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

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Protocol Synopsis

NCT Number	NCT04916808
Brief Title	The AUS-PREDICT Registry for DCIS Patients With DCISionRT Testing
Official Title	A Prospective Registry Studyto Evaluate the Effect of the DCISionRT Test on Treatment Decisions in Patients With DCIS Following Breast Conserving Therapy
Brief Summary	This is a prospective cohort study for patients diagnosed with ductal carcinoma in situ (DCIS) of the breast. The primary objective of the study is to create a de-identified database of patients, test results, treatment decisions and outcomes that can be queried to determine the utility of the DCISionRT™ test in the diagnosis and treatment of ductal carcinoma in situ of the breast.
Study Design	Observational Model: Cohort Time Perspective: Prospective
Intervention	Diagnostic Test: DCISionRT - The Prelude DCISionRT Test was developed by Prelude Corporation and is performed at its CLIA laboratory facility. The biomarkers used to evaluate the biologic signature of DCIS tissue are based on over a decade of research including the University of California, San Francisco, Yale University as well as Prelude Corporation. The test is prognostic for 10-year recurrence risk and predicts RT treatment benefit for invasive breast cancer. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing and is accredited by the College of American Pathologists (CAP).
Study Population	The study population will be selected from the clinical practices of the participating investigators and institutions. Patients who have been recently diagnosed with DCIS and are being evaluated for the need for further therapy will be screened for eligibility per the following eligibility criteria.
Eligibility Criteria	Inclusion criteria: • A clinical decision has been made to order the DCISionRT™ Test as part of routine patient care • Patient must have histologically confirmed ductal carcinoma in situ (DCIS) in a single breast (presence of lobular carcinoma in situ (LCIS) or other benign breast disease in addition to DCIS is acceptable) • Patient must be consented within 120 days after surgery • Patient must be eligible for, or have already received breast conserving surgery • Patient must be eligible to receive radiation and/or systemic treatment • Patient must be female and greater than 25 years old • Patient must be able to provide informed consent Exclusion criteria: • Patient tissue is insufficient to generate DCISionRT test results or required DCISionRT inputs (age, tumor size, margin status, palpability) are missing • Patient has invasive breast cancer or evidence in the ipsilateral or contralateral breast of invasive breast cancer, including microinvasion, lymph node involvement, or Paget's disease of the nipple • Patient has already been surgically treated with a mastectomy for primary DCIS • Patient has prior in situ or invasive breast cancer

Protocol Synopsis, continued

Study Groups/ Cohorts	Ductal Carcinoma In Situ (DCIS) Patients must have histologically confirmed ductal carcinoma in situ (DCIS) in a single breast without evidence of invasive cancer (presence of lobular carcinoma in situ (LCIS) or other benign breast disease in addition to DCIS is acceptable).
Primary Outcome Measures	Percent of Cases with Changes in Treatment Recommendation [Time Frame: 5 years] The study will collect details on physician treatment recommendations before and after availability of the genomic test (DCISionRT) results. The data elements include type of surgery (lumpectomy, therapeutic mastectomy, contralateral prophylactic mastectomy), type of radiation therapy (none, IORT, APBI, whole breast RT) and endocrine therapy (yes, no). The main measure will be percent of cases in which treatment recommendations are changed after the test results become available.
Secondary Outcome Measures	Function of Demographic Factors [Time Frame: 5 years] Percent of patients for which the recommended treatments change after DCISionRT results are known as a function of demographic factors (age groups <40, 40-50 and >50; ethnicity; family history) Function of Tumor Factors [Time Frame: 5 years] Percent of patients for which the recommended treatments change after DCISionRT results are known as a function of tumor factors (tumor size, grade, architecture, necrosis, palpability, surgical margins, hormone receptor status).
Other Pre-specified Outcome Measures	Distribution of DCISionRT scores across the cohort [Time Frame: 5 years] Each patient will receive the following results from the DCISionRT test: Risk Score (0 - 10.0), Risk Category Low (<=3.0) or Elevated (>3.0), Risk Prognosis with Breast Conserving Therapy Alone (0 - 40%) and Risk Prognosis with Breast Conserving Therapy and Radiation (0 - 40%). Function of Geographic Region [Time Frame: 5 years] Percent of patients for which the recommended treatments change after DCISionRT results are known as a function of the geographic region of the investigator.
Status	Recruiting
Enrollment Target	1500
Start Date	July 2, 2021
Est. Completion	May 2034 (Final data collection date for primary outcome measure)
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Responsible Party	PreludeDx
Study Sponsor	PreludeDx
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Publications	Bremer T, et. al, Clin Cancer Res 2018 Dec 1;24(23):5895-5901; PMID: 30054280 Weinmann, et. al, Clin Cancer Res 2020 Aug 1;26(15):4054-4063; PMID: 32341032 Shah C, et. al, Ann Surg Oncol. 2021 Oct;28(11):5974-5984; PMID: 33821346

Figure 1. Clinical Sites (n=50)

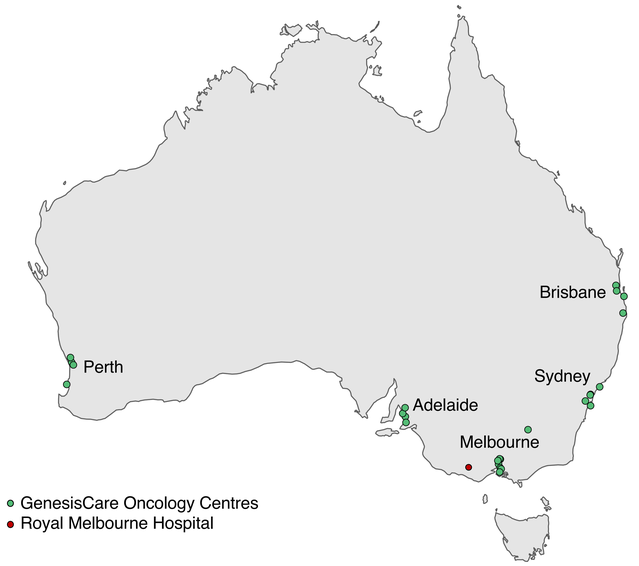
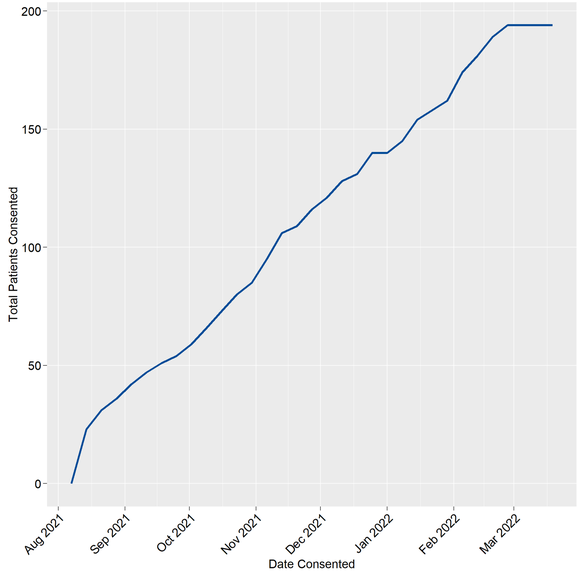


Figure 2. Patients on Study



All Patients Consented	Patients
Screening Failure	9
Withdrawn	2
On Study	197
Total Consented	**208**

Current Sites Registered	Sites
Academic Cancer Centers	1
Regional Hospitals	0
Specialty Private Practices	49
All Sites	**50**

Physician Participation	Physicians
Surgeons	85
Radiation Oncologists	49
Medical Oncologists	0
All Investigators	**134**

Summary

- The AUS PREDICT Study has consented 194 women.
- There are 50 sites currently enrolling and additional sites are pending activation.
- The goal is to activate up to 100 sites and consent 1,500 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.