Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Idea

Beyond the Project Manager: Developing a Prioritization Decision Framework to Optimize Protocol Amendment Processing

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1. Background

Clinical trial amendment processing represents an area of increased work effort at academic cancer centers. Between 2022 and 2025, the University of Florida Health Cancer Institute (UFHCI) Clinical Research Office (CRO) received an average of 185 amendments annually, a volume attributed to the growing complexity in study designs that require iterative protocol updates to address emerging safety and efficacy requirements. Site-level implementation of each amendment is labor- and time-intensive, requiring engagement of 10+ independent contributors, managing seven points of hand-off across five operational areas.

In 2025, 94 amendments were fully activated, excluding FYIs to the Central Unit, the Clinical Research Hub. While the Project Manager role has improved transparency and collaboration, there is a need for a formal, risk-stratified prioritization framework to systematically prioritize amendments based on urgency, complexity, or financial impact.

2. Goals

1. Design and implement a formal priority scoring framework to guide amendment processing order when competing demands exist.
2. Develop a decision tree to standardize routing of amendments across regulatory, finance, and clinical teams based on amendment type, study status, and complexity.

3. Solutions and Methods

The proposed initiative builds upon the existing amendment tracking infrastructure by introducing two interrelated enhancements: a priority scoring system and a decision tree for amendment routing.

<u>Priority Scoring Framework</u>

Each amendment will receive a priority score (one through nine) upon receipt, based on sponsor type, study design, phase, and enrollment potential, mirroring the existing Protocol Activation Coordinator (PAC) prioritization schema used in study start-up. Scores one through three will route to an expedited track with a target completion window of 14 calendar days; scores four through seven to a standard track of 30 days; and scores eight and nine to a 45-day window.

<u>Amendment Routing Decision Tree</u>

A structured decision tree will be embedded within the amendment notification email template, introduced in the 2024 process enhancement, to guide coordinators through a consistent triage sequence. The tree evaluates whether an amendment requires calendar, budget, or Medicare Coverage Analysis (MCA) updates; whether the trial is currently active with patients accrued or not; and which teams must be engaged. Amendments requiring only regulatory action (Internal Review Board (IRB)/Scientific Review and Monitoring Committee (SRMC) review) will be routed separately from those

with financial implications, preventing unnecessary engagement of the finance team and reducing task volume.

4. Outcomes

Implementation of a structured priority scoring framework is anticipated to reduce variability in amendment activation timelines by establishing measurable, score-aligned completion windows. By embedding the decision tree within the existing amendment notification infrastructure, routing decisions will become standardized, reducing reliance on individual judgment.

5. Lessons Learned and Future Directions

The proposed amendment prioritization and routing framework represents a logical and necessary evolution of the Project Manager model implemented at UFHCI in 2024. By moving from process visibility to structured triage and risk stratification, the CRO will be better positioned to manage a growing amendment volume with finite staff resources. This initiative aligns with the center's operational excellence goals, its commitment to billing compliance, and its NCI designation standards for efficient clinical trial administration.