Category: Training, Career Development, and Staff Retention - Completed project

Increasing Regulatory Staff Engagement Through Disease Team Alignment

J. Frazier, S. Jorfi, E. Lambert, H. Figueroa, S. Osipowicz

Sidney Kimmel Comprehensive Cancer Center at Jefferson

1. Background
The Clinical Trials Office (CTO) Regulatory Operations Team was previously organized such that regulatory coordinators (RCs) were assigned to support only one type of study: Industry, Investigator-Initiated Trials (IITs), National Cancer Trial Network (NCTN), or Early Phase. This meant that most RCs worked with many investigators and clinical research coordinators across many different multidisciplinary disease groups (MDGs). Working with a large number of people meant that many RCs did not have strong relationships with the teams they supported, which contributed to frustration from regulatory and clinical staff.

2. Goals
Our goal was to encourage more meaningful interactions between clinical and regulatory staff and result in increased staff engagement and satisfaction.

3. Solutions and Methods
The CTO Regulatory Operations Team established a working group to develop plans for aligning Industry and IIT RCs with single MDGs. The working group reviewed and updated existing work instructions and created additional guidance documentation to support RCs in learning new study types. RCs were trained on regulatory workflows of both Industry and IITs, including start-up, maintenance, and close-out tasks. Eighty studies were transferred among 13 RCs in three phases over the course of six months. The working group surveyed clinical and regulatory staff at each stage and incorporated their feedback into planning for the next phase.

4. Outcomes
RCs went from supporting up to five MDGs to a single MDG. All RCs who previously supported only Industry or IITs are able to support both types of trials for a single MDG. When surveyed, RCs reported this change increased meaningful interactions and improved communication between them and clinical staff. RCs now meet biweekly with the MDG project manager to review the priorities for the MDG's study portfolio. RCs attend monthly virtual MDG meetings, where they have an opportunity to interact with physician-investigators and clinical research coordinators. With more exposure to other teams, RCs have gained a deeper understanding of clinical research operations, including budget development, and report higher satisfaction being part of a specific MDG team.

5. Lessons Learned and Future Directions
We hope this will empower MDG leadership to take staff into consideration when making decisions about their study portfolio. Regulatory Operations should further assess the MDGs' regulatory needs and determine if expanded regulatory support is warranted, and continue to evaluate RC workload for equity to ensure they feel valued as part of the study team. Leadership should assess workload impact to determine if efficiencies in communication enable RCs to support more studies.