

The Current Versus Ideal State: Optimizing Operations With the Expansion of the Clinical Trials Network

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1. Background

At the Rutgers Cancer Institute's (RCI) Cancer Center Support Grant (CCSG) renewal in 2017, interventional clinical trials accrual was 318 patients with most from the academic cancer center. In 2018, a "single site" model was created; by 2020, eleven partner sites were integrated and clinical trials operations were centrally administered. The 2022 accrual goal for the CCSG renewal was 550; surpassed with 602 patients accrued. With the incorporation of multiple sites, several important decisions were made. Teams (i.e., Finance, Regulatory, etc.) became centrally resourced, and new Disease Study Groups (DSGs) were formed, inclusive of physician leadership, managers, Research Nurse Clinicians and Clinical Trial Specialists. Each DSG was tasked with central resource collaboration, significantly increasing operational complexities. For the next grant cycle and year of review in 2027, 1,000-1,200 accruals are anticipated, with majority from partner sites. Developing strategies to optimize efficiencies in clinical trial operations to meet accrual goals within budget while ensuring research compliance and integrity, and patient safety remains challenging.

2. Goals

- Identify an optimal organizational structure with an appropriate staffing model and clearly defined roles and responsibilities
- Delineate and implement workflows to enhance team communication and collaboration
- Upskill and empower teams to use those workflows in resolving day-to-day operational challenges
- Develop an efficient organizational structure allowing the Office of Human Research Services (OHRS) to meet challenges of doubling accrual goals in 2027

3. Solutions and Methods

Managers met for multiple sessions. A current versus ideal state exercise was performed. Brainstorming included role clarity, dependencies, interactions, interpersonal dynamics, tangible and objective "pain points," and challenges associated with staff supervision, administrative operations and protocol and patient management. Next, the managers embarked on a process mapping activity to define study anatomy, role descriptions, concerns, and desirable goals for the study life cycle. Leadership then met with other teams' management (i.e., Regulatory, Data, etc.) to ascertain their workflows, roles and responsibilities, and interactions. Finally, a debriefing occurred with the DSG managers focused around (in)efficiencies, complexities and redundancies of intergroup communication and collaboration.

4. Outcomes

For the current state, a process mapping diagram was developed; this allowed each manager to identify process improvements within their immediate DSG and amongst OHRS at large. To meet the 2027 portfolio and accrual goals, role and responsibility descriptions will be updated, and an optimized operational structure will be established.

5. Lessons Learned and Future Directions

A two-part leadership retreat, comprised of medical, administrative, and operational executive leadership, will occur in March 2024 to collaborate on planning for the ideal, future state. Mission and vision for the next four years (to fiscal year 2027) will be the focus. A strategic plan on how to achieve the goals for accrual, budget, portfolio, staffing and organizational structure will be developed. Actionable items to address the top three priorities to achieve that strategic plan will be defined.

Longer-term, leadership will collaborate with DSG physician directors to develop appropriate protocol portfolios, along with prescreening and screening methodology, to meet the community and patient needs within the budgetary, investigator, institutional, scientific and community priorities.