A Quality Connection … An enhanced leadership structure through the implementation of a Project Administrator

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BACKGROUND

Continued growth and increasing enrollment along with added trial complexity in clinical research portfolios requires flexibility in organizational structure to ensure appropriate management and quality oversight of daily operations.

At Huntsman Cancer Institute (HCI), we have disease-oriented clinical trial research groups (CTRGs), each with an assigned program manager (PM) tasked to oversee each of these areas. In addition to the growth in enrollment, portfolios and complexity of trials, 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.

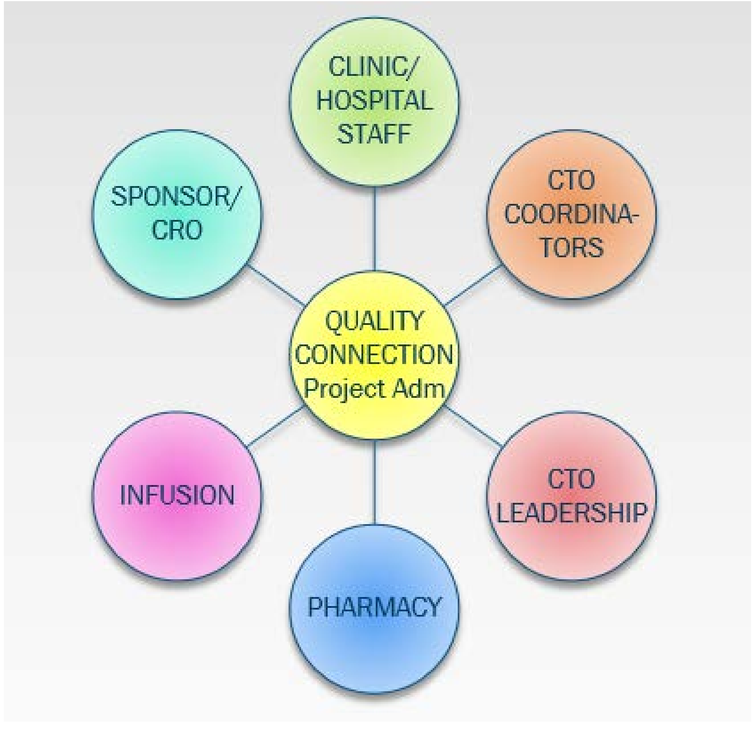
Furthermore, without adequate oversight and support for our study teams, training and mentoring in disease specific areas can suffer and workload can become more burdensome leading to threatened quality, decreased job satisfaction, and added turnover.

METHOD

- Fully implement restructure of leadership team with addition of project administrators (PAs) to serve as a supportive link between CTO leadership, coordination teams, investigators, Huntsman Cancer Hospital/clinic staff, and our sponsors and CROs.
- Continue to provide added opportunities for professional growth and development, increased job satisfaction, and reduced turnover

RESULTS

- Senior staff are most frequently promoted into the PA role. These added promotional opportunities have allowed us to retain our more senior, experienced staff for longer periods of time
- We have seen improved communication between our coordination teams and the ancillary groups working both internally at our cancer center as well as externally with our sponsors and CROs
- Strengthen disease-specific training and mentoring to ensure appropriate level of staff competency and confidence in support of quality assurance program
- Improved audit and monitoring outcomes.
- More seamless transition of trial assignments due to turnover or job reassignment



RESULTS (CON'T)

- Provide resources for more seamless coverage and transition plans within the team to help balance workload
- Improved efficiency in trial activation.
- A more refined PA focus in our Phase I experimental therapeutics group has helped to
- Improved communication and education with community providers, patients and their families to help navigate the increasing number of molecularly targeted therapies and cellular immunotherapy trials.

CONCLUSIONS

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

FUTURE PLANS

- 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.
- Improve overall quality of research conducted at HCI

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