



A novel assay predicting disease recurrence in HR+/HER2- breast cancer

Introduction

Hormone receptor-positive, human epidermal growth factor 2-negative (HR+/HER2-) breast cancer represents the most common breast cancer subtype (~70% of all breast cancer diagnoses).

Despite showing better cancer-related outcomes compared to other subtypes, ~15% of patients with HR+/HER2- breast cancer suffer from disease recurrence.

Medical Need

The identification of patients with HR+/HER2- **breast cancer at low clinical risk/high genomic risk of recurrence** has represented the cornerstone for treatment modulation in the adjuvant therapeutic space. Novel compounds, such as cyclin-dependent kinase 4 and 6 inhibitors (CDK4/6i), have recently expanded the therapeutic options for patients considered at high-clinical risk of relapse. Still, no tool has shown clinical utility to detect patients at low-medium clinical risk which might benefit from escalated adjuvant regimens.

Solution

ER-Predict is a novel **multigene signature** designed to **identify HR+/HER- breast cancer patients at high genomic risk of recurrence**, providing a powerful tool for precise clinical decision-making.

ER-Predict effectively calculates a risk score by combining the determination of:

- the expression level of a gene signature,
- the tumor size of the primary tumor,
- the nodal status,
- the tumor grade

Advantages

- **Prognostic tool** allowing better management of HR+/HER2- breast cancer patients thanks to **recurrence risk stratification**
- **Outperformed multigene panels currently approved** in early-stage HR+/HER2- breast cancer
- First tool specifically designed for **therapeutic escalation** purposes
- Developed on a large cohort of 1413 HR+/HER2- early breast cancer with extended follow up; external validation was performed across eight publicly available cohorts (n=1118)

Opportunity

Istituto Europeo di Oncologia is seeking **investors** interested in supporting the development of ER-Predict signature for clinical applications.

Main Inventors



Prof. Giuseppe Curigliano, MD, PhD

Vice Scientific Director and Chair of the Division of Early Drug Development at Istituto Europeo di Oncologia, he is the President of ESMO and Full Professor of Medical Oncology at the Università degli Studi di Milano.



Dr. Yinxiu Zhan, PhD

Data Scientist specialized in multi-omics and imaging data integration and interpretation; he is Head of Data Science Unit at Istituto Europeo di Oncologia and Tenure Track Researcher at Università degli Studi di Milano.



Dr. Luca Boscolo Bielo, MD

Fellow at the Division of Early Drug Development at the Istituto Europeo di Oncologia and Università degli Studi di Milano. Clinical Research Fellow at Memorial Sloan Kettering Cancer Center

IP asset: patent application EP26161281.6; co-owned by IEO and University of Milan

Relevant publications: A machine learning assay to predict disease recurrence in hormone receptor-positive breast cancer; ESMO Open, Volume 0, Issue 0, 106064