Category: Trial Start-up and Activation – Work in Progress

Enhancing Transparency and Interoperability: Developing an Enterprise-Level Portal to Streamline Trial Activation Processes

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1. Background

The protocol activation timeline is one of the most critical areas for process improvement at Sylvester Comprehensive Cancer Center (Sylvester). To accurately track metrics and identify roadblocks, we recognized the need for collaborating departments to communicate effectively and access data easily and efficiently. The many applications and various methods for collecting information (i.e., paper, digital, etc.) resulted in competing data sets and data islands; therefore, we sought a way to consolidate key dates and data in one easy-to-use portal. This study describes the process for developing and implementing this portal, the Operational Portal Enhancing Research Activities (OPERA), with the goal of capturing all steps within the clinical trial life cycle to provide transparency to research staff and faculty.

2. Goals

The implementation of OPERA was intended to integrate and automate the work packages comprising the protocol life cycle, creates a single "source of truth" that aggregates data from multiple systems, minimizes the number of physical/paper processes, helps visualize workflows and captures relevant data for understanding and managing workload and performance.

3. Solutions and Methods

OPERA was built to gather data from several independent data sources, both external and internal, as well as to capture supplemental data that align with Sylvester's operational requirements. Due to the scale and complexity of OPERA, and the current constraints on internal resources, the project work was implemented one milestone (module) at a time; prioritized by the sponsor; and delivered, through a hybrid-agile project management method. Each module was estimated to take about 48 business days to complete. Each module was treated as an individual project and adhered to the project life cycle/resources available to support the project work.

4. Outcomes

- 100 percent of new studies have benchmark data to monitor progress toward achieving goals for trial activation
- More than 1,000 protocols have been captured in OPERA to date
- 323 accrual reviews and 519 amendments have been captured in OPERA in its first year of use
- Having the data electronically accessible in a single place has allowed for an easy transition to a remote work environment due to COVID-19

5. Lessons Learned and Future Directions

Iteratively adapting each module allowed for testing and drawing feedback before and after launch. With each newly implemented module, we made tweaks to help improve the process for the next iteration. As a result of the data collected, we have begun incorporating the data into dashboards and reports, enabling further improvements in protocol activation time and transparency. For the future of OPERA, to further enhance transparency and interoperability, the implementation of trial maintenance and closure components will be implemented.

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