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

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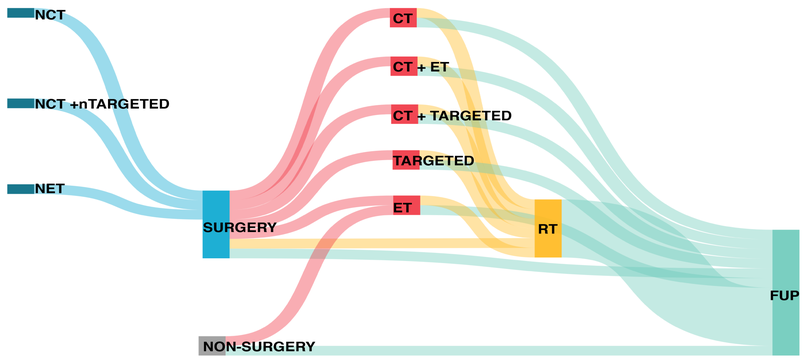
BACKGROUND

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

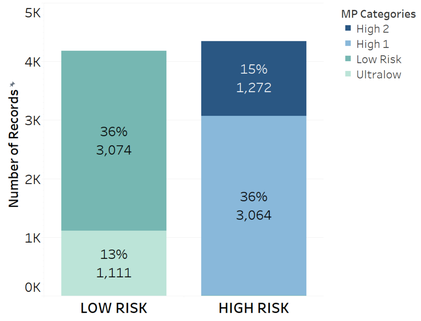
To date, 38 investigator-initiated sub-studies have been approved, resulting in 23 published abstracts at national congresses. Sub-study research categories include: Breast Cancer and age, Optimization of Therapeutic Strategies, Breast Cancer tumor types, Biomarker advancements and Quality of care.

CLINICAL VALIDITY



FLEX ENROLLMENT AT A GLANCE

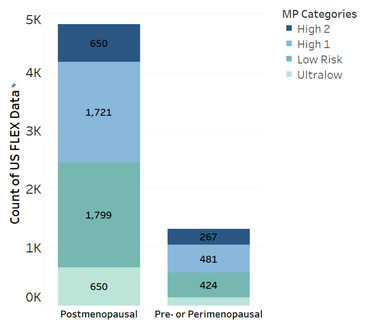
MammaPrint Risk of recurrence



Distribution of extreme MP risk groups in FLEX

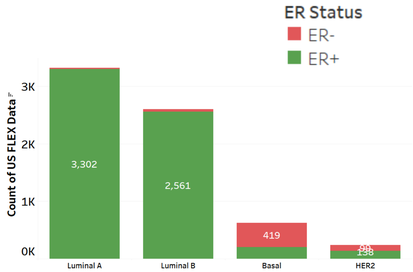
- ~1100 patients at ultra low risk (MP score 0.355 to +1.0)
- >1200 patients at MP risk High 2 (MP score -0.57 to -1.0)

Menopausal status



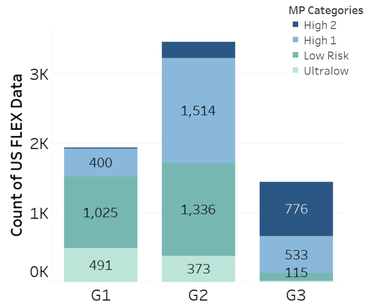
- ~1500 patients premenopausal
- Critical to understand the biologic basis for worse outcomes in young women with EBC

BluePrint + ER IHC subtype



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

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

FLEX STUDY NETWORK

KEY STATISTICS

- > 90 STUDY SITES 9 NCIs
- > 250 ENROLLING PHYSICIANS
- > 8,600 FLEX PATIENTS
- > 800 CLINICAL DATA POINTS
- 38 IN PROGRESS SUBSTUDIES

SELECTED RESEARCH CATEGORIES