

Keynote Speaker



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Time: September 13 (Monday): 9:00-10:00AM (Eastern Time)

Host: Guoqing Diao, Ph.D., ICSA 2021 Applied Statistics Symposium Executive Committee Chair and Professor, Department of Biostatistics and Bioinformatics, George Washington University

Title: The Catalyst to Better Answers: More Thoughtful Questions

Abstract: We often debate how to design, conduct, or analyze a study. At its core, what we are debating is not the answer, but the question. Once the intricacies of the question are well defined and understood, the path forward becomes clear. Unfortunately, we often fail to recognize the most important questions and tailor the design, conduct, and analysis of studies to address these questions. As a result, we fail to get optimal answers to the most important questions.

For example, randomized clinical trials are the gold standard for evaluating the benefits and harms of interventions but often fail to provide the necessary evidence to inform practical medical decision-making. Typical analyses of clinical trials involve intervention comparisons for each efficacy and safety outcome. Outcome-specific effects are estimated and potentially combined in benefit:risk analyses with the belief that such analyses inform the totality of effects on patients. However summing marginal analyses of each outcome does not effectively characterize the effects on patients. Such approaches do not incorporate associations between outcomes of interest or the cumulative nature of component outcomes on patients, suffer from competing risk challenges when interpreting outcome-specific results, and since efficacy and safety analyses are conducted on different analysis populations, the population to which these analyses generalize, is unclear.

Identification of the most important clinical questions and adjusting our approaches to address these questions is the greatest opportunity to advance medicine and public health. In clinical trials and diagnostics studies, increased interest on questions of a pragmatic origin is needed to match their clinical importance and real-world utility. Ideas for adjustments to trial design, conduct, analyses, and reporting, to answer the most important questions for medical-decision making, are discussed.