

# Navigating Complexities:

## How Caidya Enabled Success in a Global Phase 3 AML Study

### Situation

A global, Phase 3, double-blind study in the field of Acute Myeloid Leukemia (AML) aimed to evaluate the efficacy and safety of a novel treatment combination in patients diagnosed with AML who were unfit for standard induction chemotherapy. The study required 140 sites in 18 countries across North and South America, Europe, and Asia Pacific.

### Challenges

The global Phase 3 study in Acute Myeloid Leukemia (AML) faced several challenges, including delayed start-up in certain countries due to contract negotiations, the need for ongoing data entry and cleaning for independent data monitoring committee (IDMC) meetings, complex patient selection criteria including the need to treat immediately following diagnosis, and the addition of China as a participating country after study start, with a specific patient recruitment goal.

### Solutions

To address these challenges, the team focused on early site contract negotiations to minimize delays. They also coordinated data management and clinical operations to ensure timely data entry, verification, and cleaning. The eligibility process was simplified, and additional resources were allocated to the medical team for centralized data review. In the US, affiliates were engaged to support site contact, and an expedited site selection and activation process was initiated. Caidya's strong presence in China facilitated seamless site selection and activation.

### Outcome

Despite the initial delays, the study went on to enroll the planned patients with a maintained enrollment rate. The revised timelines and enrollment projections were regularly reviewed to ensure adherence to the plan. IDMC meetings were conducted on time with positive outcomes. The activation of China sites stayed on track, and successful investigator meetings were held. Non-enrolling sites were closed to reduce costs.

### Focus on Delivery Excellence



**Proactive planning, coordination, and strategic solutions led to successful enrollment and study execution**



**Continuous monitoring enabled agile shifts to optimize recruitment strategies to ensure successful and timely completion**