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 Study 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 FLEX real world data platform explores new gene expression profiles and investigator-initiated protocols in early stage breast cancer. The FLEX Study network includes over 90 sites in the United States, including 10 National Cancer Institute Designated Cancer Centers. Nearly 7,000 FLEX enrolled patients have been recruited since April 2017. The FLEX collaborative platform allows participating investigators the opportunity to author their own sub-study protocols, as approved by the FLEX Scientific Review Committee, of which 31 have been approved. FLEX is currently recruiting patients for sub-studies, including one that aims to assess the efficacy of Docetaxel/Carboplatin neoadjuvant therapy in BluePrint ER+ Basal tumors and MammaPrint ER+ Luminal High Risk 2 tumors, and a second that will evaluate transcriptomic changes, modified treatment strategies, and clinical outcomes as a result of neoadjuvant therapy during government-mandate hospital resource conservation for COVID-19 patients.