

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

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### **1. Background**

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. Traditionally, the SIV length and agenda varies by sponsor, burdening the staff and causing inefficient resource allocation.

### **2. Goals**

Reduce TTA through focus on the SIV:

1. Standardization across all SDGs
2. More efficient use of resources

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

The following solutions were implemented to improve scheduling and conduct of the SIV:

1. Standardization across all SDGs:
  - a. Trigger to indicate process start for scheduling SIV
  - b. Streamline processes:
    - i. Step-by-step work instructions with templates
    - ii. Assigned roles and responsibilities
    - iii. Contact information of required personnel/departments
2. Sylvester owned SIV agenda - more efficient use of resources:
  - a. Four-hour limit including one hour of investigator involvement
  - b. Clear delineation of roles and responsibilities per section

### **4. Outcomes**

The standardized process was rolled out to the stakeholders January 31, 2023 and implemented on February 3, 2023. Sylvester’s preliminary data and survey collection is based on eight SIVs and shows the following findings:

1. Reduced TTA:
  - a. 11 days reduction from notification of trigger to the SIV occurrence, with a median of 34 days

- b. The time between the SIV is scheduled and conducted has reduced to a median of 22 days with three studies taking less than ten days
- 2. Survey results:
  - a. 50 percent agree that the process reduces the SIV scheduling time, while 33 percent selected that a significant reduction is experienced
  - b. 100 percent note that this process is preferred
  - c. 66.7 percent agree that the process significantly reduces SIVs total time
  - d. Managers stated that the standardized process is very smooth, user-friendly, efficient and provides more control of the SIV process
  - e. So far, we had 0 percent push back from any sponsor on this standardized process

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

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