

Molecular residual disease (MRD) in solid tumors.

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Background: Pragmatically designed clinical studies facilitate rapid accrual of representative populations by aligning research with routine care and enabling study execution in community practice settings. In addition, the implementation of technologies to streamline patient ascertainment and data collection further reduce site burden and improve efficiency. Herein we describe the initial cohort under a platform study designed with pragmatic elements initiated within a technology-enabled community oncology research network. This substudy establishes a prospective observational registry that collects routinely documented clinical data plus intentionally collected biomarker samples, including blood, for the purpose of isolating circulating tumor DNA at specified intervals to enable exploration of MRD in patients with early stage solid tumors. **Methods:** This is a prospective, multicenter, observational, biospecimen collection study in participants (pts) diagnosed with early stage cancers in select solid tumors who have planned curative-intent surgery. The scientific objective is to collect tumor tissue, longitudinal blood samples, and associated clinical data to explore applications of blood and/or tissue-based cancer biomarkers for cancer detection, prognosis, therapy selection, surveillance, and therapy response. Approximately 1350 pts will be enrolled across ~30 Flatiron Research Network community oncology sites. Participants are grouped by tumor site of origin and histology into 7 cohorts (Table). Patients provide informed consent and are enrolled before starting neoadjuvant or adjuvant therapy. Study visits correspond with routine care. Research tissue and blood samples are obtained upon enrollment and at study-specified intervals up to 5.5 years or until disease recurrence for analysis by Exact Sciences laboratories. Technology enablement includes near real-time, AI-assisted, centralized patient ascertainment and integrated electronic health record-to-electronic data capture system data transfer. Under the parent protocol mechanism, the study was IRB approved 65 days from commencement of protocol writing. Target enrollments are based on the number needed to enroll to observe at least 30 events in 3 years. Clinical trial information: NCT06605404. Research Sponsor: None.

Study cohorts.

Tumor type	Disease stage	Target enrollment
Muscle invasive urothelial carcinoma	II-III	200
Esophageal	I-III	150
Gastric & gastroesophageal junction	I-III	150
Melanoma	II-III	300
Non-small cell lung cancer	I-III	200
Exocrine pancreatic cancer	I-III	150
Other solid tumors (excluding central nervous system, colorectal, breast, skin squamous and basal cell, gastrointestinal stromal tumors, thyroid, uveal melanoma, and low or intermediate grade neuroendocrine tumors)	II-III	200