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REINVENTING THE WHEEL IN CLINICAL TRIAL DESIGN

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Recent publications by the Institute of Medicine have unearthed several fundamental flaws in clinical trial methodology that, if corrected by the next generation of clinical investigators, can transform the field of mental health intervention research. Using a clinician-friendly approach, this workshop will succinctly review the essential elements of optimal design and implementation of a randomized controlled clinical study and the strategies to enhance signal detection. These include minimizing bias in the estimate of treatment effect while maintaining a nominal level of type I error (i.e., false positive results) and maintaining sufficient statistical power (i.e. reducing the likelihood of false negative results). Particular attention will be paid to reducing the problems of attrition and the hazards of multiplicity. Methods to examine moderators of the treatment effect will also be explored. Examples from psychopharmacologic, psychotherapy, and vocational rehabilitation trials for the treatment of posttraumatic stress disorder, depression, and panic disorder will be provided to illustrate these issues. Techniques to reduce the study's costs, risks, and participant burden will be described. Following the didactic session, the participants are encouraged to bring forth their own questions regarding clinical trial design for a 45-minute interactive discussion with the presenters. The objectives of the workshop are to improve the participants' understanding of the goals of clinical trial design and methods to achieve those goals in order to improve their own research techniques, grantsmanship, and abilities to more accurately judge the results of studies presented in the literature.