

Study Conduct Stabilization and Finding the Balance

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1. Background

As many other facilities experienced, we had a large exit of our study conduct coordinating team members that resigned during and following the COVID pandemic. Many of our team left for remote roles or promotional opportunities. The sudden drop in staff impacted study accruals, quality, and burnout to those that remained. We had to rebuild our cancer study conduct team, so we took the opportunity to create new processes, develop a different approach, and implement a culture change needed to hire, train, and retain a strong stable team.

2. Goals

The primary goal was to stabilize the study conduct team with the appropriate number of staff to support the principal investigators (PIs) and portfolio for safe, efficient, consistent patient care. The secondary goal was to create a system that encouraged staff to grow within their teams and provide opportunities to reduce gaps in transition.

3. Solutions and Methods

- Assess our portfolio to determine the appropriate number of staff needed for each team based on open protocols, protocols in development, complexity of portfolio, and numbers of active patients and follow-up patients
- Recruit new hires and provide an onboarding training program for strong foundation
- Change from immediate assignment to a new approach using the training program phase to assess strengths, weaknesses, and personalities of new hires to determine team assignment
- Find the balance by creating a bench to support sudden resignation or unplanned leave of absence
- Create a career ladder within disease teams to provide continuity of care and growth opportunities without transitioning staff

4. Outcomes

We are currently 98 percent staffed with bench staff in the training program. We have decreased the number of resignations and transfers significantly. We have been able to increase accruals, reporting for 2023 the highest interventional treatment accrual we have accomplished in over a decade. This improvement is not reflected just in our accrual volumes, but we are able to review for quality, including first and third patient as well as implementing an audit readiness preparation process.

5. Lessons Learned and Future Directions

Implementing the career ladder provided excellent growth opportunities for our experienced coordinators, resulting in higher retention rates within each disease team and we were able to do that without financially impacting the protocol budgets. For example, when we promote a Clinical Research Coordinator (CRC), instead of backfilling with the same role, we backfill with an Associate CRC and add to the team a Senior CRC. This balances out the budget by splitting the two roles while providing a career ladder within that disease team. We intentionally hire Associate Coordinators, train them to the top of their scope, and promote when ready. This allows the newly hired member to train with the coordinator that was the lead on the protocol to help reduce gaps during transitions. This means an

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Associate CRC can promote to CRC and to Senior CRC without transitioning out of the team looking for promotional opportunities. This new model has provided opportunities for Associate Coordinators, Clinical Research Coordinators, and Senior Clinical Research Coordinators to stay with the same physicians and provide continued knowledge of the protocol portfolio.