WORKFORCE PREPAREDNESS

A Proven Method to De-Risk Your Development

Protocol non-compliance is the most common violation cited in FDA inspections of investigators. The best method to improve compliance and ultimately de-risk your development is thorough training of study staff.

Sponsors routinely underestimate the importance of workforce preparedness during the rush of clinical trial planning. The impact, as measured by feedback from clinical trial sites and the results of regulatory inspections, includes increased risk for sites, sponsors, CROs and patients. In a recent webinar, we investigated this topic and shared actionable steps for sponsors to de-risk their development with a focus on workforce preparedness.

When we gather feedback from those on the front lines, they self-assess that they feel ill-prepared. Sponsors are in the best position to influence workforce preparedness, especially for investigational sites, in how they plan for, deliver and support the training of site personnel for optimal clinical trial conduct.

Our webinar moderator was Melissa Bomben, SVP of Clinical Solutions & Strategic Partnerships for WCG. Special thanks to our panelists:

Wendy Curran, VP of Clinical Operations, Insmed, Inc.

Ralph Lee, Site Director, Irvine Clinical Research

Patty Leuchten, Founder, WCG Avoca

Ericka Atkinson, Senior VP & COO, WCG Trifecta

Q: How can sponsors take a proactive approach to workforce preparedness?

A: From an operations perspective, we face competing priorities when setting up clinical trials, with the workforce and training activities filling in as we move through study start-up. A proactive plan for training site personnel is critical in risk mitigation, and should be designed to ensure:

- facilitation of effective virtual investigator meetings
- universal access via an on-demand, virtual training platform
- achievement of upfront compliance in partnership with sites
- effective documentation of site training for inspection readiness in a central repository allowing real time verification of site training records by CRO and sponsor staff

Visit the InvestigatorSpace online.

Ralph Lee - Site Perspective: "When training is married to the other elements of investigator meetings (IM), we have a cohesive system. Using technology, we can transition from questions during the IM with the medical monitor and continue that engagement through the study start-up process. On one occasion, one of the inclusion criteria was not recruitable, so our feedback led to a protocol amendment that saved the study's ability to recruit effectively. This was a Phase II big pharma trial involving several hundred people, it mattered. True benefits occur when we are engaged and the sponsor is listening."

Wendy Curran - Sponsor Perspective: "We chose WCG Trifecta to accomplish these goals with a standardized training platform to control the training, customize it in a video format, and manage it from a central repository. We also gained flexibility, as several clinical trial centers were participating in multiple trials across different protocols, and we did not want to repeat training. The most amazing aspect, resulting in compliments from our staff and sites, was the functionality to run virtual investigator meetings through the Trifecta platform. Following investigator meetings, we placed the training certificate into the repository, and we had our training record. It was well-orchestrated and incredibly seamless."

Q: How can sponsors help alleviate administrative burden for site personnel?

A: Training is how investigators and coordinators are exposed to sponsors at study outset. Historically, it comes with a heavy administrative burden – both in the time required to complete it, and the documentation required to demonstrate compliance. Cohesive, complete, efficient training is the biggest win in reducing administrative burden for site investigators and coordinators.

Investigators are most engaged during study start-up, and routinely provide positive feedback when the sponsor values their time with an organized solution. Having the right training at the right time and verifying the competency of team members already trained goes a long way in fostering successful site-sponsor relationships.

See Site Burden Calculator.

Ralph Lee - Site Perspective: "Technology is vital; it is a shame when working on a drug addressing a huge public need—such as Alzheimer's—and the training technology lets the sponsor study team down. Now that training is virtual, this technology is even more important. Remember that sites are having a tough time post-pandemic with workforce competency, as COVID research projects drew many qualified, experienced people away from sites. Efficient training is more crucial than ever."

Q: How can workforce preparedness help sponsors accelerate study start-up?

A: There are number of practical ways a proactive focus on workforce preparedness can help. From information capture to training delivery, WCG Trifecta is routinely sought out by sponsors for their experience in delivering on-demand training. Implementation timelines are accelerated due to integrated production and technology capabilities. On-demand training can be made available within five business days.

See case study: Accelerating Study Study-up

Ericka Atkinson - Provider Perspective: "A common question I hear from sponsors is 'How quickly can you get our training captured and launched?' This is critical because the study teams are under immense pressure. The focus is on speed to start."

Q: Where can sponsors find reliable guidance and resources to support their workforce preparedness activities?

A: WCG Avoca leads the industry in GCP quality and compliance solutions and hosts the Avoca Quality Consortium (AQC) – a cross-functional, collaborative network that unites sponsors, CROs, and clinical service providers to address challenges and maximize opportunities to mitigate risk and improve both quality and execution in clinical trials. The Knowledge Center houses over 400 leading practices, guidelines, tools, templates and process documents, as well as AQC research and archived webinars in a self-serve repository.

Visit the AQC knowledge center.

Patty Leuchten - Provider Perspective: "The most popular assets in the AQC Knowledge Center pertain to inspection preparedness. These tools prepare sites for difficult questions from inspectors. Having practical checklists helps sites feel more confident of being ready for an inspection."