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## **Genomic Classifiers in Colon Cancer: Clinical Utility**

Daniel Sargent, PhD

Mayo Clinic

Rochester, Minnesota, USA

Rapid technologic advances are allowing for the development of algorithms to predict both patient prognosis, and possibly, responsiveness to specific therapeutic interventions. Such classifiers may potentially be based on hundreds or thousands of possible factors, including data from genomic, proteomic, pathologic, or other factors. As such, in the absence of careful experimental design, there is considerable potential for an over-optimistic assessment of a classifier's true performance in the clinical setting. In this talk, I will present a multi-step methodology for the development, assessment, and finally, clinical testing of genomic classifiers in the setting of colon cancer, drawing from examples in both colon and breast cancer. Critical issues include the stability and reproducibility of the assay methodology, appropriate choice of patient population, proper segregation of data into learning and validation cohorts, inclusion of known prognostic and predictive factors (eg, staging), and a critical examination of the most relevant performance characteristics. The need for prospective vs. retrospective confirmation will also be discussed.