

Restructuring the Research Team-Activation

L. Sego, G. Lander, L. Rohn

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

The Indiana University Simon Comprehensive Cancer Center (IUSCCC) Adult Clinical Trials Office (CTO) is home to over 400 clinical trials in varying stages of clinical trial life, from trials in the pipeline to trials waiting for study closure. To date, the CTO has approximately 126 trials actively accruing patients, 60 trials that have begun activation procedures but have not opened to accrual, and approximately 96 more trials in the pipeline are on hold for various reasons, including insufficient staffing to start and manage the upcoming trials or the trial is not ready to open. The remaining trials are in the maintenance or closeout phase. As with many institutions, activation timelines are a significant issue at the CTO with activation taking an average of approximately 6 months.

An additional challenge the CTO faces is that the study coordinators do not activate trials at the frequency or volume to become experts, which leads to errors and delays. With 16 disease-oriented teams (DOTs) each opening their own trials, recurring issues and trends are more difficult to identify.

2. Goals

Create a dedicated study activation team that exclusively opens new trials from confidential disclosure agreement/feasibility assessment to open to accrual.

- Include the following roles:
 - Study Coordinator
 - Regulatory Coordinator
 - Financial Analyst
 - Pharmacy Technician
- Accurately track metrics for activation timelines
- Identify bottlenecks and recurring issues
 - Project Specialist to help with solutions to bottlenecks and recurring issues
- Reduce activation timelines from ePRMS/SRC submission to Open to Accrual to under three months
- Develop additional rungs to the CTO career ladder

3. Solutions and Methods

- Start with the study coordinator role on one disease team
- Expand to add other diseases
- Expand to add additional roles focusing exclusively on activation

4. Outcomes

This project is very early in the pilot phase. One experienced study coordinator on the breast DOT will take over all activation tasks for new studies on the breast DOT. If success is observed by lowered activation timelines, they will expand to the GYN DOT and Supportive Care DOT. If continued success is observed, other roles such as a regulatory coordinator and financial analyst will be added to the activation team.

Due to discussions with other cancer centers that have adopted an activation team, it is expected to see:

- Reduced activation timelines by half
- Increased content expertise by both activation and maintenance teams
- Improved communication and responsiveness
- Streamlined and more efficient processes
- Improved staff morale

5. Lessons Learned and Future Directions

At this early stage, it is difficult to determine what lessons have been learned. Feedback has shown concern for ensuring the maintenance team is familiar with the study since they may not be involved in the activation process and limiting promotional opportunities if staff have exclusive start-up or executive maintenance experience but not the other. Future directives include developing a process for study handoff from the activation team to the maintenance team as well as addressing the career ladder to ensure staff gain the experience needed in study coordination to promote within the office.