Innovative Designs for Early Phase Oncology Trials

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Yuan Ji\textsuperscript{1} & Sue-Jane Wang \textsuperscript{2}

1: The University of Chicago  
2: US FDA

In this half-day short course, we will introduce, describe, and demonstrate innovative designs for early-phase oncology trials. The classroom teaching will be delivered by the two instructors through projected slides. There will be two sessions with a Q&A portion in each session. One session will be taught by Dr. Sue-Jane Wang. She will recap types of methodological advances in light of recent regulatory experiences with use of early phase innovative designs. The other session will be taught by Dr. Yuan Ji, who will present novel statistical designs for phase 1a dose escalation, phase 1b expansion cohorts, drug combination dose finding, designs accommodating delayed toxicity like in immune oncology, and designs for master protocols. Most designs introduced in the short course will use Bayesian modeling and adaptive decision rules. A brief introduction of Bayesian statistics will also be provided. Lastly, at the end two software packages will be demonstrated, one of which is freely available and the other commercial.

Outline of Topics:

**Session 1:** Methodologies and applications

1. Designs for early-phase dose escalation studies  
2. Designs for early-phase cohort expansion studies  
3. Designs for early-phase drug combination dose finding studies  
4. Designs for immune oncology dose finding with delayed outcomes  
5. Designs and methods for exploratory basket trials

**Q&A and break** (30 minutes)

**Session 2:** Regulatory consideration and rationales

1. Regulatory guidance overview related to early phase dose finding/cohort expansion/adaptive design/master protocol/new drug combinations  
2. Key methodologies recap and some regulatory experiences in early phase design strategies

**Session 3:** Software demo.