A Prospective, multicenter REgistry to observe the treatment patterns, clinicaL oUtcomes, and Decision-making in patients with early breast cancer eligible for Endopredict® testing (PRELUDE)

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BACKROUND

The luminal subtype of breast cancer (Luminal BC), characterized by hormone receptor positivity and HER2 negativity, encompasses a variety of phenotypes with heterogeneous biological behavior and prognosis, requiring distinct treatment approaches. EndoPredict® test enables a more precise distinction between patients with Luminal BC with a variable risk of recurrence, thereby guiding individualized decision-making regarding the need for adjuvant chemotherapy, therefore optimizing treatment selection.

The establishment of a prospective registry provides a unique opportunity to comprehensively collect, evaluate, and analyze real-world data on Luminal BC patients. The main advantage of collecting real-world data is that they reflect real-world patient populations including diverse demographics and comorbidities making the findings more applicable to everyday clinical practice.

The biological heterogeneity of breast cancer, its diverse clinical behavior among distinct patient subgroups, and the expanding availability of novel therapeutic strategies and agents add considerable complexity to real-world clinical practice. Thus, this study allows for the generation of contemporary evidence that aligns with evolving standards of care and addresses existing knowledge gaps.

STUDY AIM

The **PRELUDE** registry aims to provide prospective, real-world evidence on how genomic profiling aligns with clinicopathologic parameters and influences adjuvant treatment decisions and long-term outcomes in patients with Luminal BC.

STUDY DESIGN (NCT07389408)

Prospective multicenter investigator-initiated registry

Target accrual: Up to 2,000 participants

Study duration: 3 years (enrollment) + 10 years (follow-up)

FPFV: April 01, 2025

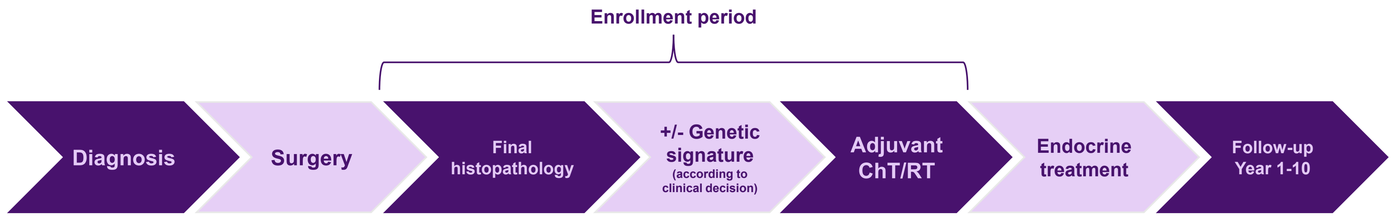

Figure 1. PRELUDE study flow chart

KEY ELIGIBILITY CRITERIA

Inclusion criteria

- Age ≥ 18 years old
- Histological diagnosis of invasive breast cancer
- T1-T3 tumor size
- 0-3 positive axillary lymph nodes
- Documented ER-positive tumor by immunohistochemistry
- Documented HER2-negative tumor by immunohistochemistry and/or in situ hybridization
- Subject with signed and dated informed consent form

Exclusion criteria

- History of another primary malignancy within the last 5 years, except for resected non-melanoma skin cancer
- Pre-operative chemotherapy administered
- Subject without signed and dated informed consent form

CURRENT STATUS

Current accrual (Feb 2026): 281 participants

Open study sites: 13 sites in Greece

Additional international and Greek sites are planned to be activated.

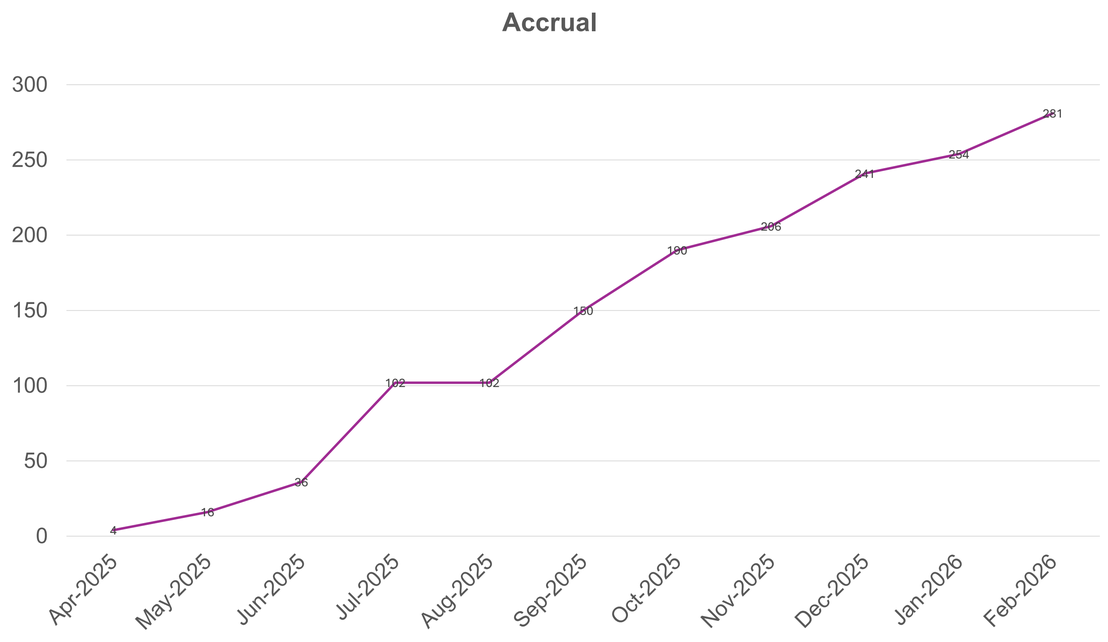

Figure 2. Cumulative recruitment over time (by enrolment date).

STUDY OUTCOMES

Primary outcomes

- Distant relapse free survival (DFRS) at 5- and 10-years
- Overall Survival (OS) at 5- and 10-years
- Distant relapse free interval (DRFI) at 5- and 10-years
- Proportion of adjuvant chemotherapy administration and association with baseline clinicopathologic characteristics and EPclin score

Secondary outcomes

- Concordance between EPclin-based risk stratification and traditional clinicopathological tools
- Outcomes in discordant cases
- Estimate the performance of EndoPredict® in specific patient subgroups
- Identify subgroups with a very low likelihood of sentinel node biopsy positivity
- Evaluate the association between tumor focality and the EP and EPclin scores
- Capture real-world treatment patterns

For more information, please visit https://prelude-study.gr/