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

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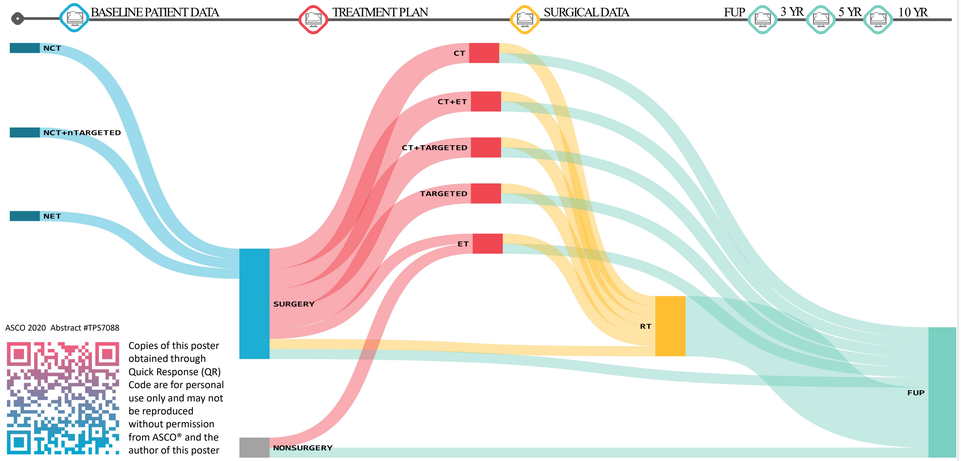
BACKGROUND

Genomic expression profiles have enabled the classification of breast cancers into molecular subtypes and provide prognostic information about the metastatic potential of the tumor, both of which have implications for the personalized treatment of breast cancer beyond clinical and pathological features. However, to precisely stratify tumors into actionable subgroups, full genome expression data should be combined with comprehensive clinical information. The FLEX Registry aims to aggregate a large, real-world dataset, which will enable discovery of novel genomic profiles, particularly for patient subsets that are poorly represented in traditional clinical trials and will contribute to improved precision in the management of breast cancer.

FLEX will enroll a minimum of 10,000 patients aged ≥18 years with histologically proven invasive stage I-III breast cancer. The study is a multicenter, prospective, population-based, observational trial. All patients who receive MammaPrint (70 gene signature risk of recurrence score), with or without the BluePrint (80 gene signature molecular subtype) on a primary breast tumor are eligible for enrollment. The study's primary aim is to create a large scale, population-based registry of full genome expression data matched with clinical data to investigate new gene associations with prognostic and/or predictive value in a real-world setting. Secondary objectives include utilizing the shared study infrastructure to examine and generate hypotheses for targeted subset analyses and substudies based on full genome expression data. Any participating FLEX investigator has the opportunity to submit their own substudy proposal to their peers on the FLEX Steering Committee. To date, 16 substudies have already been identified and approved.

CLINICAL VALIDITY



ASCO 2020 Abstract #TPS7088

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ACTIONABLE DATA

14	45	20
ABSTRACT & POSTER PRESENTATIONS	SUBMITTED SUBSTUDIES	IN PROGRESS SUBSTUDIES

NEOADJUVANT THERAPY & SURGERY

- Comprehensive gene expression profiling of breast cancer in patients receiving short-course endocrine therapy prior to surgery
- Evaluation of MammaPrint, BluePrint, & full genome data pre- and post-neoadjuvant therapy

GENOMICS & BREAST CANCER SUBTYPES

- Molecular profiles & treatment recommendations for invasive lobular carcinoma in a real-world prospective breast cancer registry **(ASCO 2020)**
- MammaPrint & BluePrint in male breast cancer
- Evaluation of MammaPrint & BluePrint in metaplastic breast cancer
- High Risk breast cancer genes at 8q22-24 and their role in over 5000 patients evaluated with MammaPrint risk of recurrence assay **(ASCO 2020)**
- Gene expression profile and clinical implications of lymphovascular invasion in early stage breast cancer

ctDNA & LIQUID BIOPSY

- Monitoring residual disease and predicting treatment response with ctDNA analysis

OPTIMIZING THERAPY STRATEGIES

- BluePrint reclassification of HER2+ by IHC tumors **(ASCO 2020)**
- Correlation of the microbiome with breast cancer gene expression
- Response to standard chemotherapy regimens in clinically triple positive (ER+/PR+/HER2+) patients according to BluePrint molecular subtypes
- MammaPrint & BluePrint in relation to clinical progesterone receptor positivity
- MammaPrint & BluePrint in relation to clinical Ki67 score

AGE & BREAST CANCER

- MammaPrint & BluePrint evaluation in breast cancer patients over age 70
- Deciphering the inferior prognosis of young women with early stage estrogen receptor positive breast cancer (ER+ EBC) with full genome expression analysis

SOCIAL & ANCESTRY

- Stability of MammaPrint, BluePrint, and normalization genes across ethnicities
- DEG in breast cancer patients with a family and/or personal history of breast cancer and those with sporadic breast cancer
- Distinct molecular profiles of interval and screen-detected tumors in a real-world breast cancer registry **(ASCO 2020)**
- Ethnic disparity of BluePrint Basal Tumor subtypes **(SABCS 2019)**
- Racial disparities in breast cancer: identifying predisposing clinical and molecular features associated with African American patients **(SABCS 2019)**

PATIENT POPULATION

ELIGIBILITY

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

KEY STATISTICS

>85	>200	>4700
STUDY SITES **7 NCI Institutions**	ENROLLING PHYSICIANS	FLEX PATIENTS

More information at ClinicalTrials.gov
Registration: NCT03053193
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MORE THAN 800 CLINICAL DATAPOINTS + FULL GENOMIC DATA