

## **Implementation of a Coordinating Center for Multisite Investigator-Initiated Trials at Cedars-Sinai Cancer: Project Review, Key Insights, and Future-Proofing**

D. Ngo, A. Tan, E. Hautamaki, P. Chang, M. Malikowski

### *Cedars-Sinai Cancer*

#### **1. Background**

Within five years, Cedars-Sinai Cancer Center (CSCC) has developed and implemented a robust Coordinating Center to support multisite investigator-initiated trials (MIITs). MIITs can enhance accrual, expand cutting-edge research to diverse populations across geographic areas, and foster collaboration between institutions. Investing in a proficient Coordinating Center is crucial for meeting this growing demand. Leveraging insights from four active MIITs offer opportunities to embrace “trial and error” and apply key strategies to future-proof our Coordinating Center.

#### **2. Goals**

Our aim is to create a scalable model to meet the increased demand for MIITs, and to enhance our Coordinating Center’s capabilities to efficiently activate and effectively manage MIITs. Building upon our initial experience, we aim to build a long-term plan for “future-proofing” the CSCC Coordinating Center operations.

#### **3. Solutions and Methods**

Qualitative and quantitative methods include site activation timelines, identifying patterns and rate limiters, accruals, site engagement, and coordinating center staff effort. Utilizing valuable insights gleaned from active observation and analysis of infrastructure performance will allow us to integrate long-term strategies for sustainability.

#### **4. Outcomes**

The CSCC Coordinating Center opened its first MIIT (“MIIT1”) on June 12, 2023 and currently have four MIITs with 14 total sites. As of February 2025, 10 of 14 sites have been activated, 14 sites IRB approved (local and single IRB), 13 SIVs and 12 monthly all-site meetings conducted, with eight resource materials developed and ad hoc trainings tailored to sites’ needs. Average attendance for monthly all-site meetings is 25 participants, with consistent communications post-calls, indicating active site engagement trends. Eight hours per month were initially estimated for ongoing site support of all sites per MIIT. Actual average is closer to 20 hours, revealing a 150 percent difference which discloses needed revisions to MIIT effort allocation in budgeting and staffing. Average time to activation was 11 months, with rate limiters linked to subsite budgets, contracting, site staff changes, ICF reviews to harmonize local vs. single IRB, site PI transitions, and level-setting institutional policies – the latter being the largest variable due to time needed to assess site policies and practices. All surmountable, early results and progress from our four MIITs show that our Coordinating Center is a worthwhile investment. Figure 1 uses MIIT1 as a case study, offering a realistic glimpse into Q1-Q4 2024 milestones achieved. The greatest value added for running a MIIT is demonstrated by MIIT1’s 145 percent jump in total accruals from Q2 to Q4 (one vs. four sites activated).

5. Lessons Learned and Future Directions

Key insights from our first MIITs present opportunities to future-proof by focusing on: accurate budgeting to secure adequate funding and staffing (increase cost-effectiveness), keener assessments at site feasibility to tease out potential conflict between institutional SOPs and requirements (reduce time to activation) and developing flexible templates and training materials accommodating sites’ needs. It is fundamental to learn and understand each site’s varied characteristics, leading to better planning for potential future needs and for running a successful Coordinating Center. CSCC anticipates that our MIITs will enable our investigators to conduct larger-scale, more impactful IITs, that allow for more equitable access to trials through community sites.

Figure

