

A Quality Connection... An Enhanced Leadership Structure Through the Implementation of a Project Administrator

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1. Background

Continued growth and increased trial complexity in clinical research portfolios require regular staffing assessments to ensure appropriate management and quality oversight of daily operations. At Huntsman Cancer Institute (HCI), we have disease-oriented clinical trial research groups (CTRGs) with six program managers (PMs) who are tasked to oversee each of these areas. In addition to increased enrollment and trials growing in complexity and volume, we have also experienced an influx of new faculty with clinical trial interests, all adding to the workload of the PM and leadership team. If left unchecked, this can present an increased threat of disconnect between day-to-day operations of our coordination teams and our clinical trials office (CTO) administrative leaders and investigators as well as the potential to negatively impact the quality and compliant manner in which clinical research should be conducted. Furthermore, without adequate oversight and support for our study teams, training and mentoring in disease-specific areas can suffer and workload can become more burdensome leading to threatened quality, decreased job satisfaction, and added turnover.

2. Goals

- Fully implement restructure of leadership team with addition of project administrators (PAs) to serve as a supportive link between CTO leadership, investigators, Huntsman Cancer Hospital/clinic staff, and the coordination teams
- Achieve positive audit/monitoring outcomes while fostering a proactive vs. reactive work environment
- Strengthen disease-specific training and mentoring to ensure appropriate level of staff competency and confidence in support of quality assurance program
- Provide resources for more seamless coverage and transition plans within the team to help balance workload
- Continue to provide added opportunities for professional growth and development, increased job satisfaction, and reduced turnover
- Improve overall quality of research conducted at HCI

3. Solutions and Methods

As full-time equivalents are approved, PAs will be strategically added to strengthen the leadership structure. To date, PAs have been added to support five of the six CTRGs, trial activation efforts, satellite site operations, CTO laboratory operations, and a liaison for our complex Phase I clinical trials.

4. Outcomes

Senior staff are most frequently promoted into the PA role. As such, this has created increased promotional opportunity and ability to retain more senior, experienced staff. To date, CTO leaders have

noted improved communication; enhanced education through extended training and mentoring; improved audit and monitoring outcomes; and more seamless transition of trial assignments due to turnover or job reassignment. Trial activation has become more streamlined, consistent, and efficient, and improvements have been seen in satellite site operations laying the groundwork for increased accrual and trial activation. A more refined PA focus in our Phase I experimental therapeutics group has helped to increase communication and education with internal and external community providers, and patients and their families to navigate the increasing number of molecularly targeted therapies and cellular immunotherapy trials.

5. Lessons Learned

- Work to further define most appropriately balanced workload at the leadership level to support coordination efforts
- Implement process to ensure balance in portfolio and coordination workload is regularly assessed
- Continue to define and implement future measurements of increased staff competency and job satisfaction