P146 THE 21-GENE BREAST CANCER ASSAY: SUMMARY OF CLINICAL EVIDENCE

Poster Abstracts I

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Goals: The Oncotype DX® 21-gene assay Recurrence Score® result predicts the 10-year risk of distant recurrence and the likelihood of chemotherapy (CT) benefit in women with ER-positive early stage invasive breast cancer. As the use of genomic assays increases, there is a need to clearly define appropriate clinical validation as the results are used for treatment (tx) decisions, recommendations by payers, and treatment guidelines. This summary aims to define the studies that meet the definition of “clinical validation” and describe additional studies that support the clinical utility of the Oncotype DX® assay.

Methods: Randomized clinical trials (RCT) that were conducted in a prospective manner using archived samples with documented clinical outcomes for prognostic or predictive utility were considered “validation studies” (Simon et al. JNCI 2009). Additional studies that generated clinical evidence on the use of the score, including studies where patients received uniform treatment but were not enrolled in a clinical trial, were considered clinical support.

Results: Seventeen studies were identified that included 5854 patients (3346 node-negative, 2200 positive, 308 unknown). All studies demonstrated an association between the score and clinical outcome (local and/or distant recurrence or neoadjuvant response) and nine studies showed a correlation between the score and tx benefit (CT and/or Tam). Six unique studies met the definition of a “validation study.” Descriptive summaries of the studies will be shown.

Study	Criteria Prospective validation
NSABP B14 (2)	X
NSABP B20	X
NSABP B28	X

Kaiser	X
ECOG 2197 (2)	X
SWOG 8814	X
TransATAC	X
NSABP B14/20	X
Toi	X
Gianni	X
Chang	X
Akashi	X
Masuda	X
Yardley	X
Mayer	X

Conclusion: In using this strict definition of clinical validation, the body of data described here shows that the Oncotype DX® Recurrence Score for invasive breast cancer meets tumor marker level IB evidence for clinical use. Future clinical validation studies of genomic assays and subsequent clinical utility and support studies should be held to a rigoroust standard for accurate interpretation and comparison so that results from different assays can be clearly understood for treatment decision making.As an employee at Genomic Health, Inc., I am compensated with salary, benefits, and stock. I also have stock options as an employee of Genomic Health, Inc.