

## **W09-04 - INDUSTRY PERSPECTIVES ON THE IMPORTANCE OF SAMPLE SIZE, STATISTICAL POWER AND PROTOCOL FIDELITY**

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An inadequate sample size, low statistical power and poor reliability in a clinical trial exposes subjects to potentially harmful treatments without advancing knowledge. An unnecessary number of subjects may be exposed to a potentially harmful treatment, or are denied a potentially beneficial one. For such an important issue, there is a surprisingly small amount of published literature. One step in determining statistical power and fidelity requires educating an effect size of scientific interest. From an industry viewpoint, it is not up to a statistician to decide this; however, it is the statistician's responsibility to try to extract this information from the industry researchers involved in planning the study. A major problem being observed is that researchers don't recognize it as a question that they are responsible for answering. This presentation will outline a model of protocol fidelity in clinical trials. The model addresses the complexity of clinical trial research, by expanding the aspects of the research process that require attention to fidelity from more simple models focusing on delivery and performance that incorporates study design and training. This will allow a more precise understanding of the elements responsible for a treatment's success or failure, improving replicability and translation to clinical or community settings.

### **Learning Objectives:**

From this workshop, clinicians and statisticians in industry and academia will learn:

1. The importance of taking protocol fidelity into account at the earliest stages of the research, beginning with procedures to ensure that the treatment components accurately reflect the theoretical underpinnings of the intervention, and that sites are trained in standardized fashion, to criterion, with emphasis on maintenance rater skills over time.
2. Mapping the treatment to theory, description of the core mechanisms of the treatment, and standardized training, monitoring, and maintenance of rater skills over time are essential to ensuring that the treatment is being operationalized as proposed.