

A Phased, Disease-Aligned Staffing Model Incorporating Protocol Complexity in a Multisite Cancer Center

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1. Background

Clinical Trial Coordinators (CTCs) and Clinical Research Nurses (CRNs) are essential to the conduct of oncology clinical trials. Traditional staffing models often rely on broad cross coverage across investigators and protocols, which can limit disease specific expertise, reduce visibility into trial portfolios, and create inefficiencies. These challenges are compounded in multi-site cancer centers where coordinators support studies across multiple clinical locations.

2. Goals

The objective of this initiative was to redesign the clinical research staffing model using a phased, disease-aligned approach to support feasibility assessment, portfolio management, and workload evaluation in a multi-site environment.

3. Solutions and Methods

The cancer center transitioned from a broad cross-coverage staffing model to a disease-aligned structure to better support protocol feasibility review, portfolio management, and workload assessment. A phased implementation strategy was employed.

In Phase One, formal disease groups were established, with CTCs and CRNs aligned to specific disease groups and paired with principal investigators (PIs) and disease group faculty leaders. This structure was designed to build disease-specific expertise, improve communication and continuity, and create an operational framework for each trial portfolio.

In Phase 2, Disease Group Lead Coordinators partnered with PIs and faculty leaders to support feasibility assessment and portfolio oversight, leveraging standing disease group meetings to reinforce disease-specific portfolio management. These meetings provided a structured review of the disease group portfolio, including visibility into studies in activation, identification of gaps within the disease portfolio, review of actively enrolling studies, and prioritization of studies across the portfolio.

In Phase 3, additional structure was introduced through the establishment of a Clinical Operations Manager role and a Disease Group Supervisor role to support staffing oversight and workload management. In parallel, a protocol complexity framework was implemented, initially categorizing protocols as low, moderate, or high complexity. The framework is being refined to incorporate multi-site coverage and to plan for portfolio evolution from primarily National Clinical Trials Network (NCTN) studies to a mix of NCTN, industry sponsored, and investigator-initiated trials.

4. Outcomes

Implementation of disease-aligned staffing improved transparency and clarity of staff assignment for PIs, regulatory teams, and operational leadership. Coordinators developed greater disease-specific

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expertise and demonstrated increased engagement in feasibility review and disease-level portfolio planning. Early application of protocol complexity categorization enabled earlier identification of workload imbalance that was not apparent when using protocol count alone, particularly in the context of multi-site coverage. These changes supported more informed discussions and provided greater visibility into portfolio composition and operational demand across disease groups.

5. Lessons Learned and Future Directions

Protocol complexity alone did not adequately reflect coordinator effort in a multisite cancer center without consideration of site-specific operational demands. Additionally, workforce experience level influenced implementation, as many coordinators were early in their careers and required time and structure to develop disease-specific expertise and operational proficiency.

Future efforts will include transitioning to protocol level staffing with designated primary and secondary coordinators and continued refinement of workload assessment as portfolio complexity increases.