FLEX: 30K Full Transcriptome, Real-World Evidence Database for Early-Stage Breast Cancer, and Investigator-Initiated Protocols

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BACKGROUND

- Genomic signatures provide prognostic and predictive information beyond those of clinicopathologic factors.
- The 70-gene MammaPrint test provides valuable information on the risk of distant metastasis while the 80-gene signature BluePrint, assesses the functional molecular subtyping of early-stage breast cancer (ESBC) tumors. Together, they enable significant improvements in personalized treatment plans and optimized management of patients with EBC.
- Development of new signatures, using full transcriptome analysis and building large real-world evidence databases, are pivotal to answer clinically relevant questions that often remain unresolved in smaller trials.

OBJECTIVES

The FLEX Study aims to create :

- **a large scale, population-based registry of full genome expression data and clinical data from 30,000 patients to investigate new signatures of prognostic and/or predictive value.**
- **a shared-registry and research platform infrastructure to generate hypotheses for targeted Investigator-Initiated Studies (IIS).**

METHODS

FLEX Patients Eligibility

- **Inclusion criteria**
  - Newly diagnosed Stage I-III EBC
  - Male or Female
  - Adjuvant, neoadjuvant or non-surgical patients
- **Exclusion criteria**
  - Metastatic breast cancer
  - Recurrent breast cancer
  - In Situ Disease

FLEX Study Design (Figure 1)

- Patients receive MammaPrint and BluePrint testing, as standard of care, using full-genome data collection.
- Treatment will be physician's choice while adhering to NCCN guidelines.
- IIS are proposed, discussed, and peer-reviewed.

ACCRUALS and TRIAL OUTPUTS

- As of May 8, 2023, more than 13,000 patients of the targeted 30,000 are currently enrolled in the FLEX trial (Figure 2).
- 96 sites across the USA, (including 10 NCI sites), 1 site in Canada, and 2 sites in Greece and Israel, are currently enrolling patients in FLEX (Figure 3), representing more than 400 investigators.
- More than 1,000 self reported Black patients are enrolled
- 43 IIS exploring treatment disparities in underrepresented populations, rare tumor subtypes, age, and patient centered specific topics have been initiated, resulting in 30 congress presentations.

FLEX AT A GLANCE

Figure 1: FLEX Study design- Patient groups

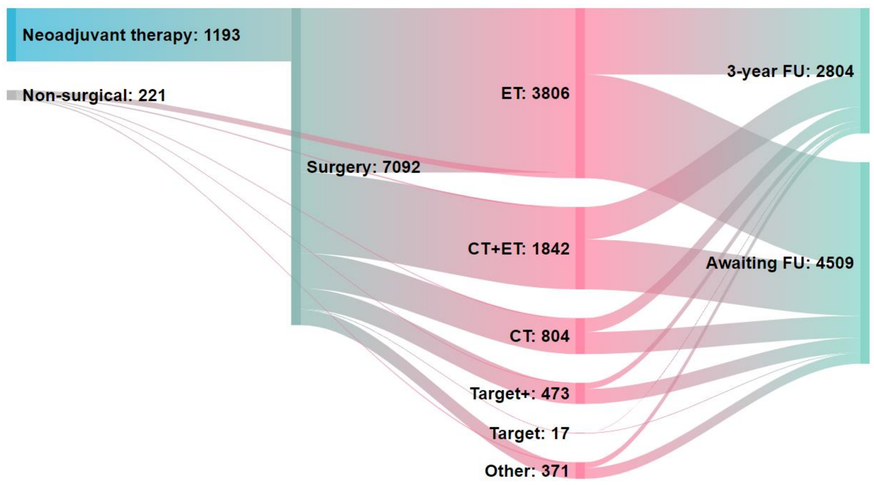
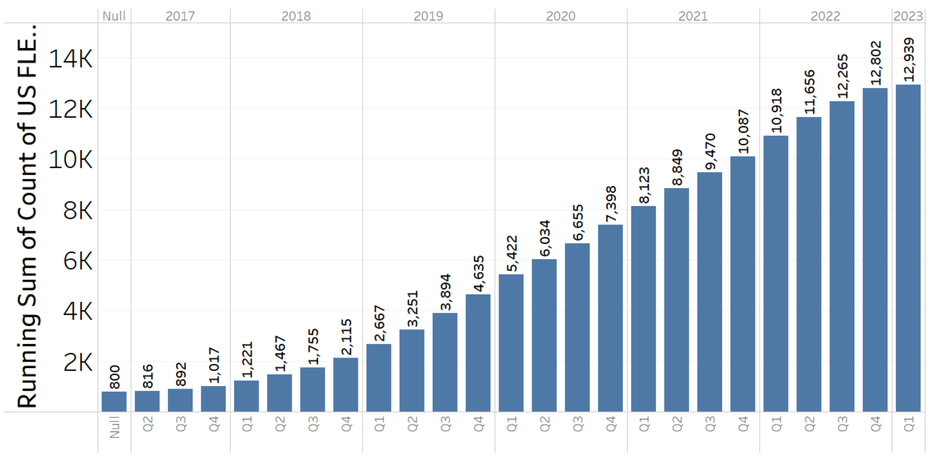


Figure 2: 13,063 patients are enrolled in the FLEX trial (as of May 2023)



Enrollment data shown is reflective of March 2023 data pull

Figure 3: 99 sites in the US, Canada, and EMEA are currently enrolling patients

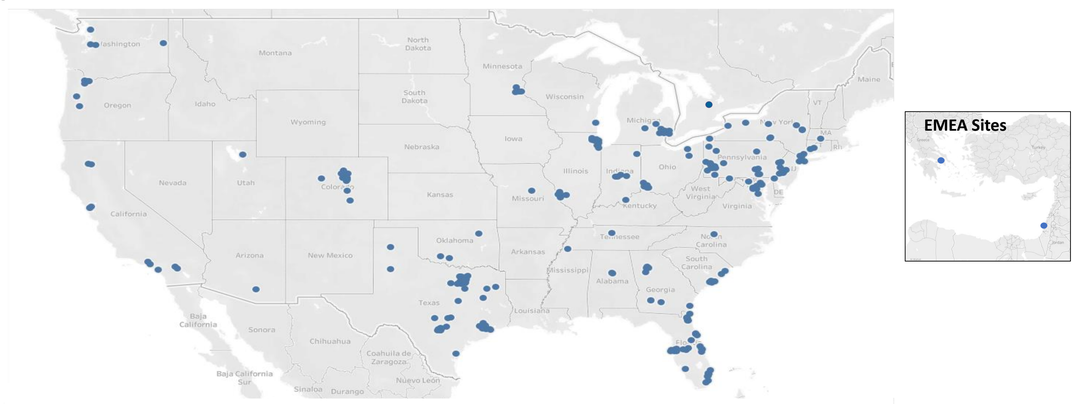
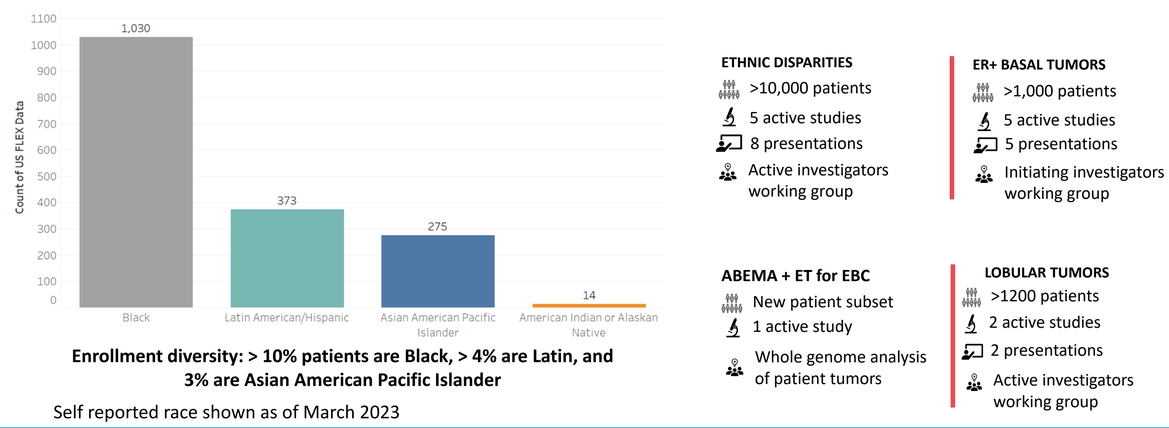


Figure 4: Diversity within FLEX and collaborative research areas



Enrollment diversity: > 10% patients are Black, > 4% are Latin, and 3% are Asian American Pacific Islander

Self reported race shown as of March 2023

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