Category: Trial Start-Up, Activation, and Protocol Development – Work in Progress

Cross-Consortium Oversight and Management of Investigator-Initiated Trials at Lombardi Comprehensive Cancer Center

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1. Background

Lombardi Comprehensive Cancer Center (LCCC) identified a need to more comprehensively support investigator-initiated trials (IITs) consortium-wide. Existing resources dedicated to multisite IITs were insufficient due to lack of centralized single-site IIT oversight, support, and IIT prioritization, and growing investigator interest and IIT portfolio. To address these urgent needs, LCCC developed and implemented an IIT Steering Committee (SC) and a Consortium IIT Office to oversee, prioritize, expand, and adequately support LCCC IITs.

2. Goals

LCCC IIT Steering Committee:

- Ensure appropriate Clinical Trials Office and IIT Office resource allocation in support of LCCC IITs
- Identify opportunities to incorporate LCCC science and LCCC shared resources into IITs

LCCC IIT Office:

- Support investigators in the development, activation, maintenance, reporting, and close-out of IITs across the consortium
- Provide accurate and concise IIT metrics to LCCC Leadership, Clinical Research Leadership (CLR), Program Leaders, and Disease Groups (DG)

3. Solutions and Methods

In 2022, the LCCC CRL established the IIT SC, chaired by LCCC's deputy director and comprised of leaders from across the consortium. The SC meets bi-weekly and accepts nascent LOI concepts to fully developed IIT protocols, and reviews for inclusion of LCCC science, program needs, relevance to LCCC's catchment area, feasibility and alignment with NCI and institutional priorities. The SC ensures appropriate allocation of resources for trial development, activation, and management throughout the consortium.

With cross-consortium institutional investment for twelve additional full-time employees (FTE), the LCCC Consortium IIT Office launched in 2022. The IIT Office provides dedicated resources to support IITs throughout their lifecycle by providing:

- Protocol and budget templates
- Protocol writing support for IIT development and results reporting
- Facilitation of biostatistical support
- All regulatory document submission, maintenance, reporting, and close-out
- Support of trial conduct including multi-site coordination
- Quality control assessments and monitoring

The IIT Office standardized:

- Tracking and reporting on metrics benchmarked against NCI standards (*e.g.,* time-to-activation, accruals)
- Processes and procedures (*e.g.,* role-specific job aids, eCRF validation)
- Templates for investigators (*e.g.,* LOI, protocols, and budgets)
- Trial oversight and monitoring plan, including Data Safety Monitoring Committee compliance

4. Outcomes

LCCC IIT SC:

- Required all new interventional treatment IITs to receive SC review prior to scientific review
- Developed SC submission forms
- Reviewed 12 new IIT concepts, leading to 4 protocol submissions for scientific review
- Identified opportunities to include LCCC science and shared resources and activate protocols consortium-wide

LCCC IIT Office:

- Enhanced metrics reporting via centralized database tracking current portfolio and accruals
- Leveraged medical and protocol writers to ensure high-quality protocols for scientific review
- Effectively ushered IITs through the activation processes to decrease time-to-activation
- Decreased barriers to regulatory management for IITs

5. Lessons Learned and Future Directions

The SC serves a critical role, after DG prioritization, to allocate clinical trials resources. The centralized IIT Office enables efficient conduct of LCCC IITs in support of the LCCC investigator and patient communities. Future directions include: expanding templates and support to interventional non-treatment IITs.