Clinical Trial in Progress: The FLEX Big Data Platform Explores New Gene Expression Profiles and Investigator-Initiated Protocols in Early Stage Breast Cancer

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BACKGROUND

Genomic signatures are revolutionizing the definition, identification, and treatment of breast cancer. To precisely stratify breast cancers into actionable subgroups, full genome expression data and matching clinical data must be aggregated into a large dataset. Patients participating in FLEX will have a Full Genome Microarray analysis performed along with MammaPrint and BluePrint testing.

The MammaPrint 70 gene signature is a FDA-cleared, multi-gene assay which is analyzed on a single tumor specimen. BluePrint is a molecular subtyping profile that analyses the mRNA levels of 80 genes that best discriminate between three distinctive subtypes of tumors: Basal-type, Luminal-type, and ERBB2 (HER2)-type. In addition, Agendia has also developed the Full Genome Microarray. This microarray analyzes the entire expressed human genome(~25,000 genes)and facilitates the study of additional biomarkers that may be found to be relevant to breast cancer therapy and prognosis.

FLEX is a multicenter, prospective, population-based, observational trial for patients with Stage I, II, and III breast cancer. The FLEX platform encompasses a matched dataset of comprehensive clinical data and full genome expression data. With a goal of 10,000 patients, FLEX is intended to accelerate discovery and power analyses of rare and uncommon patient subsets. The study's primary aim is to identify new gene expression signatures. Secondary aims include generating hypotheses for targeted subset trials and supporting investigator-initiated inquiries. FLEX currently has 62 active sites and 2193 enrolled patients.

PATIENT POPULATION

- 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

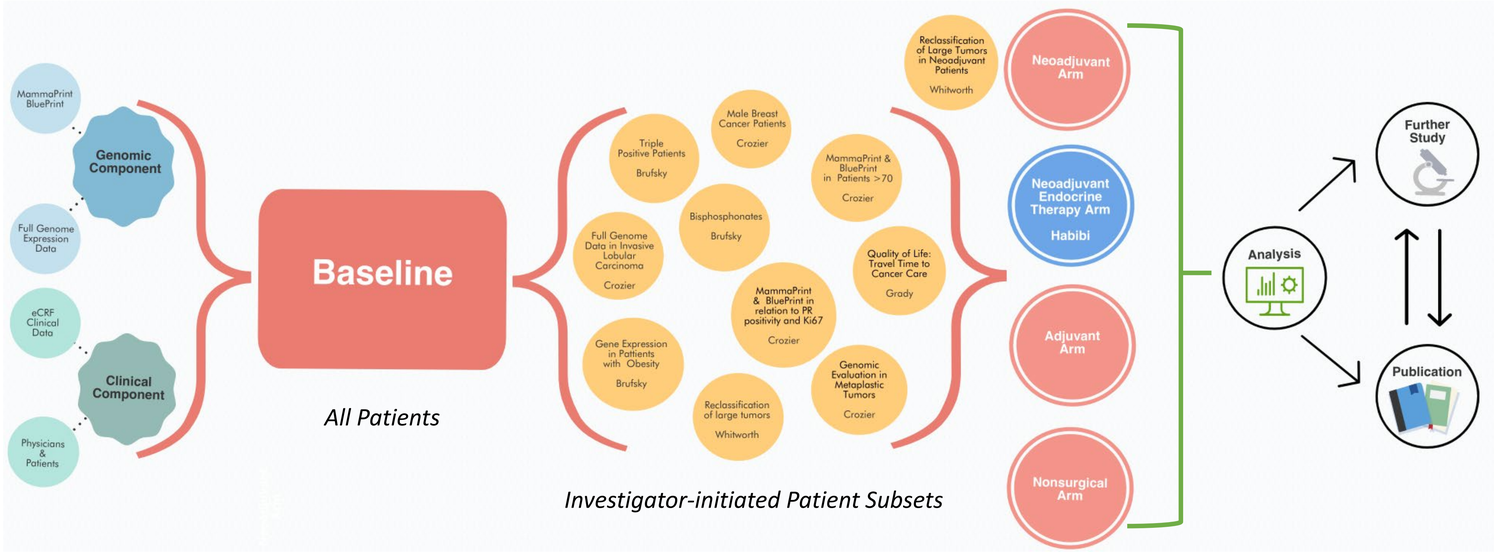
BIG DATA

69 enrolling sites

2,193/10,000 patients

10 years follow-up

STUDY DESIGN



COLLABORATIVE DATA PLATFORM

The FLEX collaborative platform allows participating investigators the opportunity to author their own sub-study protocols, as approved by the FLEX Steering Committee of their peers. 13 sub-studies have already been identified and are under development. All inquiries will utilize the entire curated dataset of full genome data matched with comprehensive clinical data. Additional analyses and protocols are added as appendices to the initial baseline study. Patients enrolled in the initial baseline are also eligible for inclusion in sub-studies where they meet all criteria and additional consent is not required. Additional clinical data will be collected as specified in the appendix protocols. FLEX investigators can enroll into multiple subsets and study arms, as well as collaborate with peers on analyses and publications.

More Information

ClinicalTrials.gov Registration: NCT03053193

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