

*Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Completed Project*

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

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### **1. Background**

In 2025, the Mayo Clinic Comprehensive Cancer Center undertook a strategic restructuring of protocol development teams to better align support with specific disease groups and foster staff specialized within certain areas of clinical trial development and support. Previously, the teams operated under a site-based model which led to inconsistent workflows, overlapping roles, and difficulties with scaling operations. To overcome these challenges, adoption of an enterprise team structure was created featuring distinct operational verticals (investigator sponsored trials protocol development unit, activation, maintenance, and regulatory) with well-defined roles, standardized responsibilities, and centralized oversight, designed to directly support and partner with disease groups through aligned team ownership. Within these verticals, dedicated staff are aligned to specific disease groups, enabling teams to build deeper expertise and stronger working relationships within their focus areas, ultimately supporting the timely delivery of important clinical trials to patients. This targeted specialization has resulted in increased operational efficiency, more effective trial activation, and an increase in cost recovery.

### **2. Goals**

The primary goals of this initiative were to improve consistency and efficiency in protocol development and trial activation, clarify roles and responsibilities across operational teams, provide enhanced support for disease-group principal investigators, and strengthen staffing and overall productivity within clinical research operations. Additional goals included strengthening collaboration between different stakeholder teams, improving scalability to support a growing trial portfolio, and creating a sustainable model that supports staff development and retention.

### **3. Solutions and Methods**

Site-based operational teams were reorganized into four enterprise verticals that included investigator sponsored trial protocol development unit, activation, maintenance and regulatory with clearly defined roles and responsibilities. Within each vertical, dedicated staff were aligned to specific disease groups to promote specialization, continuity of support, and accountability. Change management strategies were utilized that included weekly leadership implementation meetings, training, and ongoing evaluation through continuous feedback from staff and stakeholders.

### **4. Outcomes**

Preliminary outcomes demonstrate improved role clarity, enhanced collaboration between operational teams and disease groups, increased consistency in protocol development and maintenance workflows. Early observations suggest more efficient trial activation processes, increase productivity, and improved ability to balance workload across teams, supporting the timely initiation of important clinical trials for patients. During the third and fourth quarters of 2025, a total of 64 and 46 clinical trials were open to enrollment, respectively. Notably, these figures represent the highest number of clinical trials opened per quarter and stayed within the National Cancer Institute timelines. These trials encompassed institutional, industry-sponsored, national, and externally peer-reviewed studies. Cost recovery was

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enhanced during these quarters to 84 percent while our target is 70 percent. This initial data supports that the disease-aligned model is better suited to support complex clinical trial portfolios and facilitate patient access to research.

#### **5. Lessons Learned and Future Directions**

Key lessons learned include the importance of aligning organizational structure with disease-focused research needs, engaging staff early in the change process, and maintaining flexibility during implementation. Future directions include formal evaluation of operational performance metrics, refinement of role definitions within each vertical, and development of targeted training programs to further strengthen disease-specific expertise and support continued growth of the enterprise model.