Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Visibility is vital: Utilizing Project Management tools to track timelines and metrics

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1. Background

With the increasing need to optimize the study activation process, the ability to track study metrics and timelines is essential. Leveraging available project management tools enables us to identify trends in timelines, analyze delays, and pinpoint areas that require greater attention to improve overall activation goals. Typically, team such as regulatory and finance might maintain their own individual trackers and follow respective timelines. While these teams often collaborate on key steps, having a unified tracker that consolidates all details in one place enhances transparency and provides a comprehensive narrative of the entire study start up process.

2. Goals

The goal is for research sites to be able to utilize project management tools and software such as Smartsheet, Monday.com, Microsoft (MS) Project and Tableau to enhance visibility into study activation metrics. By structuring the project plans into phases with defined predecessors, teams can efficiently initiate next steps. Team leads or the project manager can track metrics, trends and report to leadership teams to assess what areas need more improvement and might need timelines to be better for future studies. This metric tracking along with dashboards, enables the institution to track, report, analyze and brainstorm any new ideas to improve timelines. At Cedars-Sinai Cancer, we transitioned from Microsoft Excel to Smartsheet in January 2024 to improve metric tracking. This shift enables greater automation, such as triggering SIV scheduling as soon as the budget and contract are finalized. A formula-driven notification system alerts the Activation PM and clinical team to initiate SIV date planning. The overall goal is to maximize Smartsheet's automation tools to increase visibility, improve efficiency, and enable teams to work more seamlessly.

3. Solutions and Methods

Smartsheet has several templates that can be utilized based on each site requirements. We built our tracker using the Project Management Office (PMO) template that enables us to track as many studies as we need through project level and portfolio level metrics creation. We built our tracker using the base PMO template and added all our tasks from scratch. We created formulas that calculate the number of days each task takes so we can calculate average number of days across all studies.

Each task in Smartsheet includes a start date, end date, and the assigned team members' name. Users can filter the view to focus on only their tasks and enter dates. Each task also has a comments button that allows for real-time updates, while a status column tracks progress with options such as Not started, In progress, Completed, Cancelled or Not applicable. Additionally, tasks with predecessors ensure that tasks can only begin once a prior linked task are completed. This template enables us to track days and tasks either from start to finish or start to start in parallel so we can view all ongoing activities in one location. The Smartsheet dashboard functionality further enhances visibility by displaying average timelines and an overall picture of project status. Features such as connecting to OnCore and Tableau, are yet to be explored. Another feature Smartsheet has is the ability to connect an entirely different sheet to our activation project, so dates are automatically populated. For example, if the finance team logs a submission date on their own tracker within Smartsheet, it can sync with the activation sheet, eliminating redundant data entry and administrative work. Multiple trackers can be integrated into one column or row to track them together under one dashboard. These smart features in Smartsheet have enabled us to move beyond conventional tracking methods, saving time and improving efficiency across cross-functional teams

4. Outcomes
Implementing Smartsheet has transformed the way we track study activation metrics in a way that was not possible before with the capabilities of a standard Excel tracker. It has provided greater transparency, enabling all teams involved in activation to view tasks, add comments, and collaborate seamlessly. This has also allowed us to track the number of days each task took to be completed. These metrics are collaborated into the dashboard to show us portfolio level metrics that help view trends, pitfalls and overall average timelines for each task. As we continue refining our study activation template in Smartsheet, our goal is to further automate processes and enhance efficiency.

5. Lessons Learned and Future Directions
Previously, our teams relied on MS Excel that did not give us much opportunity to analyze and understand metrics effectively. Calculating number of days and average timelines were manual, which was time consuming. In the past, if we needed to understand what caused severe delay, we had to compile all emails, write up a CAPA sheet or a timeline table that explains the story and background. With Smartsheet, we can now easily track comments, monitor progress, and generate real-time reports with key metrics. Moving forward, we aim to expand automation within Smartsheet to be able to reduce administrative burden, allowing teams to focus on activating more studies efficiently.

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