Title of Session: Platform Trials / Response Adaptive Trials: Overview of Design Elements

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Brief Description:

Platform and adaptive trials are not new in Oncology. However, they have become more commonplace particularly in an increasingly crowded clinical trial / clinical development space and with increasing need for rapid evidence generation; limited data to guide sample size determination; disease heterogeneity and the corresponding possibility for heterogeneous treatment effects; varying applicability of randomly assigning patients versus empirically implementing treatments; the aspiration to study (and preferentially randomly assign each patient to) multiple, potentially interacting treatments concurrently; and to minimize the number of patients treated with ineffective treatments and/or nontreated control subjects; as well as desire to create durable infrastructure for evidence evaluation. This session will define master protocols, platform and adaptive design trials and will discuss the evolution / utility of these designs as well as some of the key design elements, and efficiencies and challenges associated with their use.

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