

Study Conduct Stabilization: Finding the Balance

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ABSTRACT

BACKGROUND

As many facilities experienced, Mayo Clinic Florida's Cancer Clinical Studies Unit (CCSU) had a large exit of the study conduct coordinating team due to resignations during and after the COVID-19 pandemic. Many of the team left for remote roles or promotional opportunities outside of the organization. The sudden drop in staff impacted study accruals, quality of work, and burnout in remaining employees. The CCSU needed to rebuild the study conduct team. Leadership took the opportunity to create new processes, develop a different approach, and implement a culture change, all of which were needed to hire, train, and retain a strong and stable team.

OBJECTIVES

PRIMARY OBJECTIVE

Team stabilization: To stabilize the study conduct team of Associate Clinical Research Coordinators (ACRCs), Clinical Research Coordinators (CRCs), and Senior Clinical Research Coordinators (Sr CRCs) with the appropriate number of staff to support the Principal Investigators (Pls) and study portfolio for safe, efficient, and consistent care.

SECONDARY OBJECTIVES

Team growth: To create a career ladder that encourages staff to grow within their teams and reduces gaps in transition. **Team satisfaction:** To increase job satisfaction through hybrid work schedules that can better compete with fully remote jobs.

METHODS

Evaluate study portfolio of each team

• Determine appropriate number of staff based on open protocols, protocols in development, complexity of portfolio, number of active patients, and number of follow-up patients

Recruit new hires

• Provide a standardized onboarding and training experience to build strong and consistent foundational knowledge and skills

Refrain from assigning new hires to a team at the time of hire

• Utilize the training program phase to assess strengths, weaknesses, personalities, and interests of new hires to determine optimal team assignment

Balance

• Create a "bench" of additional staff to allow for immediate backfill in the case of resignation, unplanned leave of absence, or planned extended leave of absence

- Create promotional opportunities within disease teams that retains staff in their original teams
- Provides continuity of care and growth opportunities for staff ready to transition

Hire as ACRC

 Leads minimal risk studies; assists on greater than minimal risk studies.

 Trained to top of scope with intent of promoting.

 Coordinates greater than minimal risk Promote to CRC

studies. Exposure to portfolio and financial management.

Backfill with ACRC to offset cost

Promote to Sr CRC

 Coordinates more complex greater than minimal risk studies.

Supports portfolio and financial management.

Team growth:

- Seasoned staff promote, improving retention
- · Focus on hiring ACRCs and training to top of scope with intent of promotion; only experienced people hired as CRC
- ACRCs can promote to CRC then to Sr CRC without transitioning out of original team, so staff stay with the same portfolio
- Study budgets maintained by backfilling a newly promoted Sr CRC with an ACRC to offset the cost of the promotion

DISCUSSION

Team stabilization:

- Study portfolios assessed in detail to hire appropriate number of staff
- 6-week training program of classroom learning, online modules, and shadowing used to gauge which teams best fit new hires, providing more information than can be captured during interviews
- 1-2 "bench" staff hired, allowing backfill in a timely manner, as staff had already been hired and were in training
- To date, all "bench" staff assigned to a team by the end of training

Team satisfaction:

- Staff who have passed a 6-month competency assessment are granted up to 2 work-from-home days each week, structured around patient needs and discussed in advance with the team
- Greater staff satisfaction and work-life balance
- Hybrid work has made these positions more desirable to new hires, and remote positions are less enticing for seasoned staff to leave

RESULTS

- Currently 98% staffed
- 6-month period with no job openings
- 42% of ACRCs hired 2022-2023 have been promoted
- 5 CRCs promoted to Sr CRC
- Of 23 promotions, only 2 staff members left CSU after promotion
- 51 staff hired in 2022, compared to 5 staff by end of Q2 2024
- 27% of the staff hired in 2022 have left the unit, compared to 8% of the staff hired in 2023
- 2023 reported the highest interventional treatment accrual in over a decade
- Capacity to proactively conduct quality reviews:
- First and third patient reviews
- Audit readiness preparation process

CONCLUSIONS

When dedicating intentional time and training to the recruitment process, retention increases and staff burnout decreases. This results in team stabilization, career development, and job satisfaction that benefits the work unit and, more importantly, patients participating in clinical research.

NEXT STEPS

- Develop a training program specific to individuals promoting from ACRC to CRC
- Standardize the Sr CRC role across teams and increase responsibility
- Seek out additional growth opportunities for staff approaching eligibility for industry positions