Category: Trial Start-up, Activation, Regulatory, and Protocol Development - Work in progress

The Benefits of Early Administrative Involvement in Investigator-Initiated Trial Concept Development

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1. Background

In 2021, the Lombardi Comprehensive Cancer Center (LCCC) formed an Investigator-Initiated Trials (IIT) Steering Committee (SC) and invested cross-consortium resources for the implementation of a dedicated IIT office (opened 2022), to expand and support LCCC's IIT portfolio. The SC reviews all IITs prior to LCCC Scientific Review Committee (SRC) submission and prioritizes concepts, based on LCCC science and catchment area needs, and assigns IIT office resources accordingly. The office provides LCCC IIT support from conception through trial close-out.

LCCC IITs previously did not have adequate cross-consortium support. National Cancer Institute (NCI)-based metrics, including time to activation (TTA; >300 average days), did not meet expectations. LCCC's clinical trial portfolio was unbalanced, favoring industry sponsored trials. The IIT office provides trial development support to help change portfolio composition, increase cross-consortium participation, and reduce TTA.

2. Goals

- Submit a greater number of concepts to the IIT SC at an earlier stage of development (*e.g.,* Letter of Intent (LOI) development), to encourage early IIT office intervention and support
- Improve TTA for therapeutic IITs through trial development support, including coordination with ancillary LCCC departments and external parties

3. Solutions and Methods

The LCCC IIT Office implemented the following processes to decrease TTA and streamline study activation to better meet NCI-based standards:

- Engendered PI trust in the IIT Office through attending cross-consortium disease group meetings and offering expertise and resources for concept development
- Encouraged PIs to submit to SC at LOI stage, to streamline coordination of ancillary department requests, including budget, contract, and LCCC Shared Resources
- Collaborated with LCCC Biostatistics Shared Resource to refine an IIT specific-submission form for expediting requests
- Liaised with external funding sources and vendors to facilitate faster study development/activation
- Implemented quality control measures, to mitigate delays in SRC and regulatory approval, including two dedicated IIT medical writers, project manager protocol review, and development of IIT-specific protocol templates (*e.g.,* protocol, informed consent, budget templates)
- Encouraged opening of IITs cross-consortium, as appropriate for catchment area

4. Outcomes

Cross-consortium efforts improved the number and quality of protocols in development, supporting LCCC's efforts to meet NCI-mandated metrics. Efforts to encourage early PI submission were successful, resulting in an increase in concepts submitted at the LOI stage from 29 percent in 2022 to 69 percent in 2023. This led to more efficient coordination of budget/contract initiation, access to LCCC Shared Resources, communication with external parties – all potentially rate limiting steps in trial activation.

The early intervention and wrap-around support led to a significant decrease in TTA, by approximately 33 percent (348 days in 2022 to 235 days in 2023).

5. Lessons Learned and Future Directions

IIT office support throughout the lifecycle of therapeutic trials must be robust. Efforts to improve protocol development and TTA required a wrap-around approach. Earlier involvement of the IIT office led to more accurate protocol development in a shorter timeframe and facilitated streamlined communication between the PI and ancillary offices, as well as external funding sources/vendors. Future directions include: expanding study document and budget templates, including for non-treatment trials; creating a formal list of external funding sources; and increased utilization of cancer survivors in protocol development.