Biostatistics Internship in Tissue Diagnosis

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This summer I worked as an intern-biostatistician at Ventana Medical Systems, Inc., a member of the Roche Group, Tucson, AZ. Ventana provides innovative tissue-based cancer diagnostic solutions to the pathology market, including automated immunohistochemistry (IHC)/in situ hybridization (ISH) slide staining platforms, clinical reagents, assays for clinical testing, etc. The currently most rapidly growing area in tissue diagnosis is the development and commercialization of companion diagnostics (CDx) for cancer patients. CDx helps a health care professional determine the best course of therapy for each individual patient, which is the essence of Personalized Healthcare. The value of the Personalized Healthcare approach is rooted in positive outcomes for the patient—saving lives and improving the quality of life.

I will briefly introduce the journey of a tissue biopsy for cancer testing. The main focus will be on the co-developing process of a CDx assay with the Pharma industry partner and the role of biostatisticians in it. The general idea of the projects I worked on, a simulated study for inter-laboratory reproducibility study design and a retrospective study of CDx assays to investigate the association of scoring algorithm with reader precision, as well as the statistical approaches used will also be descried.