

Enhancing the Pathway to Treatment: a Structured Approach to Slot Management in Competitive Phase 1 Oncology Trials

J. Sobecks, C. Chukri, J. Tomer

Cleveland Clinic Cancer Center

1. Background

In Phase I oncology trials, effective slot management is essential for patient enrollment in competitive studies. These trials involve multiple dose-escalation and dose-expansion cohorts with limited availability, and sponsors use varying methods to assign slots. Timely, organized tracking of cohort-level availability is critical to improving patient access. Given our large population of patients seeking Phase I trials, we are developing structured strategies to standardize communication and strengthen coordination between clinical and non-clinical teams to increase slot acquisition.

2. Goals

To develop a standardized slot management framework that maintains real-time slot visibility, improves communication, increases slot acquisition, and enhances patient access to Phase I trials.

3. Solutions and Methods

We propose a three-tiered slot management approach: notification, patient identification, and slot acquisition.

1 – Notification of Slots:

Our primary tracking tool is a Study Schema listing open Phase I trials, genetic mutations, and slot availability. Regulatory team members update cohort and dose-level information based on sponsor communication, and clinical team members review the schema weekly to identify candidates. To reduce variability in sponsor notification methods, we are implementing a defined distribution process. When a slot becomes available, the regulatory/data coordinator distributes cohort and eligibility details to the lead nurse, lead clinical research coordinator, and recruitment specialists, in addition to updating the Study Schema.

2 – Identification of Patients:

We maintain a centralized patient tracker requiring ongoing clinical review to identify potential Phase I candidates. The tracker includes tumor type, molecular testing results (NGS, MSI, TMB, specific mutations), prior therapies, and eligible studies. Clinical team members reassess molecular data and eligibility criteria to ensure accurate trial alignment. Because cohort availability and protocol requirements frequently change, this process requires continuous coordination. Integrating real-time molecular information enables proactive identification of candidates as cohorts open. Ongoing refinement includes maintaining current molecular data and routinely reviewing the tracker for accuracy.

3 – Slot Acquisition:

We proactively track sponsor-specific slot request requirements and prepare documentation to streamline submissions. For requests requiring investigator signatures, submissions are coordinated based on availability. Approval tracking ensures backup coverage for key personnel and clear communication of assigned cohort and dose level within the workflow to support accurate treatment preparation.

4. Outcomes

Early development of this three-tiered strategy has identified variability in notification and acquisition processes, prompting efforts to standardize communication and refine the Study Schema.

Enhancements to the patient tracker support proactive identification of Phase I candidates based on tumor type and molecular profile. By aligning notification, patient identification, and acquisition workflows, this framework aims to reduce delays between slot availability and submission, improve coordination, and expand access to Phase I trial opportunities.

5. Lessons Learned and Future Directions

A structured three-tiered approach emphasizes the importance of standardized communication and defined workflows in competitive enrollment settings. Continued refinement will focus on strengthening collaboration between clinical and non-clinical teams and incorporating routine discussion of slot availability into program meetings. These strategies may extend beyond Phase I trials to support other teams managing competitively enrolling studies.