

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

Topic: Phase II Trials

Speaker: **Elizabeth A. Eisenhauer**

Educational Objectives:

At the end of the session the participant will be able to

1. Define the usual primary objectives of “screening” *versus* “definitive” cancer trials
2. Describe the possible endpoints for phase II screening trials
3. Understand basic concepts of phase II design including:
 - a. Non-randomized two-stage designs
 - b. H_a , H_o , alpha and beta errors in sample size determination
 - c. Types of randomized phase II design and their possible uses
4. Understand the role of correlative studies within phase II screening trials
5. Understand some of the controversial aspects of phase II designs for trials of molecular targeted agents.