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

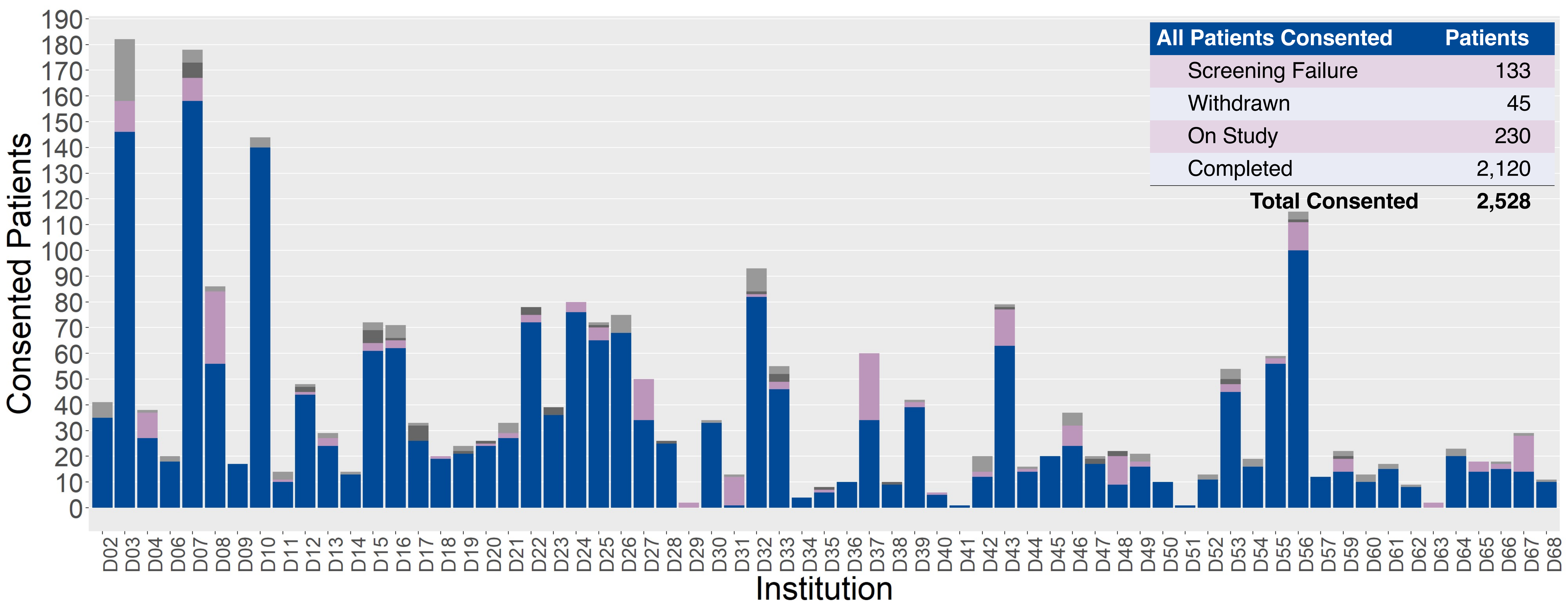
SC Shivers[1], P Whitworth[2], R Patel[3], T Bremer[1], CE Cox[4]

[1]PreludeDx, Laguna Hills, CA, [2]Nashville Breast Center, Nashville, TN, [3]Good Samaritan Cancer Center, Los Gatos, CA, [4]University of South Florida, Tampa, FL, USA

Protocol Synopsis	
NCT Number	NCT03448926
Brief Title	The PREDICT Registry
Official Title	A Prospective Registry Study to 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	Prospective Observational Cohort [Patient Registry]
Intervention	Diagnostic Test: DCISionRT - The DCISionRT Test was developed by PreludeDx (Laguna Hills, CA) 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: • 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 have the DCISionRT Test ordered during routine patient care • Patient must be planning to undergo breast conserving surgery • Patient must be eligible to receive radiation and/or systemic treatment • Patient must be greater than 25 years old • Patient must have been diagnosed with DCIS within 120 days of consent • 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 evidence of invasive breast cancer, including microinvasion, lymph node involvement, or Paget's disease of the nipple or suspicious mammogram findings in the lymph nodes or contralateral breast • Patient has been surgically treated with a mastectomy for primary DCIS • Patient has prior in situ or invasive breast cancer • Patient is pregnant

Protocol Synopsis, continued	
Study Groups/ Cohorts	Female patients with DCIS, 25 years and older. 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 w/ Changes in Treatment Recommendation [Time: 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	2500
Start Date	February 27, 2018
Est. Completion	February 2022 (Final data collection date for primary outcome measure)
Contacts	Steven C Shivers, PhD 813-215-1749 sshivers@usf.edu
Responsible Party	University of South Florida
Study Sponsor	PreludeDx
Lead Investigators	Charles E Cox, MD — University of South Florida — Tampa, FL Rakesh R Patel, MD — Good Samaritan Hospital — Los Gatos, CA Pat Whitworth, MD — Nashville Breast Center — Nashville, TN
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 Wärnberg F, et al., Cancers (Basel). 2021 Dec 3;13(23):6103; PMID: 34885211

Figure 1. Patients Enrolled by Institution.

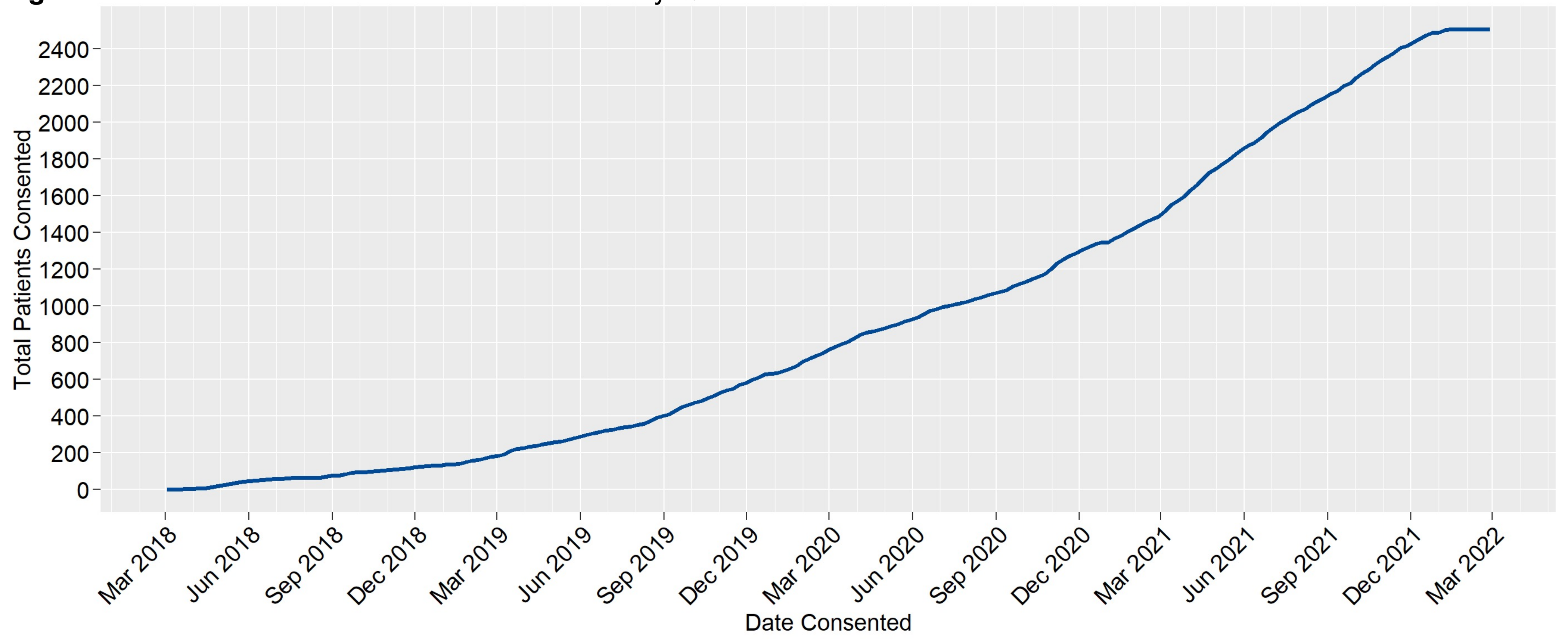

Screening Failure
Withdrawn
On Study
Completed
Consented Patients
Institution

All Patients Consented	Patients
Screening Failure	133
Withdrawn	45
On Study	230
Completed	2,120
Total Consented	**2,528**

Current Sites Registered	Sites
Academic Cancer Centers	21
Regional Hospitals	35
Specialty Private Practices	11
	67

Physician Participation	Physicians
Surgeons	147
Radiation Oncologists	218
Medical Oncologists	33
	398

Figure 2. Cumulative Number of Patients Enrolled by Quarter


Total Patients Consented
Date Consented

Summary

- Phase I of the PREDICT Study consented 2,528 women from 67 sites and 398 physicians.
- Phase II of the registry is planning to reopen soon and enroll up to 1,500 additional women.
- The purpose of the study is to evaluate the percent of cases in which treatment recommendations are changed after the test results become available.
- A similar DCISionRT PREDICT registry has opened in Australia and others are planning to open soon in Europe.

Copies of this poster obtained through Quick Response (QR) Code are for personal use only and may not be reproduced without permission from the author of this poster.

Copyright 2022 I PreludeDx I 26051 Merit Circle, Suite 103, Laguna Hills, CA 92653 I Corresponding Author: Steve Shivers, PhD sshivers@preludedx.com I For further information about PreludeDx, contact Cory Dunn, cdunn@preludedx.com I Miami Breast Cancer Conference – March 3-6, 2022