Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

Accelerating Consent to Enrollment: Initiatives and Escalation Plans to Reduce Time to Initiation of Treatment

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1. Background
Operational barriers within protocol-mandated screening processes delay initiation of critical cancer care, increasing the risk of screen failures due to expired screening windows. To address these delays, a multidisciplinary committee—Accelerated Consent to Enrollment (ACE)—was established to identify root causes and implement targeted operational solutions. Baseline data were extracted to evaluate time from informed consent to enrollment and initiation of therapy for patients enrolled during the first three months of 2025, with longitudinal data review planned to assess the impact of sequential interventions implemented in Q2–Q4 2025. Screen failure rates and reasons were also analyzed to evaluate the effectiveness of new processes.

2. Goals
The primary objective of ACE is to identify and mitigate internal and external operational barriers that delay initiation of study-related therapy and clinical trial enrollment beyond 14 days from the date of informed consent.

3. Solutions and Methods
Baseline performance metrics were derived from the OnCore clinical trials management system to quantify time from consent to enrollment across the Winship Cancer Institute Clinical Trials Office (CTO). Barriers were categorized as internal or external and further stratified by degree of controllability within the clinical trials infrastructure. Imaging scheduling and limited access to tissue for pathology and molecular testing were identified as the most significant contributors to screening delays and screen failures. Initial interventions prioritized reduction in time to screening imaging (MRI, PET, CT) through a centralized Microsoft Teams escalation channel approved by leadership, enabling direct coordination with scheduling teams to optimize appointment availability. Secondary interventions included standardization of fax access and development of uniform templates for external tissue requests to improve turnaround time and reliability of documentation workflows.

4. Outcomes
In Q1 2025, 177 patients consented for interventional clinical trial participation and were deemed eligible to initiate therapy. The mean time from consent to Cycle 1 Day 1 (C1D1) was 21 days. while analysis of Q2–Q4 2025 data following ACE committee implementations demonstrated no statistically significant reduction in time from consent to C1D1 across all working groups, this intervention has allowed for escalation pathways and promoted accountability of key services.

5. Lessons Learned and Future Directions
Additional escalation pathways for RECIST/YUNU interpretation and pathology slide workflows were

implemented in February 2026. Future initiatives will expand this framework to audiology services, infusion chair availability for Cycle 1 Day 1 scheduling, and pathology workflows related to bone marrow processing and laboratory turnaround times within internal laboratory systems. We plan to integrate Principal Investigator (PI) involvement in the next phase, with a goal mean time from consent to C1D1 of 14 days. Continued emphasis will be placed on cross-disciplinary collaboration, standardized escalation models, and data-driven process improvement. Working group–specific reviews of screening measures will be conducted in 2026, with ongoing data collection required to assess the impact of current and future interventions.