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

Automatic Study Cost-Outs: A Tool Designed to Objectively Assess Trial Operations Costs for More Standardized and Efficient Budget Negotiations While Improving Overall Study Time to Activation

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1. Background

One aspect considered for protocol time to activation includes the preparation, development and negotiation of the budget. During budget preparation clinical research managers must prepare an operations cost-out to determine the amount of staff hours required for each visit. The current cost-out process is subjective and has demonstrated, on occasion, to over or underestimate staff efforts on the studies, and cause delays as clinical research managers try to open an increased number of protocols relevant to the catchment area's needs. The lack of detail and standardization also negatively impacts the timeline for budget negotiation when sponsors request justification for requested costs. An automatic and objective summary of operational efforts standardized across the Hillman Cancer Center Clinical Research Services (HCC CRS) trial portfolio can significantly improve each of the aspects referenced above.

2. Goals

Our automatic cost-out evaluates specific tasks described in protocol study calendars and assigns those study related tasks a pre-determined level of effort. This calculation allows our clinical research fiscal team to objectively prepare comprehensive and accurate budgets. The automation can generate time savings in many aspects of budget preparation and negotiation. Primarily, it will eliminate the time required to prepare a manual cost out; likewise, the fiscal team will no longer need to wait for the cost out to prepare the study budget. Automation will also streamline communication between the fiscal team and the clinical research managers by providing additional task-specific details to justify budget requests to sponsors. Our expectation is that the above will result in a decrease in our overall trial activation time at the Hillman Cancer Center and a comprehensive, detailed and consistent reflection of time needed for each task.

3. Solutions and Methods

Our home-grown database, Clinical Trial Management Application (CTMA), is populated during study start up with a study schema that includes each assessment required at each time point per the protocol calendar of events. Each assessment is given a specific code that is associated with an allotment of time that will be multiplied by the hourly budget rate relevant to the study team member performing the task. The clinical research fiscal team is then able to run an automated report that will produce a study specific cost out with calculated efforts for nurse coordinators, data coordinators, and clinical research managers.

4. Outcomes

The outcome of this automated process will allow HCC CRS to reduce the number of days it takes for a cost-out to be developed, prepared for submission and negotiated. Its implementation will give clinical

research managers vital time back to focus on staff and protocol execution and provide the fiscal team with a more objective and consistent budget for efficient budget negotiations.

5. Lessons Learned

The Hillman Cancer Center is currently assessing many aspects of trial activation including contracts, IRB review, and implementation. A key element and identified sticking point are budget negotiations. The Automatic Study Cost-Out tool will assist in reshaping how study start up is organized and carried out leading to improved time to activation, comprehensive and consistent budget detail, and the ability to process more studies in a shorter timeframe.