HCCA HEALTH CARE COMPLIANCE ASSOCIATION

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an interview with Mike Joyce

Vice President, Chief Auditor
& Compliance Officer
Blue Cross Blue Shield Association
Chicago

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

Little things make big things happen

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

Basketball legend John Wooden once said, "It's the little details that are vital. Little things make big things happen." As in basketball, the little details in clinical research can be detrimental to the integrity of study results.

Willenberg

Many clinical investigators ignore the small things, thinking nobody will notice, because they are insignificant, such as a lab value reported incorrectly or a performance status improperly documented. Recent publications have opened a dialogue about under reporting of negative trial results. What would happen if clinical researchers paid more attention to their oversight responsibilities, carefully followed the investigational plan, and reported all deviations or adverse events correctly?

Perhaps a few Good Clinical Practice (GCP) choices would push for better data overall with your clinical research team. Implement a self-monitoring review of a sample of patient research binders against the medical chart each month. Follow all deviations on every patient and validate the data in a timely manner. Improve your communication with your Institutional Review Board (IRB) of record. Start a weekly huddle on adverse events and informed consent issues. Hold your clinical researcher accountable with quarterly meetings on data integrity.

On March 20, 2017, the *Endocrinology Advisor* published an article by Linda Peckel titled "Underreporting Negative Clinical Trial Data Raises Ethical Concerns with WHO, FDA, NIH."[1] The article discusses the concerns over negative results of trials. This pressure, along with the ethical challenges involved, have caused major sources to restructure data reporting, including the World Health Organization (WHO), the National Institutes of Health (NIH), and the U.S. Food and Drug Administration (FDA). We are starting to see some of these changes with new guidelines and actions. Of note in the article, several objections were specifically raised to the practice of not reporting negative clinical trial results, citing that it:

- causes duplication of negative results from other investigations;
- puts new trial patients at unnecessary risk;
- distorts the evidence base;
- produces incomplete knowledge and creates misconceptions that get incorporated into guidelines and daily practice;
- undermines trust of patients participating in trials if the results are never published; and
- results in poor allocation of product development resources and slows drug development

It is up to the research compliance community to take data integrity seriously. Pay attention to the little things like data! Keep an eye on the timeliness of data reported. These little things make big things happen, and you are the compliance piece necessary for the little details that have significance!

1. Available at http://bit.ly/2ri2fSv