Category: Trial Start-up, Activation, Regulatory, and Protocol Development - Work in progress

Development of a Navigation Tool to Guide Investigators from Study Concept, Through First Stage Review to Cancer Center Scientific Review

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1. Background
Scientific review of clinical protocols is a National Cancer Institute (NCI) expectation for cancer centers. Processes as to which types of protocols required first stage review, which types of protocols were exempt from the protocol review and monitoring committee review, and how these operations and composition differed were poorly defined at the University of Vermont Cancer Center. This led to confusion and frustration on the part of investigators, delays in study development and evaluation, and a breakdown in collaboration among investigators and clinical trials office staff.

2. Goals
To develop a navigation tool for investigators and transdisciplinary team (TDT, disease-focused first stage review groups) leaders that defines and improves the efficiency of protocol review, shortens study processing times, reduces stakeholder confusion and frustration, and supports improved collaboration among investigators and clinical trials office staff.

3. Solutions and Methods
We developed a user-friendly web-based navigation tool that clearly defined delineated pathways of study review for investigator-initiated, national cooperative group, and industry trials, and it guided appropriate review pathways for non-interventional and correlative research studies.

4. Outcomes
Immediate implementation outcomes included: 1) investigators and TDT leaders developed an improved understanding and acceptance of NCI review processes; 2) investigators developed an improved understanding of the role of the clinical trials office in the protocol review process; 3) a clearly defined and delineated point of entry to the protocol review and monitoring system. Additional anticipated outcomes for which data is currently being collected: 1) improved process review timelines for studies, particularly investigator-initiated trials; 2) greater acceptance of TDT leadership role and responsibilities in the first stage review process.

5. Lessons Learned and Future Directions
Before navigation tool implementation, investigators were not cognizant of the various activities performed by the clinical trials office staff or the amount of effort in shepherding protocols through the system. Confusion about the processes led to frustration and reduced enthusiasm to develop and activate trials. Since this time, investigators have had less confusion and frustration, and improved collaboration among the clinical trials office staff. Further, the navigation tool has resulted in an increased number of protocols in development. When implementing new tools, early investigator education is pivotal to enhancing engagement, collaboration, and robust clinical trials efforts.