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**Session Title:** Risk and Prevention: Risk Factors on December 15

**Presentation Title:** The OncoVue<sup>®</sup> model for predicting breast cancer risk

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**Background:** Accurately predicting individualized probability of developing breast cancer over time is clinically useful for early detection and prevention. Building upon the widely used Gail model for predicting an individual's risk of developing breast cancer, in this presentation we explore a potential improvement by incorporating genetic information.

**Materials and Methods:** Data from analysis of common single nucleotide polymorphism (SNP) variants and personal history information collected on a decade-long case-control study conducted in six distinct geographic regions of the United States were utilized to develop a predictive model. Study participants had completed a questionnaire concerning clinical and lifestyle information and their DNA was genotyped for 117 common, functional polymorphisms (mostly SNPs) in candidate genes likely to influence breast carcinogenesis. Utilizing the multivariate logistic regression technique, we built a multi-component model on a training set of 5022 Caucasian women (1671 breast cancer cases and 3351 cancer-free controls age-matched within one year). We validated the model on an independent test set of 400 cases and 793 controls.

**Results:** OncoVue<sup>®</sup> is a tri-partite model built of three integrated components. Using a number of measures of performance, in both the training and test sets, we have shown that OncoVue<sup>®</sup> has better performance in identifying women that are truly at higher risk for breast cancer (previously diagnosed breast cancer cases) than did the Gail model for the populations studied. OncoVue<sup>®</sup> correctly placed more cases and fewer controls at high risk and uniquely identified individuals at high risk that were not identified at high risk by the Gail model. OncoVue<sup>®</sup> stratified the risk of these populations, particularly for cases, over a greater range of risk scores. Analyses examining discriminatory accuracy demonstrated statistically significant improvement for OncoVue<sup>®</sup> compared to the Gail model ( $p < 0.0001$ ).

**Discussion:** OncoVue<sup>®</sup> improves upon the Gail model, by incorporating genetic information, resulting in better performance in estimating individual breast cancer risk among women.