**Lisa Meier McShane, Ph.D**., is Associate Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, U.S. National Institutes of Health, where she heads the Biometric Research Program, comprising Biostatistics and Computational and Systems Biology Branches. She earned a Ph.D. in Statistics from Cornell University and is a Fellow of the American Statistical Association. She is an internationally recognized expert on precision medicine clinical trial design; development of tumor markers and omics predictors for prognosis, therapy selection, and disease monitoring; and reporting guidelines for health research studies.  Her statistical research interests include biomarker-driven clinical trial design, analysis of high-dimensional omics data, multiple comparisons methods, surrogate endpoints, and biomarker assay analytical performance assessment. She co-led efforts to develop "Reporting guidelines for tumor marker prognostic studies (REMARK)" and "Criteria for the use of omics-based predictors in clinical trials". She has coauthored numerous statistical and biomedical papers in addition to the book *Statistical Design and Analysis of DNA Microarray Investigations*. She is a frequent invited speaker at national and international oncology and statistics meetings.

Dr. McShane serves on the Scientific Advisory Board for *Science Translational Medicine*,on the Editorial Board for *Journal of Clinical Oncology*, and she is one of the Editors-in-Chief of *Statistics in Medicine*. She has served on American Society of Clinical Oncology committees that developed guidelines for *HER2* and hormone receptor testing in breast cancer, *EGFR* mutation testing in lung cancer, biomarkers in early-stage breast cancer, and biomarkers to inform therapy for metastatic breast cancer. She interacts frequently with the U.S. Food and Drug Administration (FDA) on biomarker-based initiatives and has served on FDA Molecular and Clinical Genetics and Clinical Chemistry and Clinical Toxicology Panels. She has served as a member of Institute of Medicine *Committee for Management of the Air Force Health Study Data and Specimens*, the *Consensus Committee on Management of the Air Force Health Study Data and Specimens-Report to Congress*, and the *Committee on the State of the Science in Ovarian Cancer Research*.