

“Out of Site, Out of Mind” – Visualizing the Study Activation Process Enables the Standardization of Site Initiation Visits

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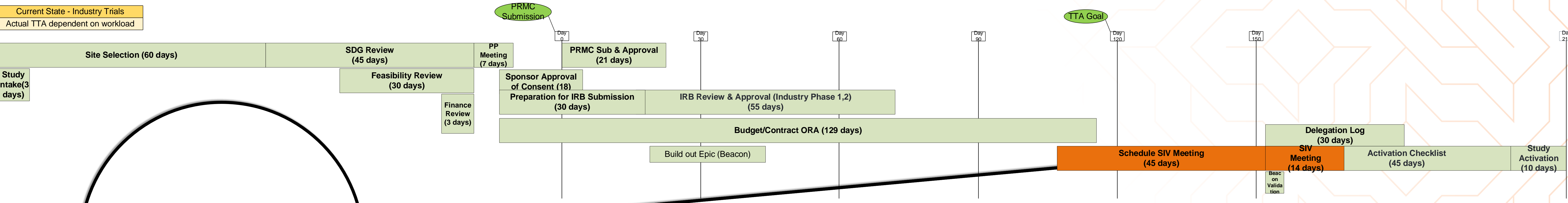


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Background Goals

Time to activation (TTA) is a crucial metric for Sylvester Comprehensive Cancer Center (Sylvester) as a matrix, NCI-designated, cancer center. One of NCI's recommendations is to reduce TTA ensuring timely activation of studies. As part of a TTA Task Force, stakeholders detected improvement opportunities by visualizing the overall study activation process through *high-level flowcharts*. One area that was identified as significantly impacting TTA was the process of *scheduling and conducting the Site Initiation Visit (SIV)*. The SIV plays a mandatory role in trial activation, ensuring that personnel are trained on the protocol and study-related processes. In 2022, Sylvester's median TTA was 45 days from the time a manager starts the scheduling process to the occurrence of the SIV, which was significantly impacting the overall TTA. There are 17 Site Disease Groups (SDG) at Sylvester with varying approaches to handling SIVs, leading to lengthy and complex processes.

- Reduce TTA through focus on the SIV:
1. Standardization across all SDGs
 2. More efficient use of resources

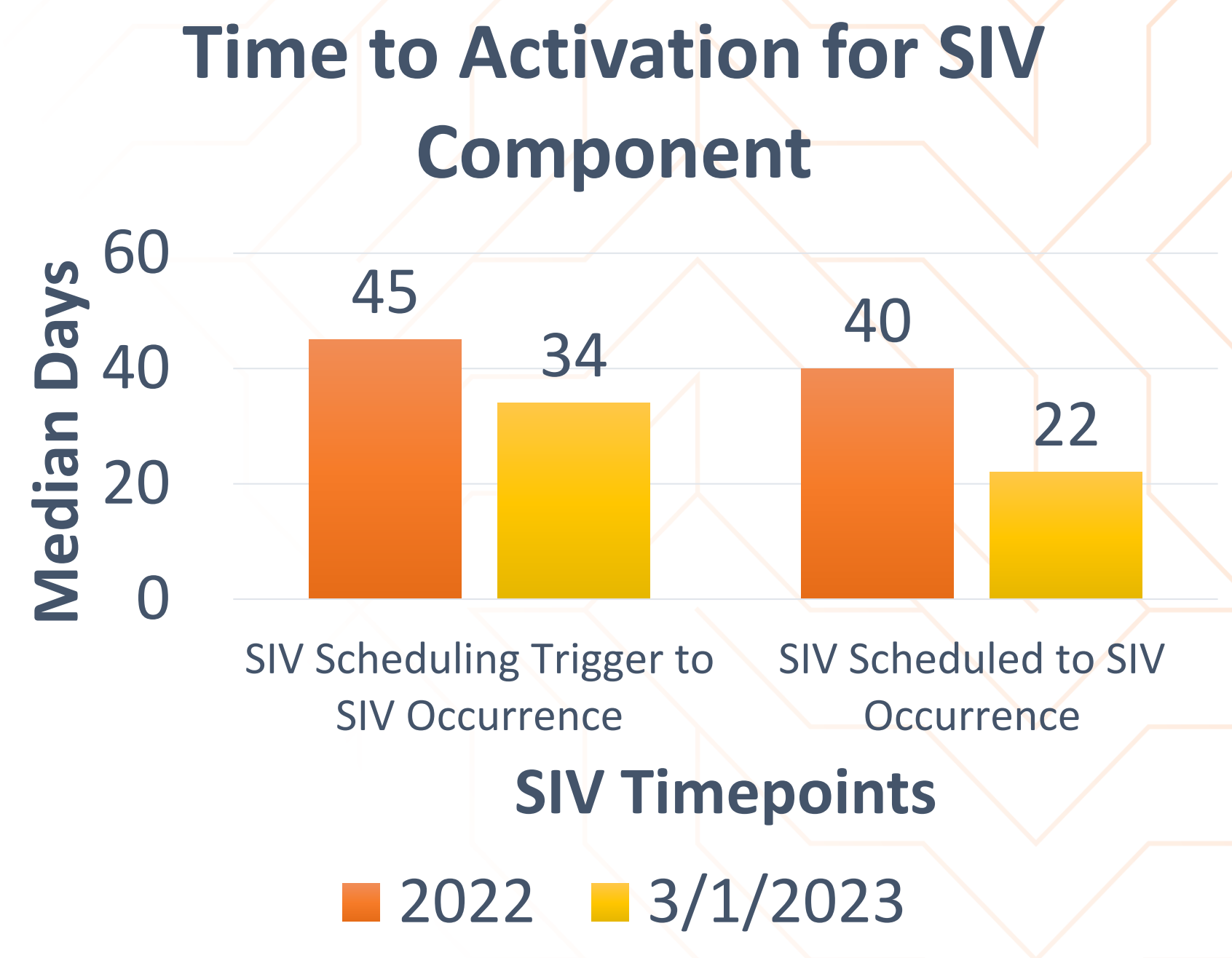
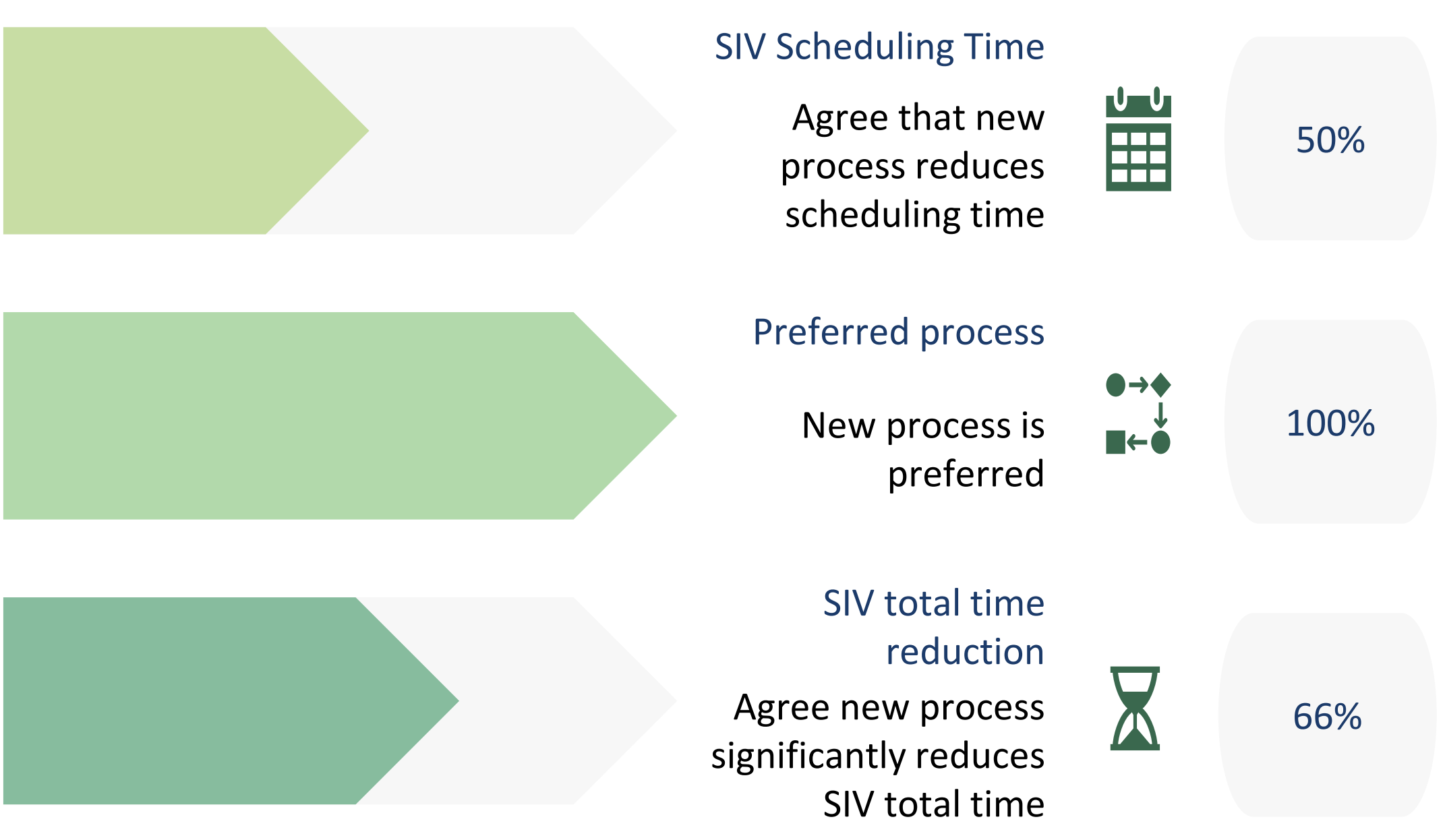


Solutions Implemented

- Standardization across all SDGs**
 1. Trigger to indicate process start for scheduling SIV in collaboration with Office of Research Administration
 2. Streamline of Processes
 - a. Step-by-step work instructions
 - b. Assigned Roles and Responsibilities
 - c. Contact information for required personnel
- Sylvester owned SIV Agenda - More efficient use of resources**
 1. 4- hour limit incl. one hour of investigator involvement
 2. Clear delineation of roles and responsibilities per section

Results

The standardized process was rolled out to the stakeholders on 1/31/2023 and implemented on 2.3.2023. The data and survey collection is based on 8 SIVs and shows the following findings:



Next steps

The impact of the improvements is tracked with follow-ups occurring every 3 months to ensure that the process is improving the study activation process and course correcting as needed.