Clinical Trials Advisor

July 18, 2013 Thursday

Coordinators Should Strive to Complete Monitor To-Do Lists During Site Visits

SECTION: Vol. 18 No. 14

LENGTH: 660 words

Site coordinators should set aside time to meet with monitors during site visits and complete as many action items on the monitor's to-do list as possible during or shortly after the visit. That's the advice from a monitor who has been on both sides of the fence.

Kristen Bauer, senior regional clinical research associate with BIOTRONIK, has 16 years of experience in the clinical research industry, with six years each as a site coordinator and monitor. "When I was first starting out as a coordinator ... a lot of times I didn't have all day to spend with my monitor, so I would take the list and be like, 'great, I'll work on this later,'" said Bauer. "But you know that never happens."

A monitor's to-do list can have action items such as errors or missing data that were noted during the visit and need to be fixed, as well as queries coordinators may need to address. Bauer said coordinators frequently put off the to-do list until right before the monitor returns, which may take up to six months. By that time, the information is no longer fresh in the coordinator's mind, making it much harder to complete the list.

According to Bauer, coordinators should set aside time to meet with the monitor during their visits and schedule time for the principal investigator to meet with the monitor as well. The coordinator should be present at that meeting, she said.

We're Not the Enemy

Among the mistakes Bauer commonly sees coordinators make are failing to understand the difference between clinical visits and study visits, failing to follow the protocol, and not understanding their role and the roles of others at the institution, such as the principal investigator. Other issues that trip up coordinators include not sufficiently educating themselves about clinical trials and failing to record all pertinent data.

Contrary to what some coordinators think, monitors are not the enemy, Bauer told CTA. But she acknowledged that not all monitors are created equal.

"Sometimes [monitors] are going to mislead you and give you incorrect information because they themselves have not been properly trained or don't have adequate education," Bauer explained. "Don't let a bad monitor convince you that you're a bad coordinator."

Monitors may also ask that tasks be done in a specific way, based on personal preference or opinion rather than regulatory policy, Bauer added. Coordinators shouldn't take what monitors say at face value and should get all instructions and action items in writing, she advised.

And don't be afraid to ask questions, Bauer said. "Use your monitor as a resource. Understand what they're doing, what they're reviewing and why. Ask to meet each day to go over findings and action items."

A site coordinator's best protection is education, Bauer stressed. Being thoroughly versed in all aspects of the site can help to avoid embarrassing and costly mistakes and clue the coordinator in to when a monitor may be taking him or her down the wrong road.

And being well-educated can help prevent coordinators from unintentionally committing fraud by making assumptions about the trial or performing a procedure for which they aren't properly licensed. Worst case scenarios can land a coordinator disbarment or even jail time.

To guard against such mistakes, Bauer encourages coordinators to seek out education, especially continuing education, following any certification they receive. "Join a national organization, see if there is a local chapter near you where you can attend meetings and meet with others who have jobs similar to yours," she said.

Bauer also encourages coordinators to talk to their employers about covering the costs of certification exams and materials, as well as annual memberships in national research organizations. "National certifications are becoming more widely recognized and, in many settings, are now

a requirement to hold upper levels of research positions," she added. -- Ferdous Al-Faruque

Release date: July 18, 2013

LOAD-DATE: July 19, 2013

LANGUAGE: ENGLISH

PUBLICATION-TYPE: Newsletter