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

Eileen Mederos, RN[1], Dina Brackman, BSN, BA[1], Maja Redzic, PhD[2]
[1]LSU LCMC Health Cancer Center, [2]Huron Consulting Group

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Background

Clinical Trial Coordinators (CTCs) and Clinical Research Nurses (CRNs) are essential to the successful delivery of oncology clinical trials; however, traditional clinical research staffing models rely on broad cross-coverage across investigators and studies, which can:

- Limit disease-specific expertise
- Reduce visibility into trial portfolios
- Create inefficiencies in coordination and workload management

In a multi-site cancer center, these challenges are amplified, as coordinators support studies across multiple locations, increasing complexity and limiting the ability to effectively assess workload and resource needs.

Goal

Develop and implement a disease-aligned staffing approach that enhances feasibility review, strengthens portfolio management, and enables more effective assessment of coordinator workload in a multi-site environment.

Methods

Phase	Disease-Aligned Staffing	Portfolio Oversight	Staffing & Complexity Framework
1	• Transitioned from a broad cross-coverage model to disease-aligned staffing • Established formal disease groups with CTCs and CRNs aligned to specific disease areas		
2		• Leveraged standing disease group meetings to review study portfolio • Implemented Disease Group Lead Coordinator role to support feasibility and portfolio oversight	
3			• Introduced Clinical Operations Manager and Disease Group Supervisor roles to support staffing oversight and workload management • Implemented an initial protocol complexity framework (low, moderate, high) • Began refining approach to incorporate multi-site coverage and evolving portfolio mix

Outcomes

Open trials: 103 | Treatment: 76 | Sites: 5

- Protocol weighting (1–3 scale) demonstrated variation in workload across disease groups (avg weight: 1.56–2.42)
- Application of protocol weighting improved visibility into workload distribution and differences across disease groups (e.g., disease groups with higher study volume but lower average complexity required different staffing approaches than groups with fewer, higher-complexity trials
- Multi-site coverage increased coordinator workload beyond protocol complexity alone due to variation in site-specific workflows, operational processes, and required onboarding across locations

Lessons Learned

Early implementation highlighted several important considerations for sustaining a disease-aligned staffing model:

- Early application of protocol complexity revealed workload imbalance not apparent when using protocol count alone, particularly across multi-site studies.
- Broad categorization of studies requires refinement to reflect differences in study type and site-specific requirements
- Coordinator experience levels influence implementation pace and require structured support to build disease-specific expertise
- Transitioning to a disease-aligned model requires time to establish consistency in workflows, communication, and portfolio ownership

Future Directions

Next steps focus on refining the model and strengthening alignment between staffing, workload, and portfolio needs:

- Transition to protocol-level staffing with defined coordinator ownership
- Refine complexity model to better reflect site and study variability
- Adapt to a more diverse trial portfolio
- Strengthen workload management to support scalability across disease groups