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

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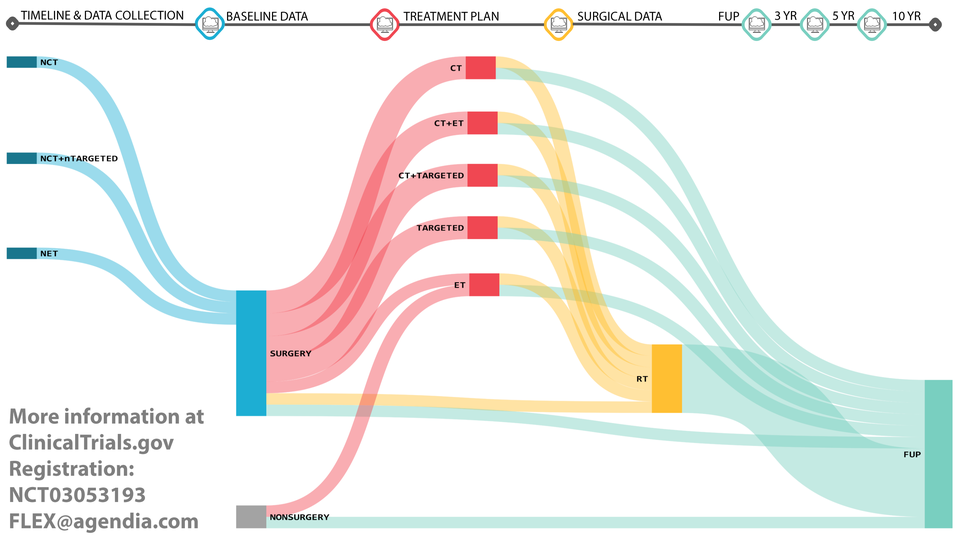
BACKGROUND & ELIGIBILITY

Genomic signatures are revolutionizing the definition, identification, and treatment of breast cancer. To precisely stratify breast cancers into actionable subgroups, full genome (FG) expression data and matching clinical data must be aggregated into a large, real-world dataset. Such a dataset will accelerate research and discovery, especially for smaller patient subsets that are not as widely represented within the current body of literature.

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 (MP), with or without BluePrint (BP) 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, fifteen substudies have already been identified and approved.

DESIGN & METHODS



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

COLLABORATIVE SUBSTUDIES

BAPTIST MD ANDERSON CANCER CENTER, JENNIFER CROZIER, MD
MammaPrint and BluePrint evaluation in breast cancer patients over 70

BAPTIST MD ANDERSON CANCER CENTER, JENNIFER CROZIER, MD
Gene expression, MammaPrint and BluePrint in male breast cancer

NORTH VALLEY BREAST CARE, IAN GRADY, MD
Impact of genomic risk classification on travel time to receive breast cancer care

JOHNS HOPKINS, MEHRAN HABIBI, MD
Comprehensive gene expression profiling of breast cancer in patients receiving short-course endocrine therapy prior to surgery

UNIVERSITY OF PITTBURGH MEDICAL CENTER, ADAM BRUFSKY, MD
Gene expression in breast cancer patients with obesity

JOHNS HOPKINS, MEHRAN HABIBI, MD
Correlation of the microbiome with breast cancer gene expression

UNIVERSITY OF PITTSBURGH MEDICAL CENTER, ADAM BRUFSKY, MD
Expression signature by response to bisphosphonates in ER+ patients receiving adjuvant therapy for osteoporosis after primary treatment for breast cancer

VALLEY BREAST CLINIC, THOMAS LOMIS, MD:
Gene expression profiles for signature discovery in patients participating in ODM201 trial

BAPTIST MD ANDERSON CANCER CENTER, JENNIFER CROZIER, MD
Full genome expression in invasive lobular carcinomas

BAPTIST MD ANDERSON CANCER CENTER, JENNIFER CROZIER, MD
MammaPrint and BluePrint in relation for clinical ki-67 scores

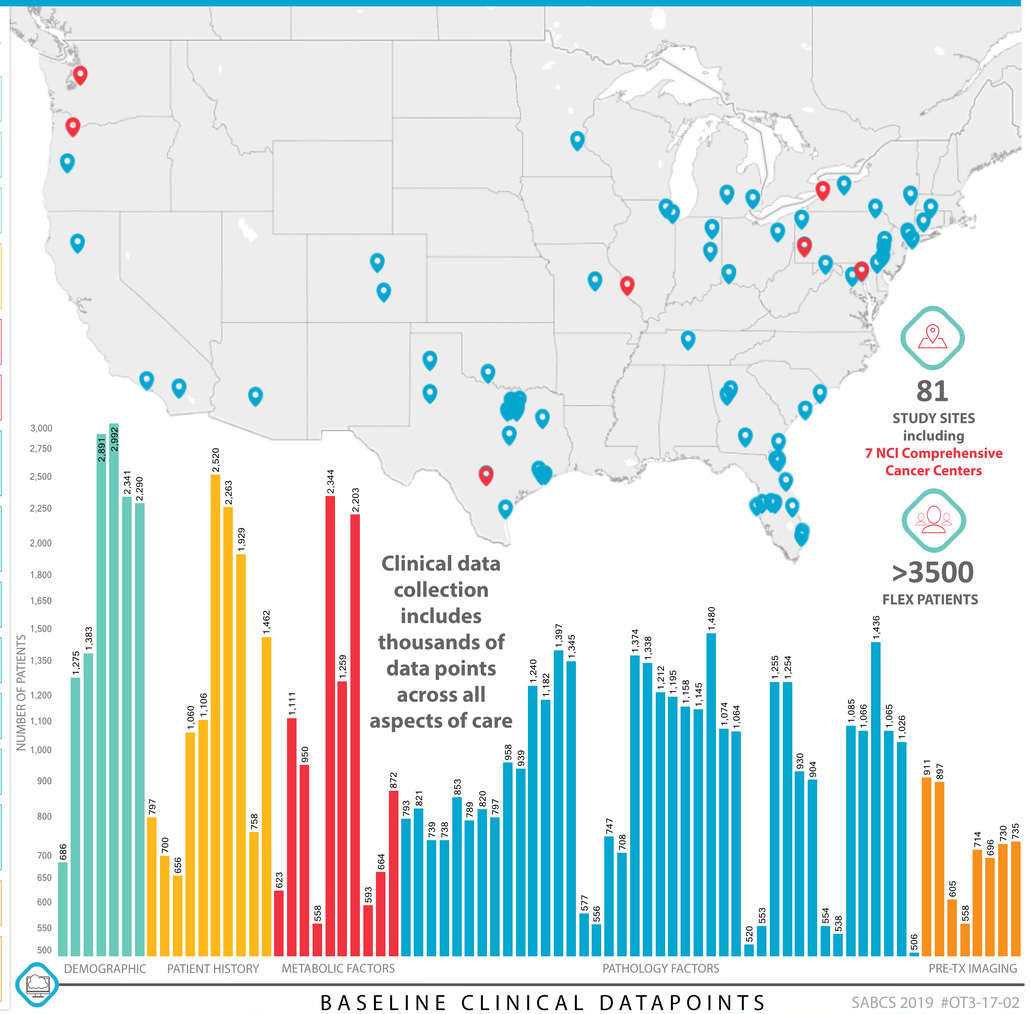
BAPTIST MD ANDERSON CANCER CENTER, JENNIFER CROZIER, MD
MammaPrint and BluePrint in metaplastic breast cancers

BAPTIST MD ANDERSON CANCER CENTER, JENNIFER CROZIER, MD
MammaPrint and BluePrint relation to progesterone receptor positivity by IHC

UNIVERSITY OF PITTBURGH MEDICAL CENTER, ADAM BRUFSKY, MD
Response to standard CT regimens in clinically ER+/PR+/HER2+ (triple positive) patients according to BluePrint molecular subtypes

NASHVILLE BREAST CENTER, PAT WHITWORTH, MD
Genomic reclassification of large tumors in patients eligible to receive NCT

JOHNS HOPKINS, MEHRAN HABIBI, MD
Safety of de-escalated radio-therapy in genomically low-risk breast cancer after breast conserving surgery



BASELINE CLINICAL DATAPOINTS