

Session Name: Workshop 10 – Statistical Analysis of Biomarker Data  
Lecture Title: Statistical Analysis of Biomarker Data (20/20 min)  
Presenter: Gary Clark

Educational Objectives:

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

1. Define and understand the terms “Assay Method Validation” and “Assay Qualification”
2. Know where to find and interpret the Reporting Recommendations for Tumor Marker Prognostic Studies (REMARK guidelines)
3. Provide examples of how different scoring and reporting protocols for biomarker assays can complicate the statistical analysis and interpretation of biomarker results
4. Understand the pitfalls of defining a cutpoint for continuous biomarker results without an external validation of that cutpoint