Session Name: Phase I Trials

Educational Objectives:

1. Formulate the objectives and endpoints of interest in a phase I clinical trial.
2. Understand the basic concepts of dose-limiting toxicity, maximum administered dose, optimal biological dose, recommended phase II dose, pharmacokinetics and pharmacodynamics.
3. Select a safe starting dose/schedule, eligible patient population and appropriate dose escalation method for a phase I clinical trial.
4. Examine a variety of rule-based and model-based dose escalation methods commonly utilized in phase I clinical trials.

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