Title: The PREDICT Registry: A prospective registry to evaluate the effect of a predictive assay on treatment decisions in patients with DCIS following breast conserving therapy.

Background: The benefits of adjuvant radiation therapy (RT) in patients with ductal carcinoma in situ (DCIS) treated with breast conserving surgery (BCS) remains controversial. Although there is level-I evidence supporting the role of RT in reducing the risk of local recurrence, the absolute benefit is variable. Current guidelines generally recommend RT for all patients having BCS, but it is important to develop prognostic and predictive tools to better assess risk and understand the impact such a tool would have on treatment decisions. The DCISionRT Test (PreludeDx, Laguna Hills, CA) is a biologic signature that provides a validated score for assessing 10-year risk of recurrence and RT benefit using individual tumor biology as assessed by clinical and pathologic biomarkers.

Methods: This is a prospective cohort study for patients diagnosed with DCIS of the breast. Treating physicians complete a treatment recommendation survey before and after receiving DCISionRT test results. Test results, treatment recommendations, patient preferences and clinico-pathologic features are stored in a de-identified registry for participating institutions from a variety of geographic regions across the US. The study will also collect 5- and 10-year recurrence and survival data. The study includes females over age 25 who are candidates for BCS and eligible for RT and/or systemic treatment with sufficient tissue to generate test results. Subjects must not have been previously treated for DCIS or have previous or current invasive or micro-invasive breast cancer. The primary endpoints are changes in treatment recommendations for surgical, radiation and hormonal therapy. Secondary endpoints are identification of key drivers for treatment recommendations, including age, size, grade, necrosis, hormone receptor status and other clinico-pathologic factors. Changes in treatment recommendations will be assessed using McNemar’s test with an alpha level of 0.05. Differences in recurrence-free and over all survival will be evaluated by Kaplan-Meier survival analysis using the log-rank test and/or the Cox Proportional Hazards model. A planned early interim analysis based on the first 200 patients has been recently completed and reported.

Results: As of July 9, 2021, 1,986 patients have been accrued from 64 institutions. Ten additional institutions are currently in the process of joining the study. We are planning to enroll up to 2,500 patients from up to 100 institutions.

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The PREDICT Registry: A prospective registry study to evaluate the effect of the DCISionRT test on treatment decisions in patients with DCIS following breast conserving therapy

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The PREDICT Study has consented 1,847 women.

There are 65 sites enrolled and about 5 sites are pending activation. The goal is to activate up to 100 sites and consent 2,500 patients diagnosed with DCIS.

The purpose of the study is to evaluate the percent of cases in which treatment recommendations are changed after the test results become available.

Similar DCISionRT PREDICT registries are planning to open soon in Australia and Europe.

Figure 1. Patients Enrolled by Institution.

Figure 2. Cumulative Number of Patients Enrolled by Quarter.