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Compliance TODAY

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Local expertise, regional teams, and multinational compliance

an interview with
Jonathan Turner

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by Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC

The audacity of evaluating capacity

Kelly M. Willenberg *(Kelly@kellywillenberg.com) is President and CEO of Kelly Willenberg, LLC in Chesnee, SC.*

A common question for research sites is, how many coordinators does it really take to perform the work before us? An article in *Entrepreneur* magazine in October, 2015 discussed that the more engaged an employee is with their job, the higher their productivity, sales, and creativity.[1]

Willenberg

There are a number of workload tools available to research teams to understand workload of clinical trials. Some sites place a value on the complexity of the trial, while others give more weight to the protocol phase. Although workload is sometimes questioned, a research compliance professional must know something about the roles and responsibilities of the research team to know the gravity of compliance risks. It is not okay to say that the team is too busy to worry about compliance.

It is common for some sites to overestimate accrual, then have staff that may not be busy with day-to-day activities. Cross-training the team is recommended, but with an understanding that a more experienced study coordinator may be quicker at screening than a rookie. The ASCO Clinical Trial Workload Assessment Tool, released in 2014, helps to assess clinical trial-associated workload based on the complexity of research protocols and the number of patients assigned to staff.[2] These types of reviews prior to a study opening can assist with how much time will be spent on a particular protocol.

Philip J. Butera from Atrium Health in Charlotte, North Carolina shared his workload tool at a recent conference in Orlando. Mr. Butera has a practical methodology to consider protocol complexity, the capacity of staff and actual work performed, and forecasting accrual. This has facilitated communication, protected some staffing time for administrative and the unknowns that occur, and accurately budgeted a trial. Mr. Butera says: "It is not enough to look at trial complexity and phase for what your research staff can handle, but to take a deeper look at your roles, responsibilities, and processes they work under, coupled with their level of research experience to determine a more realistic level of workload. You must pressure test what your model is telling you with real conversations with your research staff to drive continuous improvement in how they work, which in turn re-informs your model to evolve with your operating environment."

Have the audacity to understand the work capacity of your research team! It might just pay off in more accrual and more research revenue.

1. Sam Bahreini: "Employee Engagement Is More Important Than the Customer" *Entrepreneur*; October 19, 2015. Available at http://bit.ly/2KPIDxN
2. M.J. Good, P. Hurley, K.M. Woo, et al.: "Assessing Clinical Trial-Associated Workload in Community-Based Research Programs Using the ASCO Clinical Trial Workload Assessment Tool" *Journal of Oncology Practice*; May 2016. Available at http://bit.ly/2kpV4oT