Session Name: Plenary Session 3 – Biomarkers in Clinical Trials
Lecture Title: Design Elements of Clinical Trials Involving Biomarkers - A Biostatistician's Perspective (45/10 min)
Presenter: Gary Clark

Educational Objectives:
At the end of the lecture the participant should be able to:
1. Create a list of questions that should be answered before studies can be designed to evaluate targeted therapies
2. Define and understand the terms "Prognostic Factor" and "Predictive Factor"
3. Understand the advantages and disadvantages of single-arm vs. multiple-arm clinical trials of targeted therapies
4. Provide examples of when selection/enrichment strategies might be appropriate for Phase II and Phase III study designs