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

Norma Magallanes, MS; Emily Andreae, PhD; Phillip Arlen, PhD; Jonathan Trent, MD, PhD; Dickran Kazandjian, MD
University of Miami Sylvester Comprehensive Cancer Center

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 present 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) (e.g., protocols, informed consent forms [ICFs], protocol clarification letters [PCLs] and Investigational New Drug [IND] applications) from initial concept to activation at the University of Miami Sylvester Comprehensive Cancer Center (UM SCCC).

GOALS

- **Goal 1:** Achieve 30% open interventional treatment trials designated as IITs at UM SCCC by 2028.
- **Goal 2:** Ensure PDO support for 100% of interventional treatment IITs initiated by UM SCCC faculty by 2030.

SOLUTIONS AND METHODS

1. Defined PDO scope for key support services:

a. Assisting with CTD development (e.g., protocols, ICFs, PCLs, and IND applications)
b. Managing clinical trial packages through the project development pathway and maintenance phases

2. Standardization of Processes:

a. Investigators must meet eligibility criteria prior to collaborating with the PDO
b. Eligible IITs follow a structured CTD development process, including:
   - Gathering source documents
   - Hosting a kick-off meeting with key stakeholders
   - Iterative CTD development with key internal and external stakeholders
   - Initial IND applications to the Food and Drug Administration (FDA), if applicable
   - Addressing feedback from the Protocol Review and Monitoring Committee (PRMC), Institutional Review Board (IRB), and any other applicable ancillary committees
   - Provide support with trial maintenance (e.g., amendments)

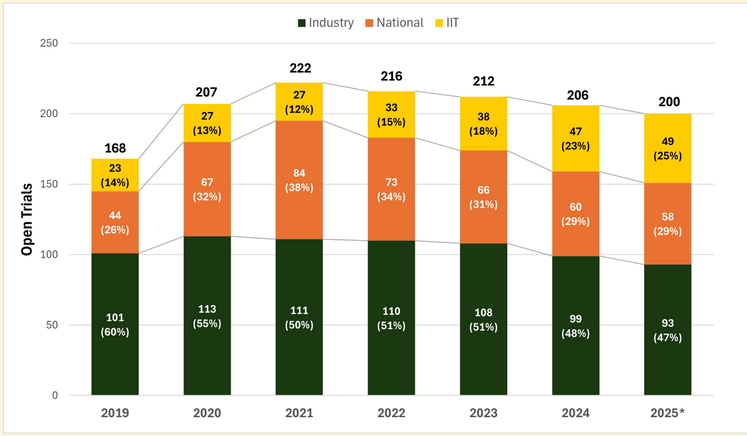
3. Tools: The PDO developed a SharePoint site with IIT templates and resources to facilitate PI engagement

4. Involvement of a Medical Director: A medical director was appointed to:
   - Enhance faculty engagement
   - Streamline IIT development
   - Expand the number of IITs
   - Serve as a liaison between PIs and the PDO by overseeing the entire IIT lifecycle from initial concept development to trial completion
   - Educate junior Investigators through formal lectures and one-on-one mentorship, guiding them through the trial development process

OUTCOMES

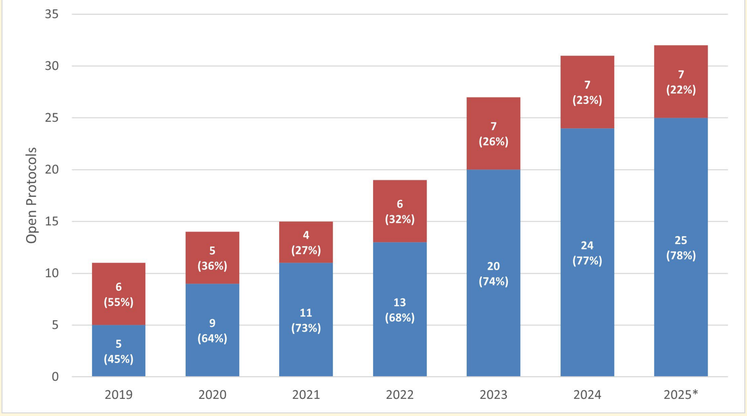
Goal 1 Progress: Percentage of ITTs increased from 14% in 2019 to 25% in 2025.*

*Partial 2025 data (January 1 to March 1)



Goal 2 Progress: PDO support for IITs initiated by UM SCCC faculty increased from 45% in 2019 to 78% in 2025.*

*Partial 2025 data (January 1 to March 1)



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.[1,2]

[1] NCCN. Clinical Practice Guidelines in Oncology. B-cell lymphomas VAoF, 2025. *Accessed on 6 May 2025*
[2] Alderuccio, Juan Pablo, et al. Loncastuximab tesirine with rituximab in patients with relapsed or refractory follicular lymphoma: a single-centre, single-arm, phase 2 trial, *The Lancet Haematology*, 2025. Volume 12, Issue 1, e23 - e34

LESSONS LEARNED

Clearly defining the scope of support services is crucial for streamlining processes and ensuring that all stakeholders are aligned. Additional considerations to enhance IIT implementation include strengthening partnerships between the PDO and other UM SCCC departments, including intramural funding programs, administrative support services, and new research programs. The PDO plans on expanding the team to ensure support for all IITs and enhance collaboration to reduce IIT-related hurdles.