JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 2, No. 5, July 2006 "Can You Handle the Truth?"

Who You Calling a Study Coordinator?

By Norman M. Goldfarb

"A rose by another name may smell sweeter."

Physicians and nurses work to schedules – Patient 1 in Exam Room A, Patient 2 in Exam Room B, and so on. They have very little control of how they spend their time during a day. The day of a study coordinator (aka clinical research coordinator) is quite unlike that of a physician or nurse. Unlike physicians and nurses, study coordinators have tremendous discretion over how they spend their day. They can walk into the office and decide to spend the entire day recruiting subjects or completing case report forms. On most days, however, the coordinator's job is a lot like running a busy one-man gas station, with numerous types of activities, multiple balls in the air, and constant interruptions.

75-90% of coordinator time is non-billable and thus invisible to management. A coordinator can work non-stop all day on exactly the right priorities and generate zero revenue. No-one can prioritize the activities of a (competent) study coordinator better than the study coordinator him or herself. Managing a study coordinator's activities is thus a fool's errand; the only feasible approach is to manage their output in a way that aligns their objectives with those of the organization.

At most investigative sites, the investigator therefore delegates management of a study to a study coordinator. The coordinator then runs the study, delegating tasks to the investigator that the coordinator is unable to perform because of expertise or regulatory requirement. The key point here is that, within the context of the study, the organizational structure is turned on its head.

The title "study coordinator" (and "clinical research coordinator") substantially understate the study coordinator's role in managing the study and performing most of the study tasks. Coordination is just one small part of the study coordinator's activities.

Clinical research associates (CRAs) are not the sponsor's equivalent of a site's study coordinator. As their ambiguous title suggests, CRAs play a supporting – albeit important – role. The sponsor's equivalent to a site's study coordinator is a "study manager". Whereas the sponsor's study manager is usually responsible for a study at multiple sites, the site's study coordinator is often responsible for studies for multiple sponsors. If clinical research were performed inside pharmaceutical companies, study managers and study coordinators would feel right at home in a matrix organization.

"Managers" have the authority to allocate resources and give subordinates orders – direct or implied – to do something. "Coordinators", by definition, have no authority; they must beg, borrow and steal resources from people they do not supervise. In other words, calling the person who runs a study a "coordinator" implicitly dis-empowers that person. It gives them the responsibility but not the authority, not a positive predictor of success.

Giving study coordinators the title – and authority – of "study director" would implicitly empower them.

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