Understanding Challenges in Clinical Research at the VA: Strengthening Collaboration in Clinical Research for Sustainable Growth

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Background

Thousands of investigators nationwide conduct research at VA facilities, addressing issues that impact Veterans. At our Indianapolis location, many VA investigators are also medical doctors, providing them with firsthand insight into patient needs. Over the years, our VA has collaborated with Indiana University (IU) Clinical Trials Office (CTO) to establish a strong clinical trial program. However, staffing shortages and training demands have resulted in high turnover, leading to decreased enrollment at the Indianapolis Roudebush VA Medical Center (VAMC).

Over the past decade, the VAMC has averaged nine annual enrollments across therapeutic and non-therapeutic oncology trials. Similar declines have been observed across all Disease-Oriented Teams (DOT) and Satellite Sites. In response, IU Cancer Center leadership tasked each team with developing business plans to establish accrual targets and outline staffing needs. As a Satellite Site, the VA primarily conducts trials in Thoracic, Multiple Myeloma, Radiation Oncology and other hematologic diseases.

Goals

Identify ongoing challenges at the VAMC as a satellite site and propose a restructuring plan to better support clinical trial staff. This proposal was submitted to IU leadership for approval, aiming to align staffing levels with accrual goals, visit numbers, and trial complexity using the Schwarz Cancer Center's success as a model.

Current Challenges

- **Understaffing**: Limited personnel hinder enrollment and research operations. Staff turnover disrupts progress.
- **Training Demands**: High learning curve due to VA security protocols, regulatory requirements, and IU policies.
- **Support Needs**: VA-based staff often feel isolated from their IU counterparts.

Plan

Dedicated Staffing Model

The Schwarz Cancer Center successfully built its satellite research program by maintaining dedicated onsite staff. Historically, the VAMC has operated as an IU Satellite Site, allowing staff to rotate between institutions. However, this limits staffing capacity. Adopting a dedicated staffing model, like Schwarz, is crucial for growth.

Core Team:

- 1 FTE Clinical Research Coordinator (CRC) and 0.5 FTE Clinical Data Coordinator (CDC) currently support 17 active trials in Thoracic, Multiple Myeloma, Radiation Oncology, and other hematologic diseases.
- Increased accruals will require additional support, including a Clinical Research Specialist (CRS), Biospecimen Lab Technician (BLT) to manage correlative sample processing and a Regulatory Compliance Coordinator (RCC) to handle VAMC Research and Development Committee approvals.
- Routine monthly meetings with regulatory and compliance teams have been established to enhance collaboration and prioritization of trials.

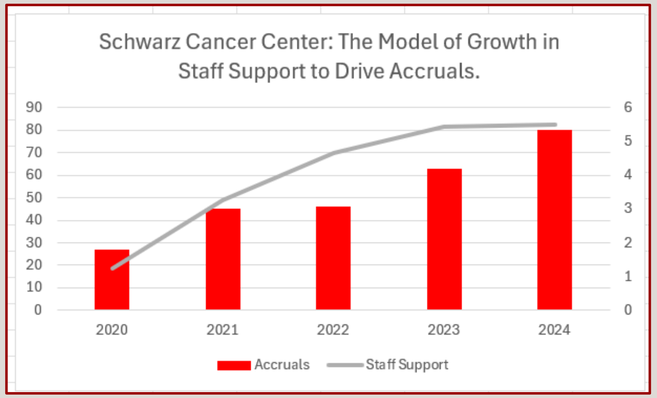
Training Program

- **Resource Development**: Enhanced orientation with VA-specific training modules and shadowing opportunities (IDS, infusion, compliance teams).
- **Compliance Overview**: Direct engagement with the VAMC Compliance Officer to ensure regulatory adherence.
- **Increased Communication**: Weekly emails featuring trial updates with QR codes for quick access to trial portfolios.

Budget Considerations

Funding for VAMC research staff primarily comes from IU's CTO, with additional VAMC support for 1 FTE CRC. A Biospecimen Collection and Banking Core position for 1 FTE Lab Tech at IUSCCC Satellite Sites is already approved and pending deployment.

By implementing these strategies, we aim to strengthen the VA's clinical trial program, enhance staff retention, and increase Veteran participation in research.



Conclusions

Staffing, training, communication, infrastructure, and staff retention are critical to the continued growth of the VAMC's clinical research collaboration with IUSCCC.

Implementing a dedicated staffing model, strengthening training programs, improving communication channels, and enhancing infrastructure support will ensure long-term success. By following our strategic plan, we aim to increase research capacity, improve staff support, and expand Veteran participation in clinical trials.