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

The Catch 22 of Becoming a Useful Resource; Lessons Learn(ing)ed by the LCCC Consortium Investigator-Initiated Trials Office

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1. Background

Since mid-2022, the Lombardi Comprehensive Cancer Center (LCCC) Consortium Investigator-Initiated Trials (IIT) Office has provided wraparound support for all interventional/treatment IITs cross-consortium. The IIT Office supports LCCC in meeting National Cancer Institute (NCI) designated metrics: time to activation (TTA), portfolio composition, and accruals. In 2023, the IIT Office successfully encouraged investigators to submit their IIT concepts to the IIT Steering Committee at an earlier stage (29% submitted at LOI stage in 2022 vs 69% in 2023) to ensure early IIT Office intervention in protocol development and study start-up. This also resulted in a reduction in TTA of therapeutic IITs by 41 percent between 2021 and 2023. In light of its successes in 2023, the IIT Office was challenged to continue its progress, a request that was complicated by LCCC leadership tasking Lombardi investigators to significantly increase enrollment to therapeutic trials.

2. Goals

Continued support of LCCC's goal to decrease TTA, balance portfolio composition, and increase accruals to LCCC IITs, by providing support for all interventional/treatment trials from concept through closeout, while optimizing workflow to navigate within changing LCCC enrollment goals.

3. Solutions and Methods

1. Enhance already existing IIT workflow by:
    a. Creating new, and better utilizing existing, trackers to maximize IIT Office staff bandwidth (e.g., regulatory start-up/maintenance, Data and Safety Monitoring Committee (DSMC) safety review, study development, patient enrollment)
    b. Intensifying protocol development assistance to ensure studies enter the regulatory process with accurate protocols, helping to decrease TTA and regulatory maintenance work
    c. Increasing communication within Lombardi Clinical Trials Office (CTO), cross-consortium, and with ancillary departments to revamp existing processes for IIT support
2. Optimize regulatory sequence to decrease TTA by doing a head-to-head comparison
3. Bolster IIT Data support by:
    a. LCCC's investment in a dedicated IIT data coordinator (DC)
    b. Delegating all DCs to all IITs, giving data team increased agility
    c. Creating case report form (CRF) questionnaire, given to investigators at study start-up to streamline the number of CRFs for all new IITs and reduce overall IIT data burden

4. Outcomes

- Increased number of activated interventional/treatment trials (8 in 2024 vs 4 in 2022 and 5 in 2023)
- Decreased TTA of interventional/treatment trials by roughly 50 percent from 2023 to 2024, with an overall 70 percent decrease in TTA since IIT Office opening
- Supported a dramatic 62 percent increase in interventional/treatment IITs accruals between 2023 and 2024, with 20 percent of these enrollments coming from IITs activated in 2024Help

inform Institutional optimization of the 2-step budget & calendar release process for billing compliance.
- Billing compliance improvements as protocols were brought up to centralized team standards and workflows.

5. Lessons Learned and Future Directions

- With increased utilization of the IIT Office came increasing challenges, taxing existing IIT resources. This year required strategic thinking and further institutional support
- IIT regulatory specialist, IIT coordinators, and the CTO data team all saw increased workloads.
- The successes of 2023 and the increasing accruals goals forced the IIT Office to optimize operations in 2024 across IIT data, regulatory, and study coordination. Better trackers, increased communication, additional protocol development assistance, and improved data team agility/support were instrumental to continued success
- Next year will require the IIT Office to further harness the power of the consortium by sharing responsibilities (e.g., study monitoring, patient enrollment) to maximize IIT support