The Current versus Ideal State: Optimizing Operations with the Expansion of the Clinical Trials Network
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Background
At the Rutgers Cancer Institute of New Jersey’s (RCINJ) 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, 1000-1200 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 as well as patient safety remains challenging.

Goals
- To identify an optimal organizational structure with an appropriate staffing model and clearly defined roles and responsibilities.
- To delineate and implement workflows to enhance team communication and collaboration.
- To upskill and empower teams to use those workflows in resolving day-to-day operational challenges.
- To develop an efficient organizational structure allowing the Office of Human Research Services (OHRs) to meet challenges of doubling accrual goals in 2027.

Methods
- Multiple leadership meetings
- Process mapping
- Leadership meetings
- Debrief

Outcomes
- Identify process improvements within immediate DSG and OHRS at large via Process Mapping

Current State

Ideal State

1. Update role and responsibility descriptions
2. Establish optimized operational structure

Future Directions
A two-part leadership retreat, comprised of medical, administrative and operational executive leadership occurred in March 2024. Goals: 1. To collaborate on planning for the ideal, future state. Focus was mission and vision for the next four years (i.e., to fiscal year 2027 – presentation for next CCSG). 2. Begin to develop a strategic plan for accrual, budget, portfolio, staffing, and organizational structure to meet the ideal, future, state.

Five projects were defined to begin addressing these goals and help DSG Leadership make informed portfolio decisions: