The FLEX Real World Data Platform Explores New Gene Expression Profiles and Investigator-Initiated Protocols in Early Stage Breast Cancer

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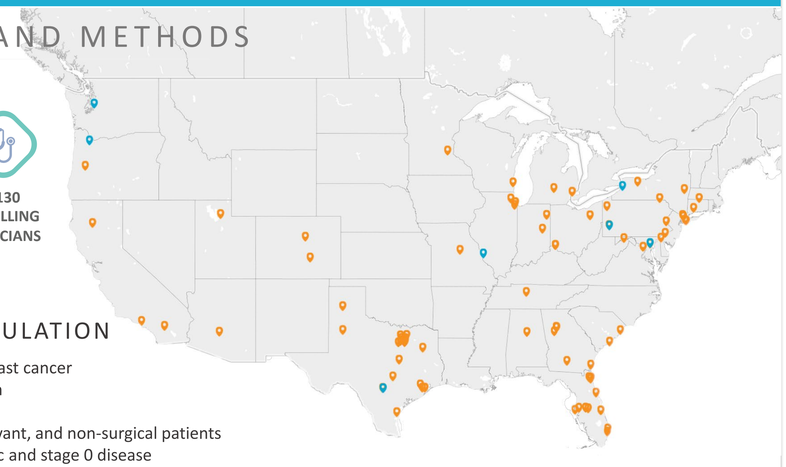
BACKGROUND

Genomic signatures have revolutionized the identification and treatment of breast cancers (BC). However, the stratification of breast cancers into actionable subtypes has been limited by the difficulty in aggregating large clinical data sets. The FLEX Registry was designed to operate as a multicenter, large-scale, prospective study that integrates full genome expression data with clinical data to investigate new gene signatures with prognostic and/or predictive value in a real-world setting. The study will enroll a minimum of 10,000 patients aged ≥18 years with histologically proven invasive stage I, II or III breast cancer who sign informed consent and receive MammaPrint (MP) with or without BluePrint (BP).

DESIGN AND METHODS



> 85 STUDY SITES Including 7 NCIs

> 130 ENROLLING PHYSICIANS

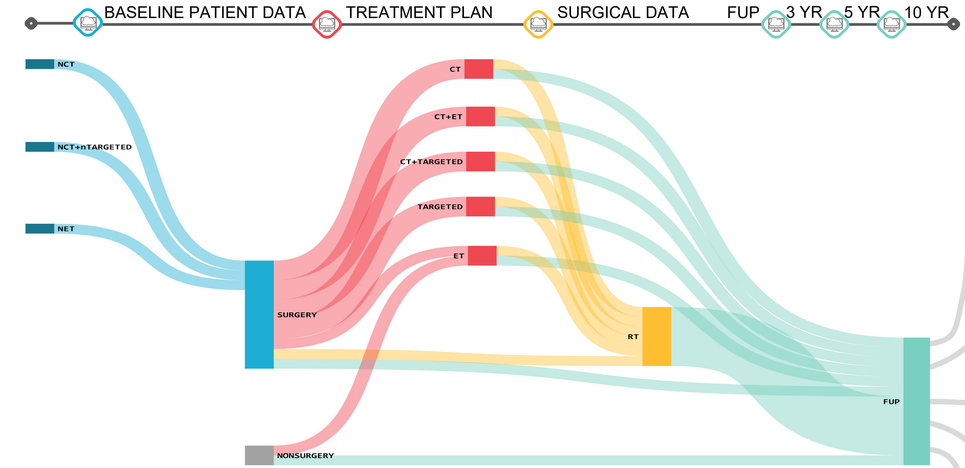
PATIENT POPULATION

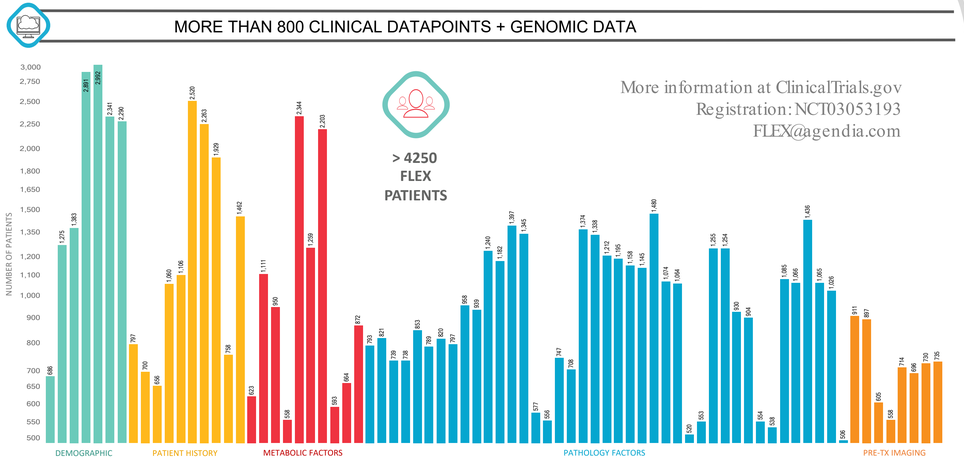
- Stage I, II, or III breast cancer
- New primary lesion
- Male or female
- Adjuvant, neoadjuvant, and non-surgical patients
- Excludes metastatic and stage 0 disease

ADAPTABLE AND COLLABORATIVE DATA PLATFORM

FLEX is intended to enable additional study arms at low incremental effort and cost through the addition of targeted substudies as appendices after the initial study is opened. Patients who are enrolled in the initial study are eligible for inclusion in any additional study arm for which they meet all criteria. Substudy analyses and protocols are added as appendices to the master protocol. Any participating FLEX investigator may submit his/her own substudy proposal(s), which will be reviewed for approval by the FLEX Scientific Review Committee. FLEX encourages investigator collaboration across the FLEX network for substudy proposals, data analysis, and publications. To date, 19 substudies have been approved and are under development.

STATUS UPDATE & APPROVED SUBSTUDIES





More information at ClinicalTrials.gov
Registration: NCT03053193
FLEX@agendia.com

APPROVED SUBSTUDIES

BIOMARKER- AND PATHWAY-SPECIFIC

- MP and BP in relation to clinical progesterone receptor positivity (Crozier, MD)
- MP and BP in relation to clinical Ki67 score (Crozier, MD)
- Correlation of the microbiome with BC gene expression (Habibi, MD)

DISPARITY / UNIQUE TUMOR SUBTYPES

- MP and BP evaluation in Invasive Lobular Carcinoma (Crozier, MD)
- MP and BP in male breast cancer (Crozier, MD)
- Diagnosis and treatment disparity in African American BC patients
- Gene expression in tumors from BC patients with obesity (Habibi, MD)
- MP and BP evaluation in BC patients over 70 years of age (Crozier, MD)
- MP and BP in metaplastic BC (Crozier, MD)
- Deciphering the inferior prognosis of young women with early stage ER+ BC with full genome expression analysis
- Basal subtype and clinical estrogen receptor status of BP basal tumors across different ethnicities (V. Kaklamani, MD)

DIAGNOSTIC

- Stratifying MP High Risk BC patients based on expression of genes at 8q22-24 (O'Shaughnessy, MD)
- Distinct molecular profiles of interval BC and screen-detected tumors (Wilks, MD)
- Gene expression profiling of BC in patients with family and/or personal history of breast cancer and with or without BRCA mutation

THERAPY

- Response to standard chemotherapy regimens in clinically triple positive (ER+/PR+/HER2+) patients according to BP molecular subtypes (Brufsky, MD)
- Expression signatures by response to bisphosphonates in ER+ patients receiving adjuvant therapy (SOC option), or for osteoporosis after primary treatment (Brufsky, MD)
- Comprehensive gene expression profiling of BC in patients receiving short-course endocrine therapy prior to surgery (Habibi, MD)
- Genomic reclassification of large tumors in patients eligible to receive neoadjuvant therapy (Whitworth, MD)

QUALITY OF CARE

- Impact of genomic risk classification on travel time to receive breast cancer care: a QOC study (Grady, MD)