Enhancing Clinical Trial Operations Through Strategic Team Restructuring: Disease Group-Focused specialization at Mayo Clinic Comprehensive Cancer Center

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Background

In 2025, the Mayo Clinic Comprehensive Cancer Center (MCCCC) restructured protocol development operations to better support disease groups and build specialized expertise. We transitioned from a site-based model with inconsistent workflows and overlapping roles to an enterprise structure with four verticals—investigator-sponsored trials protocol development unit, activation, maintenance, and regulatory—with standardized responsibilities and centralized oversight. Staff were aligned to specific disease groups to strengthen relationships and continuity. This approach has improved workflow standardization and efficiency, supported faster trial activation, increased cost recovery, and helped deliver important clinical trials to patients more quickly.

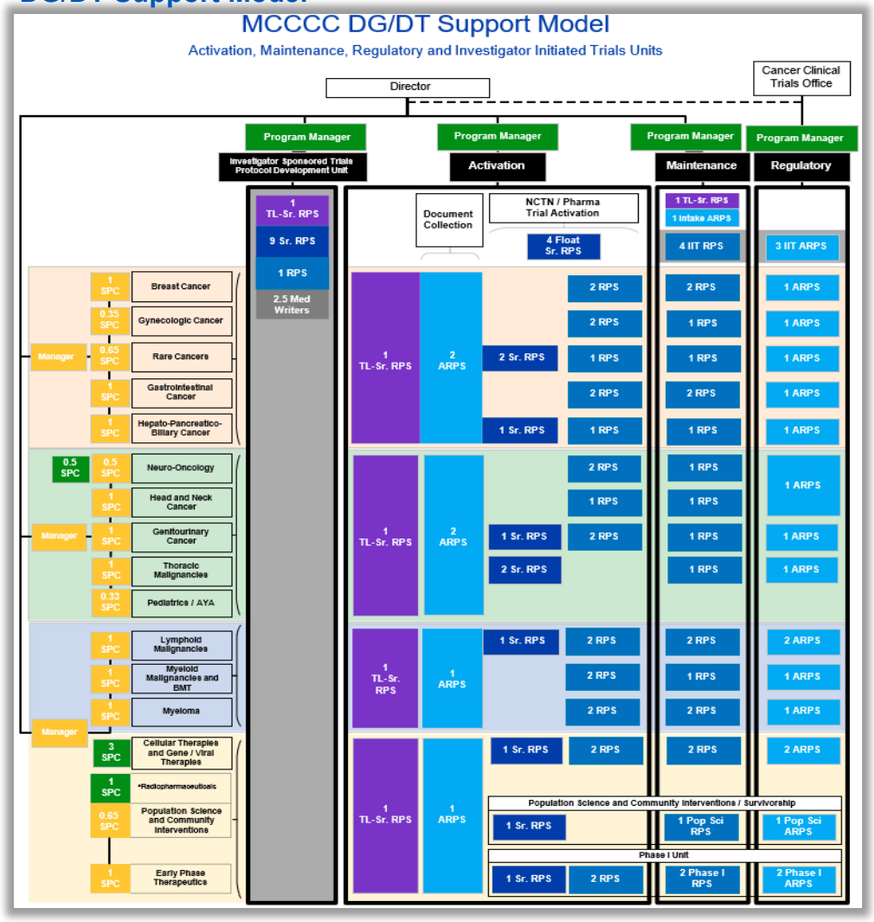
Goals

- Improve consistency and efficiency in protocol development and trial activation
- Clarify roles and responsibilities across operational teams
- Provide enhanced support for disease groups
- Increase staffing capacity and overall productivity within clinical research operations
- Enhance collaboration across stakeholder teams
- Improve scalability to support a growing trial portfolio
- Create a sustainable model that supports staff development and retention model

Methods

We reorganized site-based operational teams into four enterprise verticals: protocol development for investigator-sponsored trials, activation, maintenance, and regulatory. Within each vertical, we aligned dedicated staff to specific disease groups to promote specialization, continuity, and accountability. Implementation was supported through weekly leadership meetings, training, and continuous feedback from staff and stakeholders.

Figure 1: Re-organized operational teams – MCCCC DG/DT Support Model



Results

Preliminary outcomes indicate improvement across key workflows.

- Clearer roles and stronger collaboration between operational teams and disease groups
- More efficient trial activation, increased productivity, and improved workload balancing
- Increased number of trials opened per quarter
- Increased cost recovery

Table 1: Enrollment and Cost Recovery

Q/Yr	Trials Opened	% Cost Recovery
Q1 2025	37	66
Q2 2025	25	68
Q3 2025	64	105
Q4 2025	46	85

Note:

- The MCCCC DG/DT Support Model was approved July 1, 2025
- Cost recovery target = 70%

Discussion

It is important to align the organizational structure with disease-focused research needs, engage staff early in the change process, and stay flexible during implementation. This process requires continued evaluation of operational performance metrics, refining role definitions within each vertical, and expanding targeted training to strengthen disease-specific expertise and sustain the new enterprise model.

Conclusions

- **Enterprise restructure:** Standardizes protocol development, activation, maintenance, and regulatory work—aligned to disease groups for specialization and continuity
- **Early impacts:** Clearer roles, stronger collaboration, faster activation, improved productivity and cost recovery
- **Next steps:** Track performance metrics, refine vertical roles, expand disease-specific training