

## **Still Waiting for Your IIS to Open? Activating Investigator-Initiated Studies at a Matrix Cancer Center**

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### **1. Background**

As a National Cancer Institute (NCI)-Designated Cancer Center, Sylvester Comprehensive Cancer Center (Sylvester) faces challenges widely shared among other matrix-modeled cancer centers. One of those challenges is collaborating with the Office of Research Administration (ORA), which holds the signing authority for all budgets and contracts. All studies require an executed budget and contract for activation, thereby necessitating a collaboration between Sylvester's clinical research services (CRS) and ORA.

The NCI recommends that studies are activated within 90-120 days or less, making timely budget and contract execution critical to our overall timeline. To reduce the time it takes to execute a budget and contract for single-site investigator-initiated studies (IIS), the Sylvester project team led a process improvement project including all stakeholders (CRS & ORA) involved in activating IISs.

Using the **DMAIC** (Define, Measure, Analyze, Improve and Control) model, a lean six sigma process improvement approach, the project started by mapping and **D**efining the current state. Then the project team **M**easured the current TTA which resulted in a median of 484 days on what we considered our "CCSG timeline" (from Protocol Review and Monitoring Committee [PRMC] submission until activation). After **A**nalyzing the current state, using tools such as root cause analysis, Pareto graphs, and control charts, we were able to identify the lack of standardization as the primary issue impacting the TTA.

### **2. Goal**

1. Reduce time to activation for single-site IIS to 120 days or less

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

To address the issue with single-site IIS TTA, we implemented the innovative **I**mprovements outlined below:

1. Rearranged workflow
2. Required key stakeholder communication
3. Established Standard Operating Procedures (SOP) for the improved process of submitting an IIS to ORA, including:
  - a. Work instructions
  - b. Simplified budget template
  - c. Established tracker for SOP

### **4. Outcomes**

Sylvester successfully implemented a future state process map reflecting four adjusted processes impacting TTA for single-site IIS leading to a TTA reduction of 248 days compared to 2022, with a median of 236 days for single-site IIS (2023-YTD).

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

Sylvester is currently in the Control phase monitoring the tracker at 30, 60, and 90 days to ensure that studies are reaching TTA quickly and efficiently. To expand this effort, Sylvester is moving to improve tracking with an IIS PowerBi dashboard for increased efficiency. In addition, Sylvester will maintain weekly recurring meetings with ORA to render process improvement initiatives for other study types (such as multisite IIS, industry, and cooperative groups) and ensure a successful collaboration. ORA also implemented this process for single-site IIS submitted by other departments across the institution.