Category: Network Operations, Decentralized Trials, and Multi-site Research - Work in progress

Deploying the Enterprise-Wide Project Manager: Disease Group-Driven Clinical Trial Expansion to Regional Research Sites

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1. Background

In a span of less than five years, Jefferson Health expanded to include a total of 17 hospitals through recent mergers and acquisitions, requiring Sidney Kimmel Cancer Center (SKCC) to expand cancer services across the enterprise. SKCC presently has expanded clinical trial operations to four Regional Research Sites (RRS), requiring increased coordination of clinical trial operations between the central academic medical center and RRSs. In late 2020, leadership started a pilot project with the breast and gynecological oncology multi-disciplinary groups (MDG), establishing an Enterprise-Wide Project Manager (E-W PM) role to champion this research expansion. Though these MDGs now successfully run enterprise-wide (E-W) operations; expansion of this model across all 10 SKCC disease groups has been slow, due in part to a pause during the COVID-19 pandemic and associated staff turnover, followed by our Cancer Center Support Grant renewal. While many of SKCCs 10 disease groups do have limited trial activity at the RRSs, equipping PMs as E-W via a toolkit will provide a concerted approach to expansion.

2. Goals

This initiative will review current successes and barriers to E-W MDG expansion, development of a standardized toolkit to support the MDG PM in moving their portfolios E-W, and subsequent progress by disease groups toward E-W expansion.

3. Solutions and Methods

Current achievements include:

- Development of a site management principal investigator oversight plan
- Updated MDG SOP inclusive of RRSs
- Inclusion of E-W tasks on SKCC study start-up checklist
- E-W and RRS PM collaborative study start-up and activation
- Monthly E-W coordinator meetings with RRS staff
- E-W MDG meetings with staff and investigators participating in E-W MDG clinical trials

In-progress initiatives include:

- Comprehensive E-W PM workflow for study feasibility, start-up, conduct, and closeout – which delineates roles and responsibilities for both the E-W and RRS PM
- Development of site-specific facility/feasibility packets
- Implementation of a sponsor and physician engagement action plan to inform next steps in engaging these stakeholders as the PMs partners in E-W expansion

Lessons learned from the pilot will inform the development of the E-W Toolkit, including guidance for early communication with sponsors about SKCC RRSs, adjusted expectations for start-up timelines, inclusion of RRS investigators in E-W disease group meetings, and assignment of an MDG specific regulatory coordinator.

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4. Outcomes

Project deliverables include a retrospective and prospective timeline for E-W expansion, a comprehensive support plan for moving MDGs E-W, quantitative assessment of current E-W trial activation and accrual by MDG, and quantitative and qualitative summary of progress and challenges voiced by SKCC PMs and PIs. This E-W toolkit will guide continued E-W expansion across SKCC.

5. Lessons Learned and Future Directions

The current assessment reviews progress and pitfalls, and future analyses will evaluate change over time in E-W study activations and accruals. Key recommendations include promoting communication and documentation around multi-site approval and Investigational Product shipment; applying careful selection criteria to which studies are appropriate for E-W; and accounting for the added administrative burden of moving all MDGs to E-W.