Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Driving the Efficient Development of Investigator-Initiated Trials through Streamlined Processes and Faculty Engagement

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1. Background

Investigator-initiated trials (IITs) drive innovation at National Cancer Institute (NCI)-designated cancer centers by enabling Principal Investigators (PIs) to translate expertise, laboratory findings, and clinical observations into novel clinical trials while expanding patient access to new treatments. However, initiating IITs presents challenges such as funding constraints, complex regulatory processes, administrative hurdles, and limited resources for trial execution, including medical writing, statistics, and project management.

The Protocol Development Office (PDO) was established in 2019 to support PIs in the development and management of clinical trial documents (CTDs) from initial concept to activation at the University of Miami Sylvester Comprehensive Cancer Center (UM SCCC).

2. Goals

1. Achieve 30 percent open interventional treatment trials designated as IITs at UM SCCC by 2028
2. Ensure PDO support for all interventional treatment IITs initiated by UM SCCC faculty by 2030

3. Solutions and Methods

A variety of strategies were enacted to achieve these goals.

<u>Scope</u>

The PDO provides two key support services:

1. Assisting with CTD development
2. Managing completed CTD packages through the project development pathway

<u>Standardization of Processes</u>

- Investigators must meet eligibility criteria prior to collaborating with the PDO
- Eligible IITs follow a structured CTD development process, including:
    1. Gathering source documents
    2. Hosting a kick-off meeting with key stakeholders
    3. Iterative CTD development
    4. Support Food and Drug Administration (FDA) submission packages (for FDA-regulated trials)
    5. Addressing institutional review feedback
    6. Trial maintenance

<u>Tools</u>

The PDO developed a SharePoint site with IIT templates and resources to facilitate PI engagement.

<u>Involvement of a Medical Director</u>

From 2019 to 2021, the PDO consisted of a manager and a faculty member who defined eligibility criteria for PDO services, designed CTD templates, and built connections between the PDO and Investigators.

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In 2022, a medical director was appointed to enhance faculty engagement, streamline IIT development, and expand the number of IITs. Serving as a liaison between PIs and the PDO, the medical director oversees the entire IIT lifecycle from initial concept development, CTD management, and trial initiation. Additionally, the medical director plays a key role in educating junior investigators through formal lectures and one-on-one mentorship, guiding them through the trial development process.

4. Outcomes

Goal 1 Progress

IIT-classified trials increased from 14 percent in 2019 to 25 percent in 2025.

Goal 2 Progress

PDO support for IITs initiated by UM SCCC faculty grew from 45 percent in 2019 to 78 percent in 2025.

Impact of PDO-Supported IITs

A PDO-supported IIT led by UM SCCC faculty resulted in the inclusion of a novel combination treatment, loncastuximab plus rituximab, in the National Comprehensive Cancer Network guidelines as a treatment option for patients with follicular lymphoma who have failed at least two prior therapies, highlighting the PDO's impact in advancing innovative IITs.

5. Learned and Future Directions

IIT implementation can be improved by strengthening partnerships between the PDO and other UM SCCC departments including intramural funding programs, administrative support services, and new research programs. The PDO will expand support to all IITs and enhance collaboration to reduce IIT-related hurdles.

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