

March 16 Meeting of the San Francisco Bay Area Chapter of the American Statistical Association

Speakers: **Drew Watson, Michael Crager and Carl Yoshizawa** Genomic Health. Watson is VP Biostatistics, Data Management and Medical Operations. Michael Crager is a Genomic Health Fellow in Biostatistics and Carl Yoshizawa is Senior Director, Clinical Biostatistics.

Title: **Personalized Medicine and the Development of Clinically Relevant Genomic Predictors: A Case Study of the Oncotype DX® Breast and Colon Cancer Assays**

Time: Tuesday, 16 Mar., 4 - 6 PM light refreshments 4 - 4:30, presentation 4:30 – 6 PM

Location: Genomic Health, Inc., 101 Galveston Drive, Redwood City, CA 94063 (650) 556-9300

Abstract:

The sequencing of the first draft of the human genome, nearly a decade ago, has ushered in a new era of personalized medicine. As our knowledge of the human genome has grown, the range of therapeutic options is expanding. Similarly, rapid improvements in the performance and affordability of molecular diagnostics have enabled increasingly precise predictions of an individual's predisposition to disease, risk of disease recurrence and likelihood of response to therapies. However, the field of personalized medicine brings with it several new statistical challenges. Consequently, while scientific journals are replete with genomics studies, few of these studies have successfully established clinical relevance for key biomarkers of interest.

The presenters will discuss rational approaches to biomarker discovery (Mike Crager), algorithm development (Drew Watson) and clinical trial design (Carl Yoshizawa) based on their experience in the development of the Oncotype DX Breast and Colon Cancer assays. The Oncotype DX Breast Cancer test is a multigene diagnostic assay widely used in standard clinical practice that looks at the genomic profile of a breast tumor to quantify the likelihood that early-stage, estrogen receptor-positive, lymph node-negative breast cancer will return, or recur (distant recurrence), and provide information about a woman's likely benefit from chemotherapy (commonly used to treat early-stage breast cancer). The recently commercially released Oncotype DX Colon Cancer test is the first multigene diagnostic assay developed for the assessment of risk of recurrence in patients with stage II colon cancer. Areas of statistical research will be illustrated including gene identification using true discovery rate degree of association (TDRDA) sets, algorithm development methodologies and predictiveness curves for survival data, and prospective cohort sampling designs using banked tissue samples.

Directions:

From San Francisco Airport via Highway 101 South exit Woodside/Seaport Blvd/CA-84 and proceed left towards Seaport Blvd. Merge onto Seaport Blvd. Turn left onto Chesapeake Drive (2nd traffic signal). Make an immediate left onto Galveston Drive. Make an immediate left into Genomic Health parking lot.

From San Jose Airport via Highway 101 North exit Woodside/Seaport Blvd/CA-84 proceed right towards Seaport Blvd. Merge onto Seaport Blvd. Turn left onto Chesapeake Drive (2nd traffic signal). Make an immediate left onto Galveston Drive. Make an immediate left into Genomic Health parking lot.

From Interstate 280 North or South exit Woodside Road East. After approx. 4 miles Woodside Road will turn into Seaport Blvd when you go under the Hwy 101 overpass. Turn left onto Chesapeake Drive (2nd traffic signal after Hwy 101 overpass). Make an immediate left onto Galveston Drive. Make an immediate left into Genomic Health parking lot.

Parking will be across the street from location of the meeting. The address is 301 Chesapeake Drive. There will be signs on where to park and there will be a person from our facilities department to direct the attendees to park and

where to go for the meeting. Being that the meeting will be during office hours, parking will be limited at the 101 Penobscot office (where the meeting will be held at).

[map](#)

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