Enhancing 1st Stage Protocol Review - A Quantitative Approach

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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.

At our center, we rely on the disease programs to conduct the 1st Stage Review. However, we lacked set review standards, so it was unclear how effective these meetings were, what percentage of trials were declined, and why. We recognized the opportunity to enhance our 1st Stage Review process to make this process more robust. We set out to better understand the effectiveness and outcomes of the process and identify areas of improvement.

To this end, we worked with our 14 disease programs to enhance, organize, and document their 1st Stage Review to ensure our cancer center thoroughly vets trials, and:

- Provide a standardized system to track and streamline our 1st Stage Review documentation.
- Create a quantitative metric to guide the 1st Stage Review discussion to focus our efforts and resources on the most value-added trials.

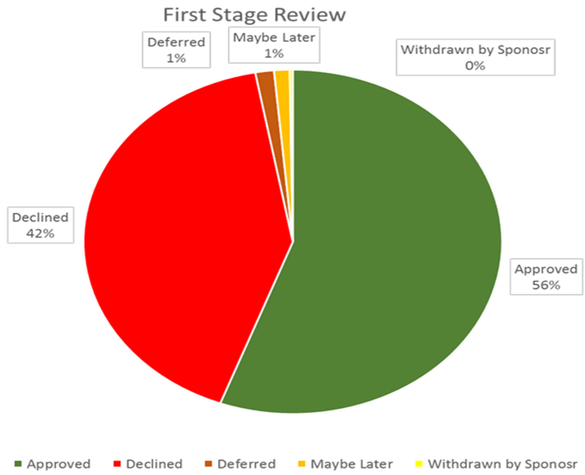
MATERIALS AND METHODS

We first developed a web-based 1st 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 then created a Feasibility Scorecard to provide a quantitative metric for programs to use when deciding whether to pursue a trial. 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.

RESULTS

The Feasibility Dashboard has increased overall visibility surrounding the volume of studies presented to our disease groups and their outcomes. It also increased conversation regarding clinical trial portfolios, resources, and needs of our program. 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 study portfolio and the scorecard provides them with a quantitative tool to guide their colleagues and recommend declining potentially risky 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.

1st Stage Feasibility Tool

Area of Determination	Points	0	1	2	Σ PTs	Wt.Score
	Trial Type		Externally Sponsored (Pharma, External Academic IIT/Foundation)	IIT/U10	2	0.04
	Phase	Compassionate use/Expanded Access or Phase IV	Phase 3 or Phase 2	Phase I/novel - first in human	2	0.04
	Competing Trials	≥ 2 competing trials	1 competing trials	no competing trials	2	0.13
	PI Authorship/Scientific Merit	no	maybe	yes	2	0.04
	Pt Population/Accrual	≤5	≥6-14	15+ or targets rare patient population	2	0.04
	Network Participation	no		Yes, maybe if sponsor agrees or NO because not appropriate (CAR-T)	2	0.04
	Financial Impact	No funding	Some funding (eg: industry- IIT, grant funded,)	adequate funding (eg: industry)	2	0.13
	System Resources (master CTA, rate cards)	Brand New Sponsor/Never worked with us before	Worked with Sponsor in past and/or Master CTA	Master CTA +Master Rate Card	2	0.13
	Program Resources (consider CRCs, DMs, Reg)	low staff	moderately staffed	fully staffed	2	0.13
	Institutional Resources (URA, Budget, IRB)	low staff	moderately staffed	fully staffed	2	0.13
	Duration until Enrollment Closes	≤ 6months	≥6-12	≥12-24 months	2	0.13
				Priority Score (22 points)	22	1.00

Green = Recommended

Yellow = Use Caution

Red= Strongly Recommend Declining

FUTURE DIRECTIONS

Initially, our 1st 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 multi-disciplinary 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 modify 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 and study performance (e.g. does a trial with red score correlate with program decision to approve or not; does the initial score reflect actual study enrollment, ease of activation).

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.