

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

## **From Fragmentation to Flow: Implementing a Comprehensive Smartsheet® Framework for IIT Management**

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### **1. Background**

The team identified a need for a centralized project-tracking and communication tool to support effective collaboration in a remote work environment. A unified system was also necessary to house key Investigator-Initiated Trial (IIT) information, reduce reliance on email communication, and eliminate the need for weekly IIT meetings.

### **2. Goals**

- Establish a centralized project-tracking platform that can provide accurate, sharable reports and is accessible to both the team and leadership for real-time visibility into project progress
- Track IIT timelines across all phases of start-up, maintenance, and closure, to identify workflow bottlenecks and opportunities for process improvement
- Improve transparency, consistency, communication, and efficiency in IIT operations
- Enable comprehensive oversight of the entire IIT portfolio by defining and monitoring key metrics (e.g., number of projects, status, and funding composition) to support decision-making

### **3. Solutions and Methods**

The process began with the development of an intake/master Smartsheet designed to log all studies submitted to the IIT Committee for review. Once a study received approval, it was transferred to a clinical trial Smartsheet, depending on the level of support requested.

The clinical trial Smartsheet also served as the hub for a study-specific task list created to track key activities and timelines, such as document reviews and regulatory submissions. Dashboards were built to visualize and report on data drawn from both the individual study Smartsheet and the master/clinical trial Smartsheet in order to easily view the IIT program portfolio as a whole.

To streamline data entry and reduce redundancy, the system was enhanced to pull select fields directly from our CTMS. Additional monitoring and financial tracking Smartsheets were developed and linked back to the study and master/clinical trial Smartsheet, where relevant.

Overall, the system evolved from broad, high-level tracking to detailed, project-specific management, supporting the diverse needs of project coordination, regulatory affairs, monitoring, finance, and leadership. Development occurred in phases guided by a project tracking Smartsheet that outlined the requirements and data needs of the team and overall program. As part of this process, clear guidance documents were produced, and targeted training sessions were delivered to ensure the team could implement the system effectively.

### **4. Outcomes**

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- Weekly IIT meetings are no longer required due to improved transparency and shared access to project information
- Leadership now receives accurate, data-driven insights on timelines, financial impacts, and operational trends in real time
- The IIT team has a clear, organized queue that enables them to prepare for upcoming tasks and manage workload more effectively. The system supports more reliable timeline estimates for Principal Investigators (PIs) regarding trial activation, especially for studies with similar characteristics
- Quality Assurance (QA) reviews on tasks are streamlined, enabling effective personnel oversight

#### **5. Lessons Learned and Future Directions**

- Expanded tracking capabilities now include finance-related metrics and monitoring of project coordination efforts, providing deeper insight into workload distribution, trends, and associated fees
- Developed a funding sponsor tracking sheet to support timely updates and improve visibility into funding status
- Created an IIT incubator tracking process to monitor concepts that may progress into full IITs
- Currently developing a metadata initiative aimed at reducing manual data entry, improving data quality, and enhancing the accuracy of reporting across all IIT activities