

CompanDX Launches 31-Gene Time-to-an-Event Breast Cancer Test

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CompanDX this week launched its "time to an event" breast cancer gene panel, which the company said can predict whether patients' cancer will metastasize based on a 31-gene signature.

The company, which recently changed its name from Compadia to CompanDX, presented data on the test at the British Breast Cancer meeting this week in Nottingham, UK. The test uses CompanDX's Risk Distiller bioinformatics tool to predict the time in which a breast cancer patient's disease may metastasize after initial surgery and biopsy.

The company said it used three publicly available clinical datasets to generate the 31-gene signature, which it then validated in a fourth clinical dataset. "Across these patient cohorts the actual versus signature-predicted time to metastases has a correlation of 0.86," the company reported, adding that this was a statistically significant finding.

Additionally, after combined analysis of all data sets, the researchers reported that the gene signature is able to predict survival via a "prospective Kaplan Meier curve". The actual median time-to-event in the patient population was 3.5 years compared to the 3.7 years predicted by the CompanDx signature. There were "no significant differences between the actual and CompanDx curves ($p = 0.555$)."

CompanDX CEO Andy Sutton touted the time-to-an-event breast cancer gene panel as a "totally new type of diagnostic paradigm with the potential to significantly alter clinical management."

There are other tests currently being marketed in the US and abroad that use gene signatures to predict distant metastasis of breast cancer, such as Genomic Health's Oncotype DX and Agendia's MammaPrint, but Sutton said that the CompanDX test differs from these because it provides an actual time to an event, whereas Oncotype DX and MammaPrint give patients' risk of recurrence.

"If you think about a classical Kaplan Meier survival curve, you could be in the good prognosis group and still nevertheless relapse after six months and reciprocally be in the poor prognosis group and relapse at five years," Sutton told *PGx Reporter*. "With the CompanDX test, each patient will receive a time-to-relapse based on the 31-gene signature."

Sutton added that none of the 31 genes in the test overlap with the 21 genes in the Oncotype DX panel, and only "a couple of genes" overlap with Mammamprint's 72-gene signature, which "leaves us well clear of patent issues."

In an effort to further validate this finding in the clinical setting, the company has joined with clinical centers in London, Nottingham, Cardiff, and The Netherlands. CompanDX has also

applied for a Wellcome Trust Translational Award "and garnered support from a top-five diagnostics company for the development of the test," Sutton added.

Clinically validating the test may take between 24 months and 30 months, at which point CompanDX will weigh commercialization options. "At that stage we will be seeking a licensing partner to take this forward into registration or seeking funding to do this ourselves," Sutton said.

New Name, New Focus

CompanDx has historically focused on providing biomarker discovery services to pharma and biotech companies. However, according to the firm, its in-house R&D is increasingly identifying biomarkers that may lead to new diagnostic services and products for commercial application.

"We have grown the service side of the business over the last nine months and are delivering biomarker discovery services to large pharma, small biotech, and diagnostic companies," Sutton said in a statement. "We and our investors have always recognized the significant upside potential in the research work we conduct with collaborators and in the laboratories of our founders."

As a result of the company's new focus on internal product development, it recently changed its name from CompanDx to CompanDX. "The new name reflects this activity as we start to build our IP portfolio around the signatures and biomarker panels we are developing," Sutton said.

According to the company's website, it is building a portfolio of novel biomarkers for breast cancer, prostate cancer, and Alzheimer's disease. CompanDX is collaborating with Bob Rees of Nottingham Trent University to discover these markers using SEREX expression cloning and expression sequence tag database analysis combined with gene expression profiling on real time PCR. The researchers are also using microarrays and next-generation sequencing technologies to gauge gene expression in the presence or absence of selected target genes.

CompanDx has "the sole rights to a number of patents arising from the research of Rees and his colleagues at Nottingham Trent University, which relates to the discovery of novel cancer genes and antigens that are at different stages of development as clinically valid biomarkers or therapeutic targets," the company states on its website.

The company on its website highlights several published studies conducted by researchers at the University of Nottingham on the prognostic value of breast cancer biomarkers CD71, PELP1, and FOXA1.

In addition to the ongoing validation work related to the breast cancer panel, CompanDX is "currently seeking and mining other datasets where longitudinal data exists to repeat this exercise leading us towards a portfolio of time-to-an-event diagnostics," Sutton said.