

# September Meeting of the San Francisco Bay Area Chapter of the American Statistical Association

**Speaker: Nancy Geller, Ph.D., President of the American Statistical Association**

**Title:** Confirmatory clinical trial designs for biomarkers

**Date and Time:** September 15, 2011 4:30-5:00pm Refreshments 5:00-6:00pm Seminar 6:00-6:30pm Q&A

**Location:** Genomic Health Inc., Redwood City. ([www.genomichealth.com](http://www.genomichealth.com))

## **Abstract:**

With the accelerating pace of biomedical discoveries and the drive for personalized medicine, many randomized clinical trials are being proposed to confirm the validity of a biomarker as predictive of response to therapy. How will we decide which trials to undertake? How will we create designs that are efficient? We discuss the level of evidence required prior to undertaking a confirmatory trial of a hypothesized predictive marker. Designs of trials to confirm that a marker is predictive are discussed and cardiovascular examples detailed. Use of unconventional endpoints and new analysis methods are suggested to illustrate how to make such clinical trials more efficient. I'll close with a few comments about the American Statistical Association.

**Driving Directions and Map:** <http://www.genomichealth.com/en-US/GloDrivingPages/ContactUs/MapDirection.aspx>

*The meeting will be held at 101 Galveston Drive. Guests may park in any marked space in the business park or along the street and should find ample parking convenient to the building. In addition to the lot at 101 Galveston Drive, parking may be available in the lots of 301 Galveston Drive (next door) or 301 Chesapeake Drive (across the street). For building entry please use the main entrance, facing Galveston Drive.*

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