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Lack of Training Compromises Trial Results, Expert Says

By John Mitchell

At its very core, a clinical trial is a measurement system. But unlike other fields that rely on measurement and data reporting, the clinical trials industry has not focused enough on training for everyone involved, from the investigators all the way down to the patients.

Lack of training, particularly for patients, creates variability detrimental to trial findings, says Nathaniel Katz, founder and chief science officer of WCG Analgesic Solutions.

"People have had magical thinking about the way clinical trials generate data," Katz told the audience of a recent WCG webinar. "There's this strange belief that if you give some people the treatment and (others) the placebo ... the trial will generate an observed effect size that somehow will accurately characterize the pharmacology of the treatment," Katz said.

That attitude, he stressed, has resulted in trials ending in expensive failure. Some of those failures could have been avoided with training to eliminate key causes of variability that undermine the scientific process.

The problem is that clinical trial research has not set a high enough training standard.

"Training is not really even viewed as a scientific topic in the world of clinical trials," Katz said. "Training has been viewed as a checkbox activity or something to do to please regulators, but not something that has a direct impact on our ability to achieve our scientific objectives in clinical trials."

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This is especially clear when it comes to training trial participants to report accurately on their reactions and experiences.

"Although pharma, device companies, CROs and regulatory agencies invest heavily in internal training, the concept of training clinical trial participants to perform their tasks better has scarcely filtered into the clinical trials managed by these organizations," Katz said.

He cited one example in which participants had not been appropriately trained on how to use electronic diaries the trial used to gather patient data. It resulted in skewed and flawed findings on drug effectiveness.

"It's rare that the skill we are asking people to do (in a trial) has been defined, yet that's what's necessary if you want (them) to do it," he explained.

Katz laid out a best practice training model for clinical trial staff and subjects based on adult learning principles used widely in other industries.

First, it's vital to understand the difference between education and training. Education is about what you know, he said, and training is about what you do. Giving someone a manual to read is education. Showing them how to perform tasks discussed in the manual and allowing them to practice is training. Education doesn't necessarily change behavior, but training does.

Practice should progress from simple to more advanced tasks and be followed by constructive and diagnostic feedback, Katz said. To facilitate the transfer of new skills to action, training and practice conditions should be increasingly difficult, trainer support should gradually decrease and practice conditions should increasingly resemble real-world conditions.

Katz also made a strong case for validating that any training done has achieved verifiable process improvement. It is the responsibility of leadership to demonstrate that there is a return on investment through more reliable clinical trial outcomes, he said.

Listen to the full webinar here: https://bit.ly/2wr21Mx.