge checks and verify that trainees can apply the knowledge in real-life situations and take the appropriate actions when things go wrong. For example, create training that mimics a patient's journey by participating in the study, starting with being included as a participant, completing the screening and randomization process, and reviewing the essential visit procedures and safety concerns. Then, challenge the learner with what they would do if things go awry. For example, use live-action video to demonstrate how to administer a test or inject IP or how to complete a particular patient assessment. Seeing a demonstration is much more powerful than listening to someone review PowerPoint slides.

2 MAKE YOUR DELIVERY COUNT

Another vital element of emphasizing a risk-based approach in your study training is how your training is delivered. Whether it's a face-to-face investigator meeting, a site initiation visit (SIV) during a live or prerecorded web meeting, or exclusively on-demand, the key to successful training is to make sure everyone receives the same level of

training. That is why it's important to develop concise training content, using real-life examples that are effective in different delivery formats.

It's also important to have training content available on-demand for participants to reference throughout their participation in the study. It's hard to remember every detail of training two months before seeing a patient. By hosting concise content on-demand, sites can go back and quickly reference the training materials right before seeing a patient. And depending on the platform, they could pull up study-specific reference tools on a tablet or mobile device right in the room.

Training should be engaging and interactive. There are several ways to create interactive content, and it doesn't have to break the bank. For example, host a live virtual meeting with your sites. Ask for input from your champion sites to help empower your other sites with knowledge and expertise. You can also have some lead coordinators talk through what they see as the most significant challenges in the protocol and the tips and tricks they have found that help them be successful.

Turn on your webcam to make your training more impactful. Virtual engagement is the new world we live in, and human-to-human interaction matters. Even if it's through a computer screen, seeing someone increases the audience's attention by 45%. And requesting the audience to share their webcam increases their attention span and their ability to pay attention by 75%. So if you turn your web came on, most likely your sites will too.

Finally, up your innovation game. With innovation, a little will go a long way. PowerPoint training slides still account for over half of the training content developed and delivered for clinical trials. But now, study teams are starting to realize that being innovative can actually increase retention. Creating an interactive module and requiring the trainee to think through different scenarios to determine the correct answers can be a powerful learning method.

When it comes to scales used to assess the severity of disease, it's important that training not only mimic the disease itself but that the assessors are challenged to perform their ratings consistently.

Using an on-demand platform that provides sponsors with inter-and

intra-results from assessors participating in the trials can be powerful information when submitting clinical trial data to the regulatory agencies.

3 ENGAGE, ENGAGE, ENGAGE

The last thing to consider for a risk-based training approach is how to keep your sites engaged after their initial training is completed and they have checked the compliance box off their list. You need to create a forwardthinking plan on keeping sites engaged and their knowledge of the protocol up to date.

Use reference materials like a mini protocol to not only allow the investigators to reference the protocol quickly, but it can also increase the site's compliance. Most of these materials can be stored in a cloudbased platform and viewed on a tablet or other mobile device. In addition, these materials should fill in the operational blanks that can be left for interpretation in the protocol, with things like pharmacy manuals and adverse event monitoring requirements, plus data entry tips and tricks.

Another way to keep sites engaged is to re-emphasize ways to avoid protocol deviations by "providing virtual Q&A sessions with your sites. Schedule regular sessions once a month or maybe on an as-needed basis when a protocol amendment needs to be rolled out. Make them short and productive, so it's worth the site's time to attend. Create an interactive Q&A session with input from the champion sites, asking them to share with their peers. And then, if an amendment is covered during the Q&A session, remember to record the content and host it in an on-demand platform after the session for those who were unable to attend to review.

Finally, use quick guides for things like inclusion and exclusion guides and photonumeric rater scales. Consider using a visual pocket guide that the coordinator or investigator can pull up while with patients. Take something complicated with several steps and turn it into a quick guide that can be referenced when needed. Extra touches like this add value to your training and help your sites be even more successful.

By focusing the training content on the key identified risks of the protocol and delivering concise and mindful training content, you will minimize the burden sites experience when they're faced with an excessive amount of required training. Help your sites work smarter, not harder. If they spend less time on training, that might lead to quicker site activation and patient enrollment. The faster the protocol enrolls, the better your chances are for shorter drug-to-market timelines. All of these things lead to overall site satisfaction, and if the sites are happy, they will instinctively want to continue to do their best work for you.

ABOUT THE AUTHOR

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Amanda has over 20 years of biopharma experience, including over 8 years of clinical site experience as a certified clinical research coordinator. In 2015, Amanda transitioned from the clinical research site space to the pharma/CRO space, where she was responsible for training strategy development and delivery of Investigator Site training in cooperation with the cross-functional clinical operations teams at Eli Lilly. In her current role as Sr. Director of Global Clinical Training, she serves as a liaison between clients and internal teams in establishing best practices for clinical trial training, including developing training content in collaboration with sponsors and research industry key opinion leaders.

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