

Session 1: Standardization and Validation of Immunologic Biomarkers

- REMARK criteria has become the standard for publication of biomarker studies-why do immunotherapy biomarker studies not adhere? (*McShane et al JNCI, 2005*)
 - Description of reproducibility, description of controls and quality control, sample preparation standards
- What should be expected of a laboratory that performs immunologic assays for clinical trials?
 - *FDA draft guidance for therapeutic cancer vaccines: at least 2 assays; assay parameters/controls should be clearly described (Sept. 2009)*
 - QA/QC, reference populations screening of reagents, assay performance characteristics
 - How to balance standardized assays for immune response with research questions?