Category: Cross-cutting Innovation and Collaboration – Work in Progress

Academic Collaborations for DSMB Oversight of High Risk IITs

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1. Background

The University of Florida (UF) Research Conflict of Interest office (RCOI) exists to ensure regulatory and institutional compliance and promote the highest ethical standards in research. In 2024, risk mitigation plans were executed by RCOI for a portfolio of cancer-related Investigator Initiated trials (IITs) because of individual and institutional COI that could potentially bias the research. Individual COI was mitigated through restricted investigator access to study data. Institutional COI mitigation required data and safety assessments through an independent external Data Safety Monitoring Board (DSMB).

To support these IITs with limited budgets, UF Health Cancer Center (HCC) sought collaboration with another academic cancer center to provide DSMB oversight for UF clinical trials governed by institutional risk mitigation plans.

2. Goals

- Facilitate translational science by ensuring RCOI concerns are appropriately managed
- Establish a relationship across National Cancer Institute (NCI) designated centers that will set the stage for mutual trial operation support

3. Solutions and Methods

UFHCC partnered with the NCI-Designated Comprehensive Cancer Center, Huntsman Cancer Institute (HCI) at the University of Utah to provide external DSMB oversight. A statement of work (SOW) outlining roles and responsibilities, including budget, was negotiated and a contract was executed. The HCI DSMB is responsible for reviewing Serious Adverse Events (SAEs) in real time, cumulative Adverse Events (AEs), deviations, cohort escalation/de-escalation decisions, and makes recommendations for study closure if concerns justify.

Study auditing is performed quarterly by the UFHCC Compliance office as outlined in the UFHCC NCI-approved Data Safety and Monitoring Plan (DSMP). Their findings are presented to the HCI DSMB. The UFHCC auditor reviews 100 percent of study participants after their first visit, and at follow-up visits, 50 percent of participants since the previous review. Complete reports are compiled by the UFHCC team and provided to the HCI DSMB prior to each meeting. The Principal Investigator (PI) and study team are responsible for attending HCI DSMB meetings when their trials are due for review.

4. Outcomes

Currently, the HCI DSMB oversees two IITs. Initial feedback reported that the submission and review process for DSMB evaluations were conducted with minimal disruption, ensuring an efficient workflow. The collaboration has been characterized by professionalism and mutual respect. Strong communication channels were established, ensuring prompt responses to queries or concerns. In addition, leveraging another DSMB's expertise enhanced the quality and depth of safety oversight and allowed important translational science to move forward under a stringent RCOI plan.

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5. Learned and Future Directions

Collaborating with an academic external DSMB provides access to specialized expertise in cancer research while enhancing the quality of safety oversight while mitigating institutional COI. Outsourcing this function proved to be a cost-effective solution compared to commercial alternatives, without compromising the quality and gaining professional networking between cancer centers. Study teams adapted well to the external DSMB processes, demonstrating the feasibility of integrating this model into existing workflows. Moving forward, we hope to explore opportunities to engage the HCI DSMB for additional clinical trials and reciprocate the oversight offerings. Cross center collaborations such as this should be highlighted in the Cancer Center Support Grant (CCSG) application and review.