Cateogry: Trial Start-up and Activation – Completed Project

Enhancing 1st Stage Protocol Review – A Quantitative Approach

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1. Background

Clinical trial success is contingent upon a thoughtful and robust feasibility assessment. Protocols that do not fit our catchment area's needs and patient population are unlikely to accrue and waste time, money, and resources. Like most centers, we experienced significant staffing challenges across the entire enterprise post-pandemic. This coupled with trial complexity and increasing pressures to decrease start-up timelines have challenged us to evolve new approaches to trial review.

Our first stage review is conducted at the disease program level. However, we lacked set review standards, so it was unclear how effective these meetings were, what percentage of trials were declined, and why. Since first stage review happens early in the protocol activation lifecycle, we recognized the opportunity to make this process more robust to ensure we use our resources efficiently. We set out to better understand the effectiveness and outcomes of the process and identify areas of improvement.

2. Goals

We worked with our 14 disease-specific programs to enhance, organize, and document our first stage review to ensure our cancer center thoroughly vets trials, and:

- Provide a standardized system to track and streamline our first stage review documentation
- Create a quantitative metric to guide the first stage review discussion to focus our efforts and resources on the most value-added trials

3. Solutions and Methods

We developed a web-based first-stage dashboard to track clinical studies our disease programs considered for participation. Teams logged all trials presented and documented the outcome (i.e., approve, decline), outcome reason (i.e., competing trials, patient population), and a prioritization ranking to focus study start-up efforts.

We created a feasibility sorecard to provide a quantitative metric for programs to use when deciding whether to pursue a trial. The scorecard considers the following elements:

- Trial source and phase
- Competing trials
- PI authorship
- scientific merit
- patient population/accrual goals /duration
- network participation
- financial impact
- Sponsor relationship (new sponsor, established sponsor, master CTA, rate cards)
- cancer center and institutional resources (staffing, facilities, etc.)

Within each category, individual responses were scored. Overall score ties to color-code of green,

yellow, red. Certain elements such as institutional trials, patient population, and competing trials are weighted higher and thus have a greater impact on overall score.

Green = Recommend
Yellow = Use caution
Red = Strongly recommend declining

4. Outcomes

The feasibility dashboard has increased overall visibility surrounding the volume of studies presented to our disease groups and their outcomes. Data shows a balanced process with comparable rates of approving and declining of studies.

Physicians and study staff have been overwhelmingly receptive to implementing the scorecard. Program leaders are challenged with maintaining a balanced portfolio and the scorecard provides them with a quantitative tool to guide their colleagues and recommend declining at risk studies. The scorecard also guides discussion around topics that have never been openly considered when deciding to move forward with a study. These upfront conversations about current staffing and workload resulted in positive staff feedback. We hope that by acknowledging their workload as part of the process will improve staff satisfaction and retention rates. Lastly, the process includes upfront input from our network physicians which is crucial to ensuring we meet the needs of our community sites.

5. Lessons Learned and Future Directions

Initially, our first stage review process felt like another layer added to an already lengthy start-up process. However, we recognized that having a robust, standardized process empowered disease programs to focus on multidisciplinary needs instead of individual investigator interests. Moving forward, we will continue to monitor this data and enhance our standard definitions of review outcomes. By doing this we can proactively assess programs and resource needs. For example, if studies that would have filled an unmet need are continually declined due to lack of staffing or other resources, we can adjust by increasing staffing levels in those programs. We also want to allow disease programs to tweak the scorecard to make it more disease-specific to increase the effectiveness of the tool. We will begin to track the scorecard metrics and compare them to outcome decisions (e.g., does a trial with red score correlate with program decision to approve or not).

Lastly, we will closely track if our enhanced review process improves our study start-up timelines, increases participation and enrollment at our network sites, increases number of trials that meet accrual targets, and improves our overall workload.

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Figure: