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

Laura Lee[1], Sami Diab[2], Julie Barone[3], Jennifer A. Crozier[4], Margret Chen[5,6], Rakshanda Layeequr Rahman[7], Robert Maganini[8], Douglas Marks[9], Amy M. Truitt[10], Lisa Blumencranz[10], Erin Yoder[10], William Audeh[10], Bastiaan van der Baan[10], FLEX Investigators Group

1. Comprehensive Cancer Center, Palm Springs, CA; 2. Rocky Mountain Cancer Center-Aurora, US Oncology, Aurora, CO; 3. Vail Health Comprehensive Breast Care, Shaw Cancer Center, Edwards, CO; 4. Baptist MD Anderson Cancer Center, Jacksonville, FL; 5. Columbia University Medical Center, New York, NY; 6. ProHealth Care , Optum, UnitedHealth Group, Lake Success, NY; 7. Texas Tech University Health Sciences Center, Breast Center of Excellence, Amarillo, TX; 8. AMITA Health, Saint Alexis Medical Center, Barlett, IL; 9. Perlmutter Cancer Center, NYU Langone Health, New York, NY; 10. Agendia Inc, Irvine, CA

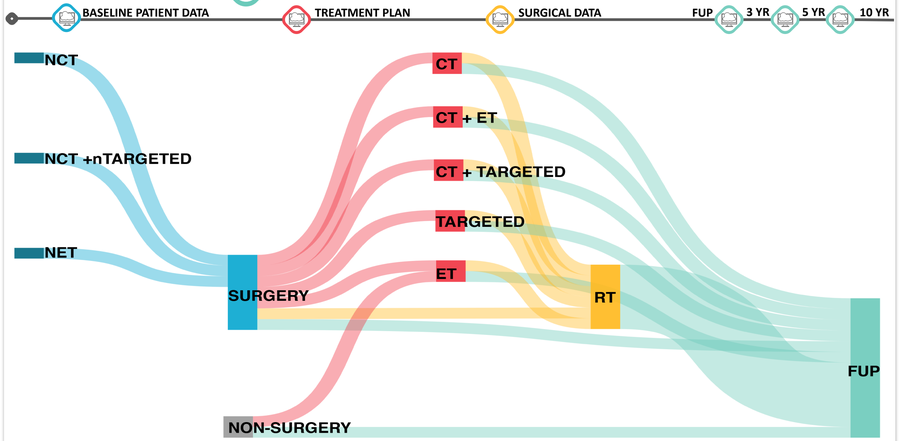
San Antonio Breast Cancer Symposium® - December 8-11, 2020 Poster #OT12-01

BACKGROUND

Genomic expression profiles have implications for the personalized treatment of breast cancer beyond clinical and pathological features by enabling the classification of breast cancers into molecular subtypes and providing prognostic and predictive information about the metastatic potential of tumors and likely response to therapy. However, full genome expression data can now be combined with comprehensive clinical information to precisely stratify tumors into clinically actionable subgroups. The FLEX Registry 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 target enrollment of FLEX is a minimum of 10,000 patients; over 6,000 patients have enrolled since April 2017 at more than 85 sites, including eight National Cancer Institute-designated comprehensive cancer centers. The FLEX collaborative platform allows participating investigators the opportunity to author their own sub-study protocols, as approved by the FLEX Review Committee. Sub-study research categories include: Breast Cancer and Age, Optimizing Therapy Strategies, Biomarker Advancement, ctDNA and Liquid Biopsy, Genomics and Transcriptomics, Social and Ancestry, Neoadjuvant Therapy and Surgery, Immunotherapy, Breast Cancer Subtypes. To date, 27 investigator-initiated sub-studies have been approved by the FLEX Scientific Review Committee.

CLINICAL VALIDITY



NETWORK RESEARCH

CATEGORIES
(list of presented studies)
N=#of proposed studies

Optimizing Therapy Strategies (n=19)

- Differential gene expression and clinical utility of MammaPrint and BluePrint in male breast cancer patients (SABCS 2020 #PS14-11)
- BluePrint reclassification of HER2+ by IHC tumors **(ASCO 2020)**

Neoadjuvant Therapy & Surgery (n=5)

- Molecular profiles & treatment recommendations for invasive lobular carcinoma in a real-world prospective breast cancer **registry (ASCO 2020)**
- High Risk breast cancer genes at 8q22-24 and their role in over 5000 patients evaluated with MammaPrint risk of recurrence assay **(ASCO 2020)**

Breast Cancer Subtypes (n=5)

- Using BluePrint to elucidate the molecular heterogeneity of triple negative breast cancers (SABCS 2020 #PS18-05)
- Differential gene expression in Luminal-type invasive lobular carcinoma and invasive ductal carcinoma by MammaPrint risk stratification (SABCS 2020 #PS18-03)

Cancer Disparities: Biological, Genetic, Socioeconomic (n=13)

- Racial disparities within Basal-type breast cancer: clinical and molecular features of African American and Caucasian obese patients (SABCS 2020 #PS7-68)
- Molecular profiles and clinical-pathological features of Asian early-stage breast cancer patients (SABCS 2020 #PS7-69)
- 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 **(ASCO 2020)**
- Racial disparities in breast cancer: identifying predisposing clinical and molecular features associated with African American patients **(SABCS 2019)**

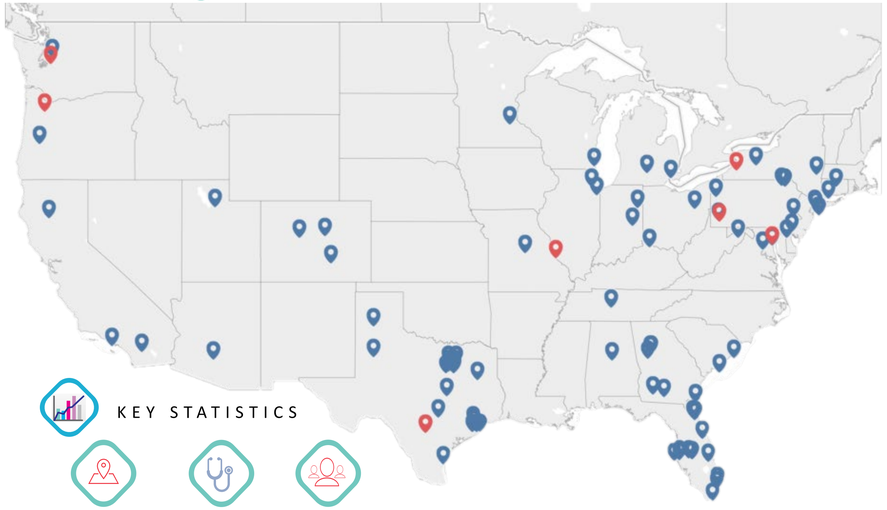
Biomarker Advancements (n=4)

ctDNA/Liquid Biopsy (n=1)

Breast Cancer & Age (n=4)

Immunotherapy (n=3)

INVESTIGATOR NETWORK



KEY STATISTICS

> 85 STUDY SITES
8 NCI-Designated Cancer Centers

> 250 ENROLLING PHYSICIANS

> 6000 FLEX PATIENTS

More information at ClinicalTrials.gov Registration: NCT03053193

PATIENTS

ELIGIBILITY

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

ACTIONABLE DATA

19 ABSTRACT & POSTER PRESENTATIONS

59 PROPOSED SUBSTUDIES

27 IN PROGRESS SUBSTUDIES

> 800 CLINICAL DATA POINTS