Lessons Learned from Adaptive RCT Designs

Daniel Gillen

University of California
E-mail: dgillen@uci.edu

Abstract: This talk will consider the current state of adaptive clinical trials designs from the perspective of the 2018 FDA guidance document on adaptive designs for drugs and biologics. We will explore the types of adaption that have been proposed and used in regulatory settings, consider the potential efficiency benefits of sample size adaptation, and discuss some of the hard lessons learned from adaptive randomization schemes. The talk will conclude with particular issues that arise when utilizing adaptive designs in the setting of time-to-event endpoints and thoughts on where we go from here in order to increase efficiency and maximize individual- and population-level ethics in randomized controlled trials.