

Plenary Session #1: Early Clinical Trials of Therapeutics: Phase I and II

Session Name: Phase II Trials

Speaker: Penny Bradbury

Educational Objectives:

At the end of the session the participant should be able to:

- Define the objectives of “screening” vs. “definitive” trials
- Describe the possible endpoints for phase II screening trials
- Understand basic concepts of phase II design including:
 - Non-randomized two-stage designs
 - H_a , H_o , alpha and beta errors in sample size determination
 - Types of randomized phase II design and their possible uses
- Understand the role of correlative studies within phase II screening trials
- Understand some of the controversial aspects of phase II designs for trials of molecular targeted agents