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TOPIC: Taming the R&D Beast: Emerging Strategies for Adaptive Clinical Trial Designs

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As R&D productivity challenges continue to beset the pharma industry, more drug manufacturers are beginning to consider adaptive clinical trial designs to accelerate drug development. About 20 percent of clinical trials currently underway are using simple adaptive designs such as early study terminations due to futility, and to a lesser degree, sample size re-estimation, according to a recent report from the Tufts Center for the Study of Drug Development (Getz & Kaitin, 2013). The report estimates that these approaches could save sponsor organizations between \$100 million and \$200 million annually in aggregate costs.

This program convenes a panel of experts from contract research organizations who have been involved in planning and executing simple and complex adaptive designs for both early and late-stage trials. They will discuss clinical, statistical and regulatory considerations for adaptive designs, sharing case studies from their own work with sponsors.