Session Name: Plenary Session 2 – Comparative Efficacy Studies of Therapeutics: Phase III

Lecture Title: Statistics for Clinical Trials: Basics of Phase III Trial Design (35/10 min)

Presenter: Gary Clark

Educational Objectives:

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

- 1. Describe the purpose/aim of a randomized comparative trial
- 2. Understand different strategies for randomizing patients
- 3. Explain the intent-to-treat principle
- 4. Describe advantages and disadvantages of various study designs
- 5. Understand the intent of Interim analysis strategies