Designing adaptive clinical trials

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Abstract

The objective of this course is to provide practical strategies and tools for efficient decision-making via interim analyses of ongoing clinical trials, using state-of-the-art methods for group sequential and adaptive designs.

Topics covered will include group sequential design and monitoring with sample size re-estimation, preserving type-1 error, computing power, obtaining point estimates, and computing confidence intervals in the adaptive setting. We will also cover modern methods for model-based dose-escalation in Phase 1 oncology studies.

Case studies in oncology and cardiology are used to reinforce the main points. The workshop includes a hands-on session with the East 6.3 software.

Firsthand experience with East will be used throughout as a running example to illustrate concepts.

Computers & Software

Participants should bring their own laptops. The software will be provided by a Cytel download link.

Yannis Jemiai *is Vice President of Strategic Consulting and Product Management at Cytel. In this capacity, Yannis leads efforts to deliver solutions that solve meaningful problems for clients in the biopharmaceutical industry. His areas of interest include adaptive designs, dose finding, multiple comparison procedures, modeling and simulation, predictive analytics, missing data, and causal inference. Yannis earned his PhD in Biostatistics from Harvard University.*

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