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KEYNOTE LECTURE

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Topic:

Is the adaptive paradigm shifting the perception of clinical trials?

Abstract:

A fundamental difference between clinical trials and other experiments (such as field, basic science, or animal experiments) is, in human clinical trials the accrual of the participants often has to occur sequentially, in multiple centers. A natural question that arises in such trials is, could the experience and the information accumulated over time be used to modify the future course and the design of the trial? Traditional designs that include interim analyses and stopping rules prespecify the course of the trial, prior to the first participant is registered in the trial and do not allow adaptations. The current paradigm of adaptation has wide acceptance in the field and several methods for adaptation have been proposed for all phases of the clinical trials. In this presentation, I will introduce basic as well as complex adaptive designs. I will discuss my philosophy regarding the application of these designs. I will also briefly present a few of the designs that my colleagues and I have proposed.