Enhancing Clinical Trial Access and Enrollment for Acute Leukemia Patients: An Innovative Single-Institution Experience of the Leukemia Expanded Access Program (LEAP)

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Background

Early engagement and streamlined pathways are critical for increasing clinical trial enrollment in acute leukemia, where timely therapy initiation is essential. The Leukemia Expanded Access Program (LEAP) was designed to expedite patient evaluation, enhance clinical trial accrual, and minimize hospitalizations at the University of North Carolina at Chapel Hill's Lineberger Comprehensive Cancer Center

Solutions/Methods

Traditionally, new patient referrals for acute leukemia would take intake 14–21 days before an attending provider visit, delaying diagnostic workup and trial eligibility determination.

Figure 1. Intake Challenges and LEAP Conceptual Framework

Initial barriers

- Initial communication: study team was not included early in the planning process.
- Infusion space: The ongoing issues of limited infusion space, has been a recurring challenge
- Appointment Timing: Clinic appointments scheduled to close to biopsy appointments resulted
- Insufficient time for consent and necessary screening labs.
- Coordinator Notification: Study Coordinators were not notified in advance, leading to delays due to competing patients needs or staff being scheduled for flex work from home.

Solutions/Methods

To streamline leukemia clinical trial operations and improve patient access, several key workflow enhancements were implemented. These included the creation of a dedicated electronic medical record (EMR) inbox for real-time tracking of leukemia referrals and timely follow-up, integration of a research advanced practice provider (APP) model to strengthen coordination between clinical and research teams, preparation of pre-assembled lab kits for select trials to reduce processing delays, and use of structured scheduling templates with built-in time for trial consent discussions.

Results

Since September 2023, LEAP has evaluated 126 patients (8 per month on average), with a median time to LEAP consultation of 3 days. Approximately 70% of LEAP referrals were from community providers. After LEAP visit, new patient provider visits are established within 6 days, significantly reducing the pre-LEAP timeframe of 18 days. Since September 2023, 52/126 (42%) patients were screened for clinical trials at the time of the LEAP visit and 38/52 (73%) enrolled in an interventional clinical trial. Overall clinical trial accrual significantly improved since the implementation of LEAP. Prior to LEAP (January-September 2023) monthly clinical trials accrual averaged 5 patients/month. Monthly clinical trial accrual rates increased to 9.3 patients/month from October-December 2023 and 10.2 patients/month in 2024.

This streamlined approach has contributed to a 70% increase in leukemia clinical trial accruals, from 2023 (n=73) to 2024 (n=124). LEAP played a pivotal role in this growth by expediting the evaluation process, improving trial matching efficiency, and enhancing patient access to investigational therapies.

Figure 2. Annual Accrual Comparison

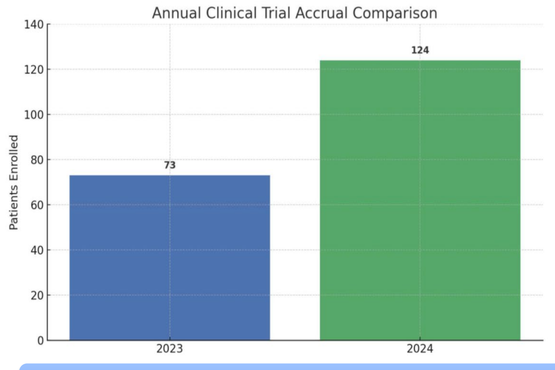


Figure 3 Monthly Enrollment Over Time

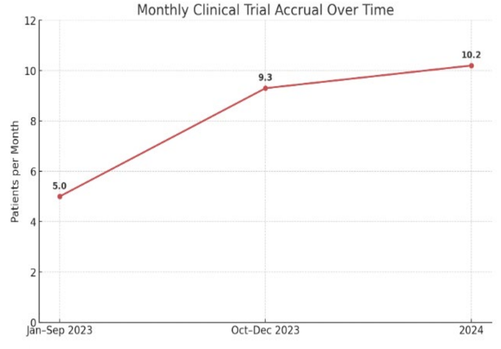
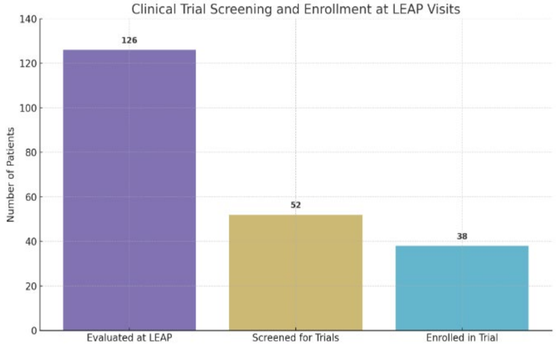


Figure 4 Screening versus Enrollment with LEAP



Conclusions

Our findings suggest that a structured outpatient pathway can improve clinical trial enrollment and patient access to novel therapies.

Future directions include expanding this model to other hematologic malignancies and solid tumor programs to further optimize early-phase trial enrollment. This framework offers a scalable approach to enhancing clinical trial participation, reducing inpatient resource utilization, and improving patient-centered care.

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