Accelerating Consent to Enrollment:

Initiatives and Escalation Plans to Reduce Time to Initiation of Treatment (Cycle 1 Day 1)

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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.

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.

SOLUTIONS & 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.

OUR MISSION: Get patients to treatment faster.

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.

KEY INTERVENTIONS IMPLEMENTED (Q2–Q4 2025)

PRIMARY INTERVENTION

Centralized Imaging Escalation Channel

A Microsoft Teams escalation channel approved by leadership enables direct coordination with scheduling teams to optimize appointment availability for MRI, PET, CT.

SECONDARY INTERVENTIONS

Standardization of Fax Access

Improved access and reliability of fax lines to expedite external communications.

Uniform External Tissue Request Templates

Standardized templates improve turnaround time and the reliability of documentation workflows.

OUTCOMES

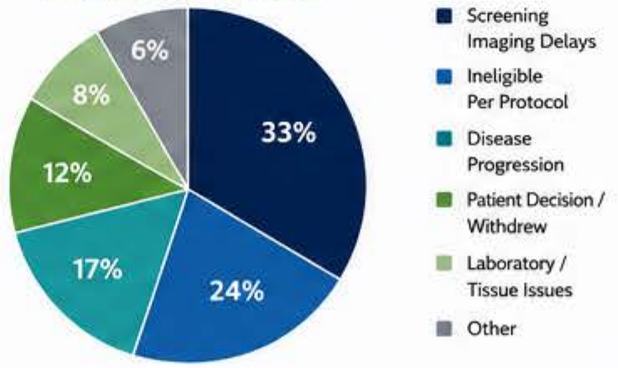
In Q1 2025, **177** patients consented for interventional clinical trial participation and were deemed eligible to initiate therapy.

TIME FROM CONSENT TO CYCLE 1 DAY 1 (C1D1)

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 or within the solid tumor subgroup.

SCREEN FAILURES IN 2025

359 screen failures recorded in 2025



No statistically significant change in screen failure rates across working groups or within the solid tumor subgroup from Q1–Q4 2025.

LESSONS LEARNED & FUTURE DIRECTIONS

LESSONS LEARNED

- Cross-disciplinary collaboration and leadership support are essential to identify barriers and implement solutions.
- Standardized escalation models and documentation improve efficiency and reliability.
- Data-driven evaluation is critical—ongoing data collection is required to assess the impact of current and future interventions.

RECENT ADDITIONAL ESCALATIONS

Additional escalation pathways for RECIST/YUNU interpretation and pathology slide workflows were implemented in February 2026.

Working group–specific reviews of screening measures will be conducted in 2026.

FUTURE INITIATIVES

- Expand escalation framework to audiology services
- Optimize infusion chair availability for Cycle 1 Day 1 scheduling
- Enhance pathology workflows related to bone marrow processing
- Improve laboratory turnaround times within internal laboratory systems

OUR COMMITMENT: Continued emphasis on cross-disciplinary collaboration, standardized escalation models, and data-driven process improvement to accelerate the time from consent to treatment and improve outcomes for our patients.