MammaPrint, BluePrint, and Full-genome Data Linked with Clinical Data to Evaluate New Gene EXpression Profiles (FLEX)

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BACKGROUND, ELIGIBILITY & ACCRUAL

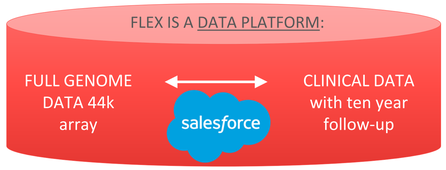
Genomic signatures are revolutionizing the definition, identification, and treatment of breast cancer subtypes. The ability of genomic signatures to enable fine grained stratification of breast cancers to the granular disease level is still generally untested because of the difficulties in aggregating large clinical data sets. In order to stratify breast cancers into actionable subtypes both the full genome data and relevant clinical data must be collected for patients at scale. Traditional one-drug, one-test, one-trial models are slow, arduous, and yield low sample sizes and high objective failures by phase III trials.

The study will enroll a minimum of 10000 patients aged ≥18 years with histologically proven invasive stage I-III breast cancer who signed informed consent. Enrollment began April 2017 and 623 patients have been enrolled as of June 2018.

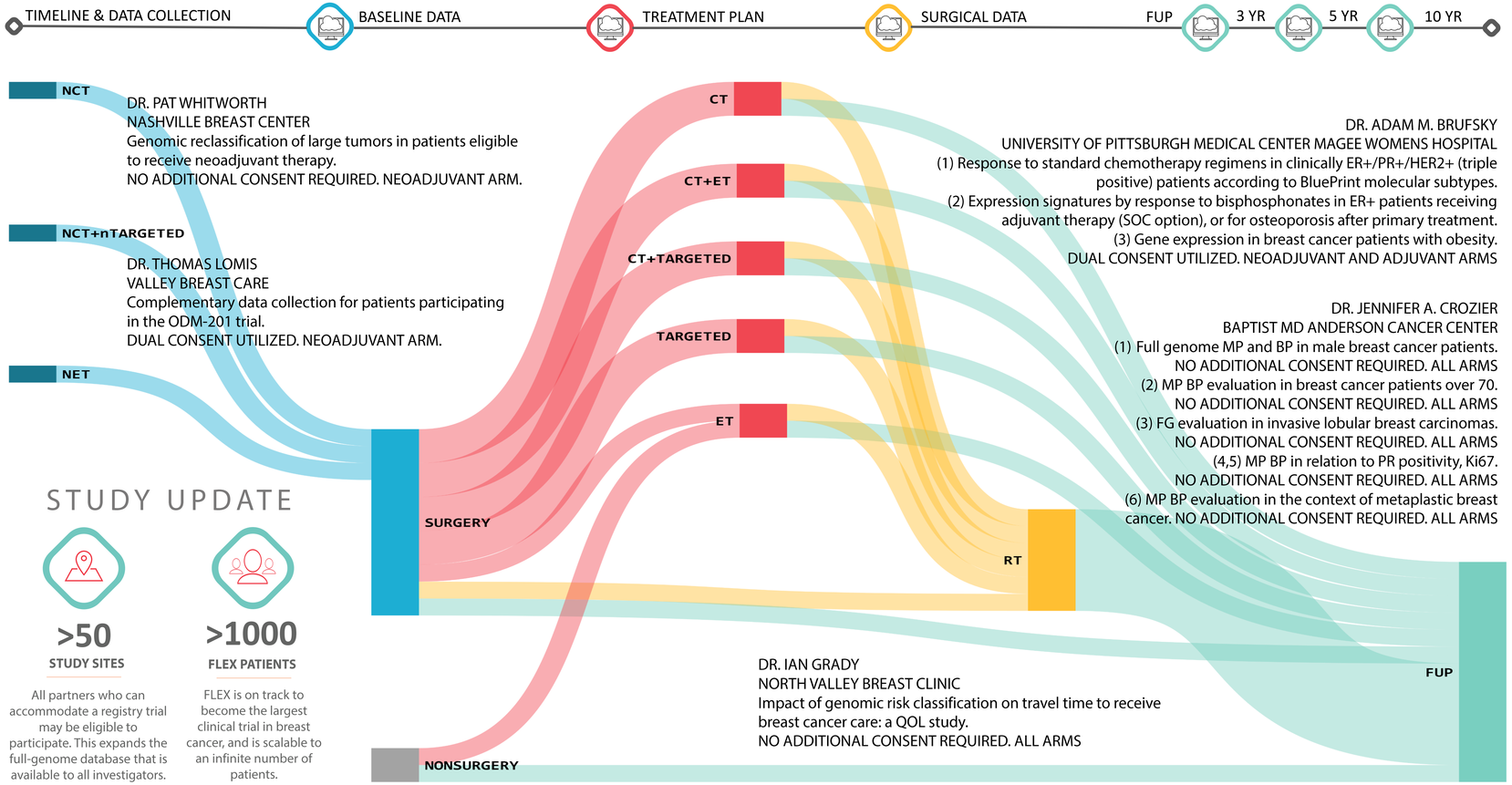
DESIGN & METHODS

FLEX is designed to operate as a novel, large-scale, population based, prospective registry. The adaptable design is intended to enable additional study arms at low incremental effort and cost by allowing targeted substudies to be added after the initial study is opened. Patients who are enrolled in the initial study will also be eligible for inclusion in any additional study arm where they meet all criteria. Additional study arms and substudies may be investigator-initiated, and will be added as appendices to the protocol of the initial, or baseline, study. Clinical data supporting the additional study arms and substudies that a patient is eligible for can be collected, as specified in appendices to the baseline protocol.

FLEX Registry Feedback Cycle



CONCEPT PROPOSALS



STUDY UPDATE

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STUDY SITES

All partners who can accommodate a registry trial may be eligible to participate. This expands the full-genome database that is available to all investigators.

>1000
FLEX PATIENTS

FLEX is on track to become the largest clinical trial in breast cancer, and is scalable to an infinite number of patients.

MORE INFORMATION at ClinicalTrials.gov registration: NCT03053193; FLEX@agendia.com

NCT= neoadjuvant chemotherapy, NET= neoadjuvant endocrine therapy, CT= chemotherapy, ET= endocrine therapy, RT= radiotherapy, FUP= follow-up

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