

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

The Power of Project Management Technology in Transforming Trial Activation Operations and Reporting

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1. Background

The Activation team at Moffitt Cancer Center is responsible for centralized facilitation and management of over 250 new trials at various stages in startup at any given time. Moffitt uses OnCore CTMS to track regulatory approvals and startup milestones at the study level, but it is not comprehensive and does not allow staff to see all assigned trials at one time. After centralizing the activation team in 2021, individual team members continued to track their assigned trials independently using various tools. This siloed approach limited visibility on trial statuses and made analysis of valuable activation data points difficult. Implementing a centralized system was essential to improve daily trial management, team member coverage, data analysis, and metric reporting.

2. Goals

Employ project management software to implement one centralized and comprehensive workspace where team members maintain trial activation statuses and document key milestones throughout startup. In addition, automate communications, reduce duplicate data entry, simplify data analysis and reporting, and increase transparency of trial activation statuses and metrics.

3. Solutions and Methods

In August 2023, a taskforce was formed consisting of activation team members to collaborate on project management tool selection and customization. Smartsheet was selected due to its versatility and integration capabilities. The grid view was an especially preferred component due to most team members' familiarity with tracking through Microsoft Excel.

Utilizing existing team member trackers, a draft grid was designed and piloted by the taskforce. The taskforce held continual design discussions and obtained feedback from key stakeholders until a final Centralized Activation Tracker template was ready.

Training was initiated July 2024 with pre-recorded demonstration videos, a team roll-out meeting, followed by 1:1 sessions. Full implementation was achieved in August 2024, followed by a user survey. Quality reviews were conducted monthly to assess team member confidence and accuracy.

Each team member tracker is templated, but Smartsheet tools, such as reports and dashboards, enable team members to tailor management to their work style.

4. Outcomes

Centralizing activation trackers has provided a complete data set which is maintained in real time. This comprehensive view of the activation pipeline can quickly be exported into reports organized by disease program, sponsor, and more. Utilizing PowerBI to pull data from both Smartsheet and OnCore into dashboard views allows us to monitor activation trends in real time for every step of the workflow.

Since implementation, team member accuracy has improved from 25 percent to 80 percent and daily use increased from 50 percent to 75 percent. Staff survey results show mixed emotional response with

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50 percent providing positive responses to Smartsheet versatility questions and 75 percent feeling confident in their autonomy and skill.

5. Lessons Learned and Future Directions

Adopting the standardized tracker was more challenging for long-standing team members who were used to functioning within personalized trackers. We feel this contributes to negative survey responses but will improve over time as we continue to make improvements.

Next, we will utilize the combined data from Smartsheet and OnCore to generate a status report to be used by activation team members when presenting updates at research meetings, eliminating the need to prepare these manually.