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

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SYLVESTER COMPREHENSIVE CANCER CENTER
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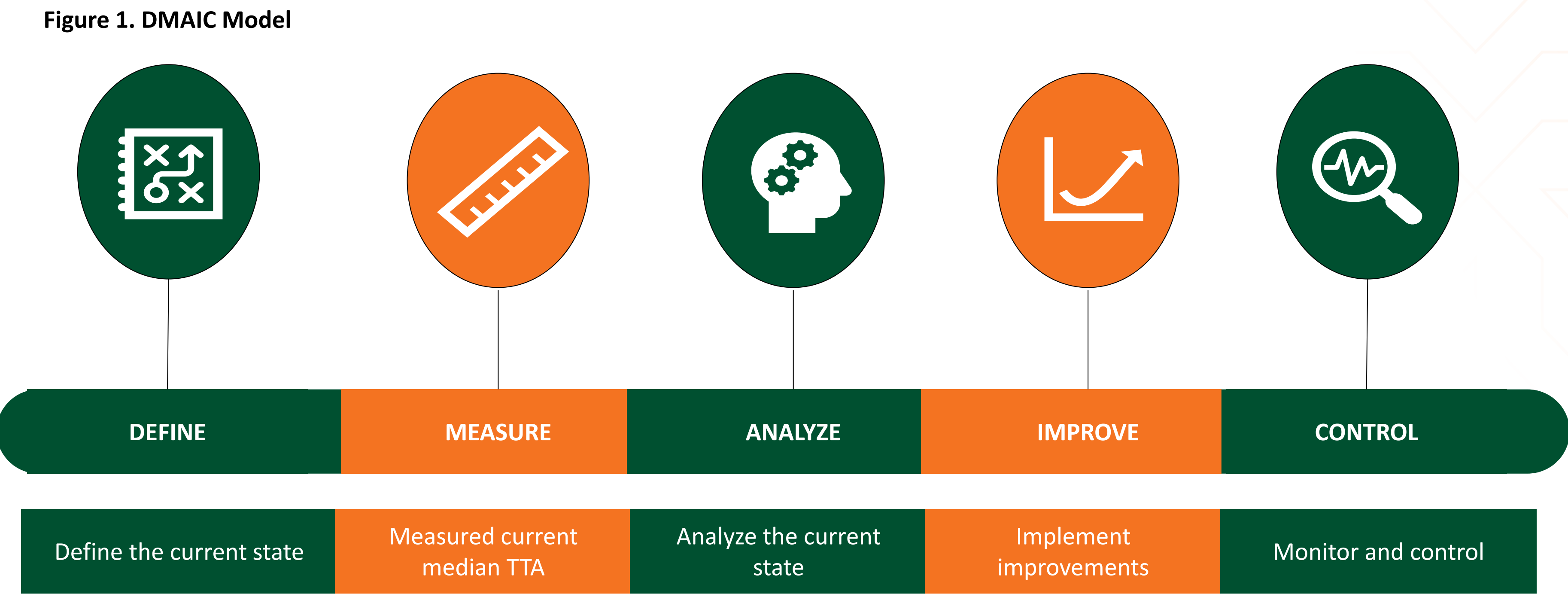
Background

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.
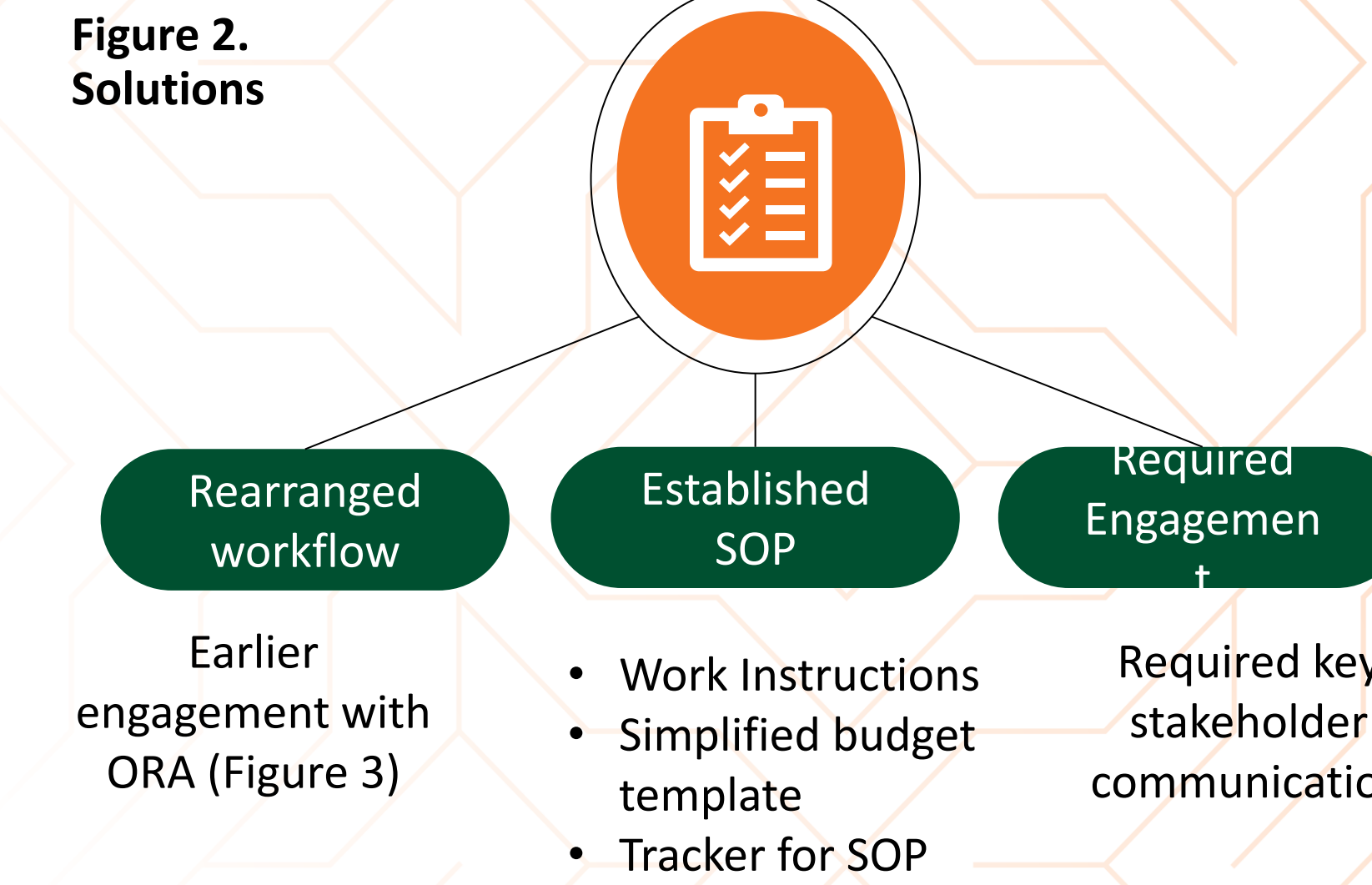
Approach

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

Figure 1. DMAIC Model

DEFINE	MEASURE	ANALYZE	IMPROVE	CONTROL
Define the current state	Measured current median TTA	Analyze the current state	Implement improvements	Monitor and control

Goal

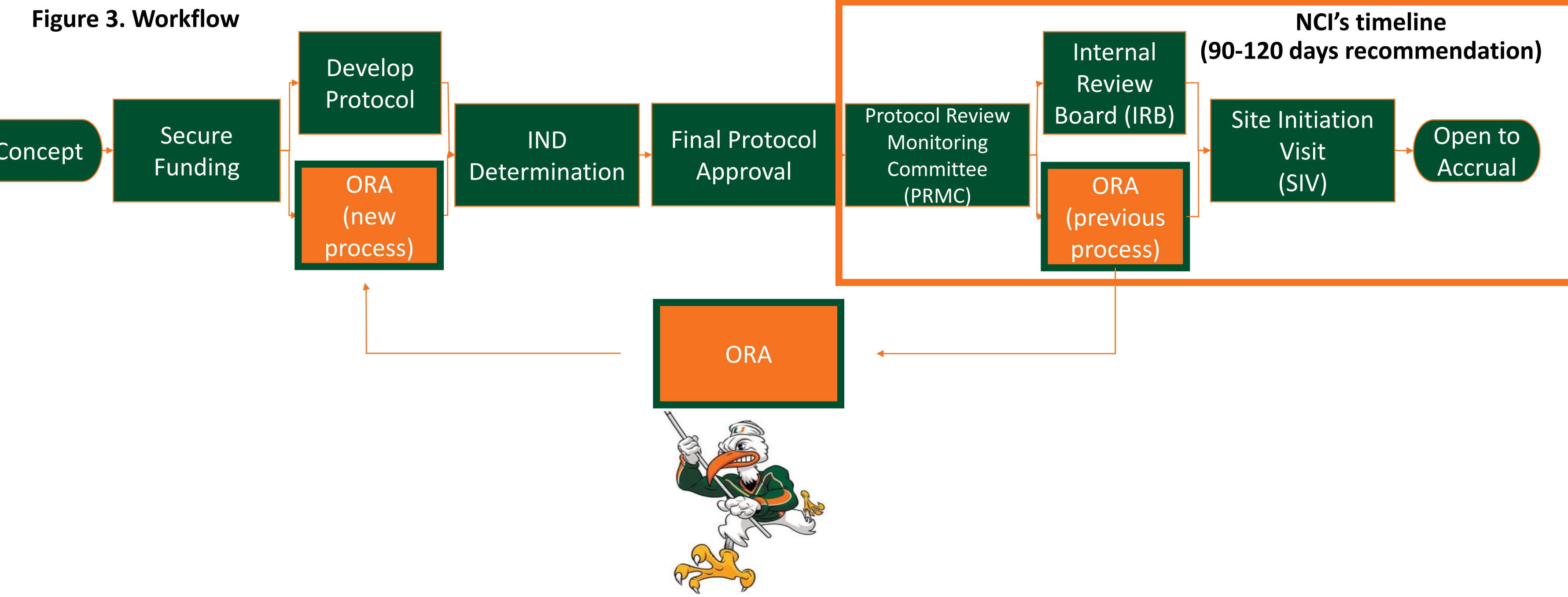Reduce time to activation for single-site IIS to 120 days or less.

Solutions Implemented

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

Figure 2. Solutions

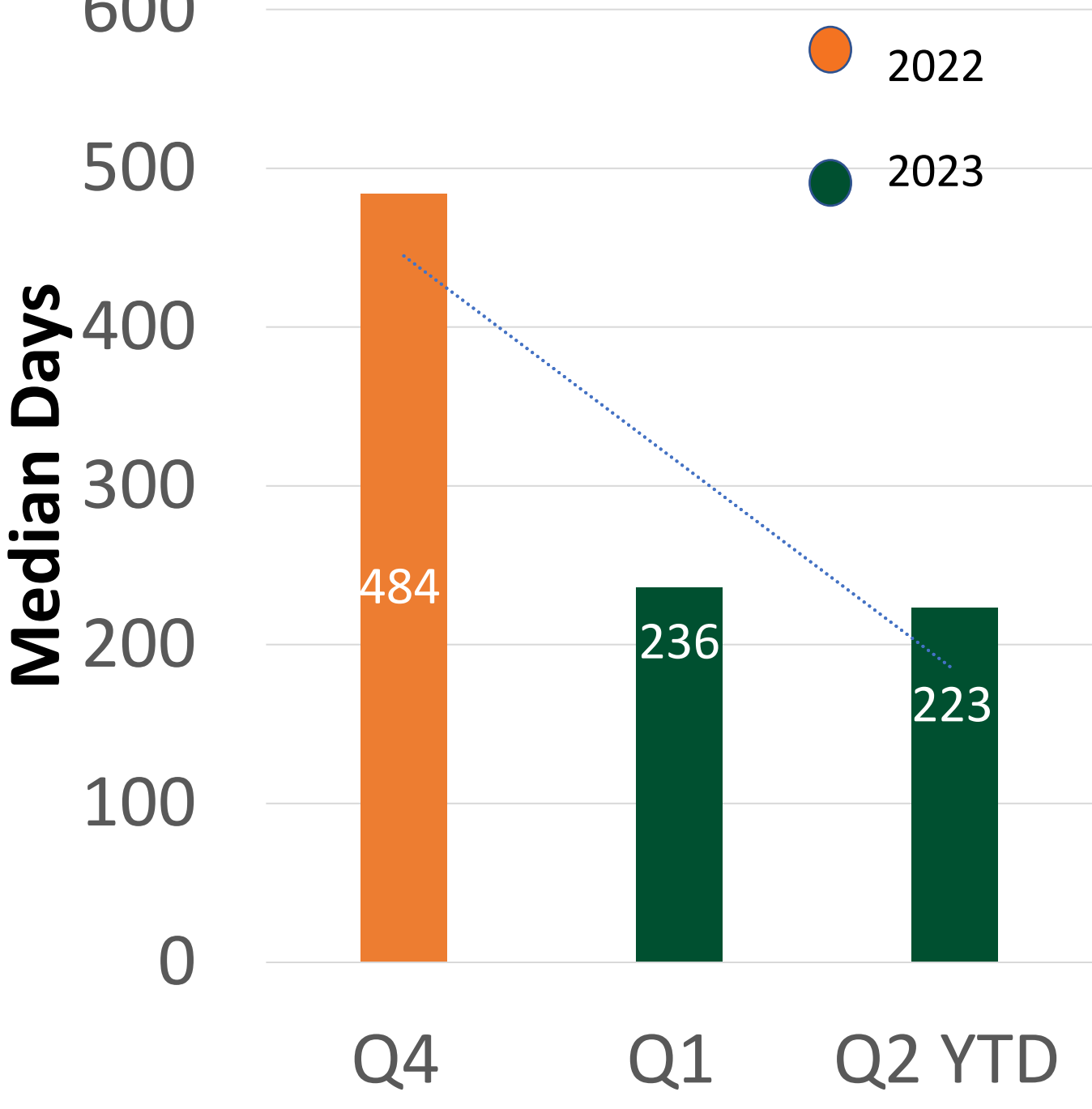| Rearranged workflow	Established SOP	Required Engagement
Earlier engagement with ORA (Figure 3)	• Work Instructions • Simplified budget template • Tracker for SOP	Required key stakeholder communication

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).

Figure 3. Workflow

Concept → Secure Funding → Develop Protocol / ORA (new process) → IND Determination → Final Protocol Approval → Protocol Review Monitoring Committee (PRMC) → Internal Review Board (IRB) / ORA (previous process) → Site Initiation Visit (SIV) → Open to Accrual

NCI's timeline (90-120 days recommendation)

ORA

Figure 4. Time to Activation for IIS

Median Days

- 2022
- 2023

	Q4	Q1	Q2 YTD
	484	236	223

Next Steps

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

Figure 5. Next steps

- Monitoring the new process at 30, 60, and 90 days
- Improve tracking with an IIS PowerBi dashboard
- Maintain weekly recurring meetings with ORA to ensure a successful collaboration.