

New Training Standards Sought for PIs

By Bill Myers

Two influential clinical industry groups are focusing on new training efforts to prevent principal investigators from burning out and it appears that the FDA is willing to work with them on the effort.

Sponsors, CROs and sites have to move away from repetitive, “one-size fits all training” for trial investigators and toward a targeted approach that addresses the needs of investigators and the protocols themselves, says the Clinical Trials Transformation Initiative.

The CTTI recommendations already have won endorsement from Jacqueline Corrigan-Curay, director of CDER’s Office of Medical Policy, who said they’re an effort “to expand the focus of investigator qualifications... toward new approaches that will further help ensure that site teams have the appropriate skills and knowledge they need to run high-quality clinical trials.”

The recommendations come just days after the Association of Clinical Research Professionals announced it was working on its own standards for investigators. Many industry experts are concerned that a lack of clear training standards is contributing to investigator burnout, heightening the risk of trial errors and driving up costs, stressing out investigators even more.

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experienced. Well, what does that mean? That’s a major problem in this industry: We don’t know how they’re trained,” ACRP Executive Director Jim Kremidas tells *CenterWatch*. “We know they’re trained as physicians. That doesn’t worry me. What worries me is, how are they trained as researchers?”

The Tufts Center for the Study of Drug Development has been ringing alarm bells about investigators for more than a decade. Its most recent analysis, issued in 2015, found that nearly half of the world’s investigators were brand new on the job. Perhaps worse, the number of new investigators entering the field was declining, Tufts found, compounding the turnover crisis.

It’s the “the one-and-done” problem: An investigator goes through a generic trials training program, lasts a single trial, and then leaves the field. The turnover isn’t just expensive — it’s potentially dangerous.

“Variance is the enemy of quality,” Kremidas says.

To help improve training, CTTI recommends that sponsors and CROs offer draft or completed protocols to sites and ask the sites’ teams for

feedback. Investigators should use their own experience to come up with policies or training manuals that focus on common pitfalls and how to avoid them.

Perhaps as important, any training program should treat investigators like grown-ups, CTTI says. That is, sponsors, CROs and sites should make sure that investigators don’t have to go through the same old processes regardless of the trial protocol. Sites can help by offering active learning opportunities such as mentoring or job-shadowing programs, knowledge-sharing networks or even simulations of patient visits and protocol requirements.

All of these are steps in the right direction — but they’re just steps, says Sofija Jovic, business transformation advisor at MedAvante-ProPhase.

“The barrier to implementation of these recommendations is that they are just that — recommendations and not requirements,” she tells *CenterWatch*.

“There is no central entity that is tasked with maintaining accreditation and enforcing it,” Jovic adds. “While recommendations are good, until we have standardized requirements, accompanied by standard curricula and a central repository of training records, not much will change in the day-to-day trial conduct.”

Change may well be afoot. The FDA last week told ACRP that it has assigned a staffer to help craft new investigator standards, Kremidas tells *CenterWatch*.

“It’s important from our perspective,” he says, “in that it recognizes how essential the clinical trial workforce is to improve efficiency and effectiveness of trials.”

Read CTTI’s recommendations here: <https://bit.ly/2Ax1qKF>. 