

Fast-Tracking Phase Ib Trial Enrollment

How Caidya delivered operational excellence for a complex colorectal cancer study involving NUC-3373



Situation

A small clinical-stage **biopharmaceutical company** initiated a two-part, Phase Ib open-label study to evaluate the safety and pharmacokinetics of **NUC-3373**, a nucleotide analogue, in combination with standard agents in patients with locally advanced or metastatic colorectal cancer who had progressed after at least two prior lines of therapy.

The study was conducted across **seven sites** in the US and Europe, with key milestones including first patient in (FPI) in October 2018 and database lock (DBL) in March 2020. **Caidya** was selected as the clinical research organization (CRO) to provide **full-service support**, including project management, study start-up, monitoring, data management, safety oversight, and biostatistics. Close collaboration with the sponsor and sites was critical to ensuring **timely and compliant study execution**.



Challenge

Despite a well-defined study design, several key challenges impacted operational timelines and study conduct:

- **Limited Sponsor Resources and Communication Gaps:** The sponsor's small team had constrained capacity, which led to delayed communication and slower turnaround times for key decisions. This impacted coordination between Caidya, the sponsor, and clinical sites, particularly during early phases of the study.
- **Frequent Protocol Amendments and Documentation Issues:** Numerous protocol changes and inconsistencies between sponsor-provided documents created confusion across functional teams. This resulted in delays to essential study activities such as eCRF development, regulatory submissions, and investigational product (IP) packaging.
- **Enrollment and Retention Difficulties:** High dropout rates in Part 1—largely due to patients progressing before completing the 28-day DLT evaluation period—slowed overall enrollment and required rapid patient replacement to meet timelines.
- **High Operational Load at Sites:** Intensive procedures at initial study visits, including pharmacokinetic and pharmacodynamic assessments, led to increased workload at sites. This contributed to enrollment delays, data entry backlogs, and quality control concerns.





Solution

To address challenges and keep the study on track, Caidya implemented a **comprehensive strategy** focused on communication, planning, enrollment, and site support. Weekly 1:1 calls with the sponsor, along with an **executive oversight** charter, improved issue escalation and alignment. Functional teams were trained to **proactively identify and resolve risks**. Joint site initiation visits promoted a unified approach with sites.

Operationally, rapid **cross-functional protocol** reviews and dedicated calls ensured clarity after amendments. Close collaboration between start-up, regulatory, and country teams enabled timely regulatory submissions.

Enrollment was optimized through a cohort management plan that provided **real-time updates** on screening slots. The screening strategy was broadened, and sites were re-educated on eligibility, with **protocol criteria refined** to reduce dropouts.

Site support was increased with more frequent monitoring visits and remote reviews, addressing data entry backlogs and scheduling. Direct communication between sponsor and sites helped resolve issues quickly, ensuring data quality and study progress.



Outcome

The implemented strategies delivered **strong operational results**, enabling the study to progress efficiently despite initial challenges. All three sites targeted for Part 1 enrollment were initiated on schedule, allowing the first patient in (FPI) milestone to be met as planned. A contingency site was prepared and ready for activation if required, **ensuring recruitment continuity**.

Enrollment in Part 1 proceeded swiftly, with all available slots filled within three weeks of the third site activation. The team demonstrated **high responsiveness**, promptly identifying and enrolling replacements for screen failures or dropouts within one to two days.

Effective internal collaboration and **consistent communication** between sponsor and sites facilitated the smooth implementation of all protocol versions without delay. Regulatory approvals were obtained on time, supporting uninterrupted study progress. Data entry backlogs were closely monitored and managed through site-specific recovery plans, **ensuring data quality**. Importantly, no critical safety information was delayed, **maintaining compliance and participant safety** throughout the study.

100%

of Part 1 slots filled within three weeks of final site activation, showcasing efficient recruitment and strong site performance.



First patient in on time at 3 global sites



Part 1 enrollment completed within 3 weeks



Handled screen failures promptly

Through strategic communication, real-time site support, and risk-aware planning, Caidya ensured rapid activation, swift enrollment, and consistent data quality—even under complex conditions.