Development of a multisite investigator-initiated trial coordinating center at Cedars-Sinai Cancer

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Background

In late 2020, the ability to internally coordinate multisite investigator-initiated trials (IITs) at Cedars-Sinai (CS) Cancer became imperative, due to several factors: a growing portfolio of IITs, investigator interest in conducting collaborative research with other institutions, challenges with accrual to existing IITs, and the cost-prohibitive nature of subcontracting with external coordinating centers for IITs with often limited financial resources. Through implementation of a multisite IIT taskforce, CS Cancer has successfully developed the infrastructure to operationalize the coordination of multisite IITs.

Objectives

- To develop the infrastructure to conduct multisite IITs at CS Cancer, including development of processes, document templates, scope of roles and responsibilities of each team member, and a budget template, for ability to successfully coordinate multisite IITs.
- To demonstrate the cost-savings to the investigator/study.

Methods

A taskforce was formed and convened at weekly meetings over the course of approximately six months in late 2020 to early 2021, with the following objectives: outline the gaps in our documents and processes, seek templates from other institutions to modify for application to CS Cancer, ensure processes are consistent with CS Cancer institutional and regulatory requirements, obtain concurrence with the roles and responsibilities of each team member, and to identify roles and reporting responsibilities of the participating sites. The task force included IIT protocol development staff, with input sought from institutional monitors, the institutional IRB, regulatory staff, and finance staff. Staff members were assigned documents or processes to take the lead on, with others providing input at the taskforce meetings.

Figure 1: Manual of Operating Procedures (MOP) Table of Contents

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Outcomes

The taskforce developed the following processes and document templates relative to multisite coordination: budget, protocol, manual of operating procedures, lab manual, pharmacy manual, site feasibility and qualification documents, site initiation visit templates, OnCore and REDCap external user guides, regulatory and enrollment trackers, site meeting agenda, and monitoring and close-out checklists. In addition, the scope and expectations of the multisite lead, as well as the role of central regulatory and finance team members contributing their efforts to multisite IITs, were outlined in detail. An estimate of regulatory and monitoring time and effort based on risk level was developed. Whereas, in our experience, the cost of subcontracting to an external coordinating center begins at around $1,000,000, we determined that the cost of internal coordination of multisite trials ranges from around $150,000 - $300,000 depending on complexity and duration, based on anticipated number of hours of staff effort and an average hourly rate, making internally coordinated multisite IITs much more feasible to accommodate within a study budget.

Lessons Learned and Future Directions

CS Cancer is currently implementing this new infrastructure with two multisite IITs. We anticipate our processes and document templates will continue to evolve as we gain experience and identify areas for improvement. In the future, depending on the speed with which multisite IITs are introduced, it may become necessary to allocate resources for a multisite IIT lead or team.