CLINICAL TRIAL STAFFING CONSIDERATIONS

-AT A GLANCE -

BOTTOM LINE



Implement strategies to increase productivity and reduce turnover.



Establish a model for team effectiveness.



Maintaining skilled staff is critical to research site success.



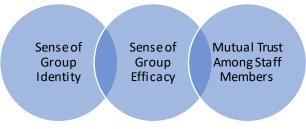
Leverage existing training and staff support resources.

Building and maintaining an effective research team can be challenging. Research program leadership, managers, and/or administrators often face the challenge of identifying the right staff, ensuring completion and maintenance of training and certifications, and maintaining and increasing staff engagement. Without the proper strategies in place, research teams can experience high turnover rates, which increases the workload of remaining staff and may affect productivity and overall staff morale. High turnover may also signal site management problems to sponsors, which could have far-reaching effects.

KEY CONSIDERATIONS, TIPS, AND BEST PRACTICES



Having skilled and knowledgeable employees who feel supported and engaged, and who are driven and committed, are key elements to a clinical trial program's success. Proper staffing is also vital to the reputation of a site and principal investigator since staffserve as liaisons between investigators, patients, care providers, regulatory bodies, sponsors, and others involved in the research process.



Model for team effectiveness. ²

Maximizing Staff Effectiveness

To build and support an effective research team, consider the following best practices:

Research staff retention strategies that may translate into higher productivity and lower turnover rates. Strategies include:1

- o Regular acknowledgement of the value of each employee
- o Increased focus on job satisfaction and team-building opportunities (e.g., special events, team educational training, etc.)
- o Encouragement of work-life balance and a flexible environment
- o Cross-coverage and task sharing between roles
- o Continuous improvement feedback programs, such as self and team assessments
- o Establishment of competencies and opportunities for career progression
- o Offering and encouraging professional development
- Following up with team around trial results, as they are published, and unique patient success stories.
- A model for team effectiveness includes mutual trust among members, a sense of group identity (i.e., the feeling of belonging to a unique and worthwhile group), and a sense of group efficacy (i.e., the belief that the team can perform well and that members are more effective when working together than separately). Consider building employee engagement and commitment to the organization by clearly defining and sharing goals. "Specific" goals produce a higher level of output than "vaguely" worded ones.
 Core research staff at sites include research administrators/managers, research nurses, clinical research coordinators, and other
- Core research staff at sites include research administrators/managers, research nurses, clinical research coordinators, and other clinical research professionals (e.g., clinical research associates, regulatory specialists, etc.). It may also be helpful to enhance a research team by employing additional staff members and/or building relationships with ancillary team members, including infusion nurses/clinic staff, pharmacists, laboratory staff, radiologists/radiation oncologists, billing and contracting specialists, various specialists (e.g., surgery, primary care, gynecology, genitourinary, etc.), and patient advocates. Refer to the ASCO The Business of Clinical Trials Toolkit³ for sample role definitions, job descriptions and career ladders.
- Developing a training checklist and utilizing existing resources (e.g., <u>CITI Program</u>, peer-to-peer training, etc.) can be helpful to ensure proper staff training and certification. Where possible, consider assigning new staff a formal mentor. *Refer to the <u>ASCO The Business</u>* of <u>Clinical Trials Toolkit</u>³ for additional training resources and tips.

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OTHER RESOURCES

Research Team Roles and Responsibilities

- Baer AR, Zon R, Devine S, et al. <u>The Clinical Research Team</u>. J Oncol Pract 7(3):188-192, 2011.
- Baer AR, Devine S, Beardmore CS, et al. Clinical Investigator Responsibilities. J Oncol Pract 7(2):124-128, 2011.
- American Society of Clinical Oncology Clinical Trial Workload Assessment Tool. American Society of Clinical Oncology; 2014. Access: workload.asco.org.

Mentorship

- Mentoring in Medicine Henry-Noel N, Bishop M, Gwede CK, et al: <u>Mentorship in medicine and other health professions</u>. Journal of Cancer Education 10.1007/s13187-018-1360-6.
- Arnold ER: As a New Nurse Myself, How Can I Become a Mentor to New Nurse Colleagues? Clin J Oncol Nurs 22(1):120, 2018.

Creating a Culture of Research

• Dimond EP, St Germain D, Nacpil LM, et al: <u>Creating a "Culture of Research" in a Community Hospital: Strategies and Tools from the National Cancer Institute Community Cancer Centers Program.</u> Clin Trials 12:246-256, 2015.



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