Still Waiting For Your IIS To Open? Activating Investigator Initiated Studies At A Matrix Cancer Center

Sergio Cardona, Gabriel Diaz, Laura Thyssen, Kelly Williams
Sylvester Comprehensive Cancer center at the University of Miami Miller School of Medicine

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), who 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 between 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.

Approach

This project utilized the Dmaic (Define, Measure, Analyze, Improve and Control) model, a lean six sigma process improvement tool as shown in figure 1.

Solutions Implemented

To address the issue with single-site IIS TTA, we implemented the innovative improvements outlined in figure 2.

Results

Sylvester successfully implemented a future state process map reflecting four adjusted processes (Figure 3) 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 (Figure 4).

Next Steps

Sylvester is currently in the Control phase and will follow the next steps as shown in figure 5.