# ENHANCING THE PATHWAY TO TREATMENT: A STRUCTURED APPROACH TO SLOT MANAGEMENT IN COMPETITIVE PHASE 1 ONCOLOGY TRIALS

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## BACKGROUND

Effective slot management is essential for patient enrollment in competitive studies. Phase 1 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 increase slot acquisition.

## 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.

## SOLUTIONS & METHODS

**Three-Tiered Solution:**

**1. Notification of Slots**:

- 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. To standardize this process, we propose the following workflow:
  i. Identifying method of slot availability (portal, email, etc.)
  ii. Monitoring for updates of current slot availability and cohort/dosage information
  iii. Updating clinical team members of slot availability
    - Study Schema
    - Email notification

**2. Identification of Patients**:

- We maintain a centralized patient tracker requiring ongoing clinical review to identify potential Phase I candidates by:
  i. Tumor Type
  ii. Molecular Testing Results (NGS, MSI, TMB, specific mutations)
  iii. Prior Therapies
  iv. Eligible Studies

**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.

## 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.

## LESSONS LEARNED & FUTURE DIRECTIONS

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.

There are no relevant conflicts of interest to disclose.