

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

Leveraging OnCore CTMS and SmartSheet for Accelerating Start-up

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1. Background

Given the complexity and interconnectedness of startup, having a well-developed toolkit of automations can greatly help in accelerating startup timelines and help improve quality & process transparency. We identified two areas where automation would be most effective:

1. Internal Budget Template
2. Integrated Dependency Enabled Project Tracking

2. Goals

Utilize automations to help streamline startup, accelerate timelines, and improve transparency and quality.

3. Solutions and Methods

We designed and implemented an Internal Budget Template that is based on the OnCore Budget Calendar. This tool allows us to effectively “copy/paste” the budget calendar with research pricing and charge types into the internal budget template to develop the comprehensive study budget. We also leverage the OnCore inflation multiplier to avoid creating manual inflation formulas within the template.

We designed and implemented a Startup Tracker template in SmartSheet Control Center. For each study in startup, SmartSheet will auto-provision a set of project templates that are standardized and dependency enabled. We use this project plan to project startup dates, track actual dates, variances between actual and baseline, and track startup metrics. A dashboard is utilized to communicate status to study team and sponsor.

4. Outcomes

Budget Template: Our budget development timeline has decreased by four days.

Integrated Dependency Enabled Project Tracking: We can project what studies are stalling in startup relative to baseline activation dates and implement interventions/escalations as needed. We have a “consolidated Gantt view” that shows all our studies at a task level on one report - Our weekly status review meetings are now concise one-hour sessions to review 40 studies. We have time savings of four-to-six hours per week in project tracking activities.

5. Lessons Learned and Future Directions

Continue to build/enhance tools and include the use of artificial intelligence-based tools to improve startup functions.