

## The impact of the 21 gene recurrence score (RS) on chemotherapy prescribing in estrogen receptor (ER) positive, lymph node positive early stage breast cancer in Ireland

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### BACKGROUND

For Estrogen Receptor (ER) positive, early stage breast cancer, the 21 gene Recurrence Score (RS) has clinical use both as a prognostic tool and to predict chemotherapy benefit. The availability of this tool in Ireland has led to a reduction in the use of adjuvant chemotherapy for women with lymph node (LN) negative disease. However, the RS is not routinely funded for patients with LN positive (LN+) breast cancer in Ireland. In addition, there are limited international data on the use of this tool in the preoperative setting. In this prospective observational study, we are investigating whether access to the 21 gene RS leads to a reduction in the receipt of chemotherapy for patients with ER+, LN+ breast cancer, and to correlate the 21 gene RS with response to preoperative systemic therapy.

### TRIAL DESIGN

This is a national, multi-site, prospective, observational study that will examine the impact of the 21 gene RS on chemotherapy recommendations in both the neoadjuvant and adjuvant setting. Prior to and following tumor testing with the 21 gene RS, Physicians will complete a questionnaire which details type and strength of systemic therapy recommendations.

### ELIGIBILITY

Cohort 1 (postoperative) will include patients with ER+ tumors of any size with involvement of 1-3 lymph nodes (N1 including micrometastases). Cohort 2 (preoperative) will include patients with ER+, T2-T4 tumors with biopsy proven nodal metastases. Both cohorts will have ECOG PS 0 or 1 and be fit for consideration of chemotherapy as determined by the Investigator.

### SPECIFIC AIMS

The primary endpoint is the percentage reduction in the number of patients for whom treating physicians recommend chemotherapy after testing with 21 gene RS. Secondary endpoints include the correlation between the 21 gene RS and residual cancer burden score, as well as pathological, clinical and radiological response rates. The economic impact of the 21 gene RS in ER+, LN+ will also be assessed.

### STATISTICAL METHODS

The sample size is based on similar decision impact studies conducted in other countries. Physician recommendations for chemotherapy pre 21-gene RS and recommendations post 21-gene RS testing will be compared and percentage change estimated with 95% confidence intervals. For secondary endpoints, the Pearson correlation coefficient ( $\rho$ ) will be used to examine the strength of the correlation between the 21 gene RS category and response. A budget impact model will be used to estimate the cost reduction in adjuvant chemotherapy as a result of 21-gene RS testing.

### PRESENT ACCRUAL AND TARGET ACCRUAL

Target accrual is 75 in each of the neoadjuvant and adjuvant cohorts to total 150 patients.  
Supported by Genomic Health.

**Session:** Ongoing Clinical Trials: Ongoing Trials -- Predictive & Prognostic Factors (5:00 PM-7:00 PM)

**Date/Time:** Friday, December 9, 2016 - 5:00 pm

**Room:** Hall 1

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