The FLEX real-world data platform explores new gene expression profiles and investigator-initiated protocols in early-stage breast cancer.

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CLINICAL VALIDITY

BACKGROUND

The ability of genomic signatures to provide prognostic information such as tumor metastatic potential, beyond clinicopathologic factors has transformed personalized treatment of early breast cancer. Combined with comprehensive clinical information, whole genome expression data can accurately stratify tumors into clinically actionable molecular subtypes. The FLEX Study aims to aggregate a large, real-world dataset, which will enable the discovery of novel genomic profiles to improve precision in the management of breast cancer, particularly in patient subsets underrepresented in traditional clinical trials.

The FLEX enrollment goal is a minimum of 30,000 patients; since April 2017, more than 8,600 patients were enrolled at more than 90 sites, including nine National Cancer Institute-designated comprehensive cancer centers. Participating sites also include community hospitals to ensure inclusion of diverse populations, particularly patient populations that are underrepresented in traditional clinical trials. To date, 38 investigator-initiated sub-studies have been approved, resulting in 23 published abstracts at national congresses. Sub-study research categories include: Breast Cancer and age, Optimization of Therapeutic Strategies, Breast Cancer tumor types, Biomarker advancements and Quality of care.

FLEX ENROLLMENT AT A GLANCE

- Number of Patients: ~1500 premenopausal
- Critical to understand the biologic basis for worse outcomes in young women with EBC

MammaPrint Risk of recurrence

- Distribution of extreme MP risk groups in FLEX
  - ~1100 patients at ultra low risk (MP score 0.355 to +1.0)
  - >1200 patients at MP risk High 2 (MP score -0.57 to -1.0)

Menopausal status

- >200 ER+ Basal patients in FLEX
- Subset of patients with worse clinical outcomes than those with ER+ Luminal B tumors

SELECTED RESEARCH CATEGORIES

- NEO-ADJUVANT TREATMENT
- OPTIMIZING TREATMENT
- BREAST CANCER & AGE
- CANCER DISPARITIES

FLEX STUDY NETWORK

- >8,000 FLEX PATIENTS
- >90 STUDY SITES ENROLLING
- >250 PHYSICIANSTOKING TREATMENT
- MICRO-ADJUVANT SUBTYPES
- IMMUNOTHERAPY
- BIOMARKER

Clinical Grade

- Genomic risk is independent of standard clinical pathological factors
  - ~430 patients with MP high risk in Grade 1 group
  - ~115 patients with MP low risk in Grade 3 group

Key Statistics

- >90
- >250
- >8,000