

Yale Center for Clinical Investigation

a Cancer Center Nicholas A. Licht, MBA; Erica J. Rocco, BS, CCRP; Nicole L. O'Dell, MLS, PhD; Rhoda Arzoomanian, MSM, BSN, RN; Tesheia Johnson, MBA, MHS A Comprehensive Cancer Center Designated by the National Cancer Institute Yale School of Medicine - Yale Center for Clinical Investigation (YCCI)

• Quick access to information related to the output of your program, teams, department and institution as a whole

Background

In 2016, the Yale School of Medicine and the Yale Cancer Center (YCC) identified clinical trial activation timelines as a strategic improvement opportunity. The intended goal of improving activation timelines is:

- advance medical care and research,
- enhance Yale's position as a competitive Medical School and Comprehensive Cancer Center, and
- ultimately improve patient access to clinical trials within the Yale Medicine network.

The Protocol Activation (PAct) Team worked with Forte to build a tool for displaying study activation progress in realtime for the investigators, disease teams and sub-process owners. Data for each activation sub-process are expected to be entered in real-time into OnCore, Yale's Clinical Trial Management System. These data are then displayed as interactive charts called "Protocol Activation Dashboards" in **Research Insights.**

Study Activation : Past Performance*



Turnkey, intuitive dashboards deliver meaningful insights, with in-depth analysis of past performance, current state and projected outcomes

Goals

The goal of implementing the activation dashboards is to increase the data transparency between the PAct team, sub-process owners, disease teams, study teams, departmental and Cancer Center leadership. Real-time availability of the data provides study team members the opportunity to:

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Increasing Activation Transparency with Research Insights Dashboards

provide transparency to where a study is in the activation process • ensure studies continue to move through the activation process • identify any roadblocks and challenging steps within the activation process

Visualizations to help you make informed, proactive decisions and take your research operations to the next level

Methods

The PAct project team introduced three study activation dashboards:

Study Activation: Past Performance

Offers a past performance view to assess the time it takes to complete an activation sub-process compared to the target duration.

Study Activation: Portfolio Task List

Offers a portfolio view to assess how protocols in a disease team's portfolio are progressing towards study activation in comparison to the expected target durations.

Study Activation: Protocol Task Lists

Offers a protocol-specific view to assess how each sub-process is progressing for a selected protocol compared to the target durations.

Study Activation : Portfolio Task Lists*

Yale NewHaven Health

Yale Medicine

Leverage OnCore data to get a comprehensive view into your research portfolio and ensure your organization is moving in the right direction

Outcomes

- To date, 60 stakeholders have been provided access to the protocol activation dashboards.
- The PAct team is integrated into disease team meetings, clinical trial manager meetings and Cancer center leadership meetings
- The disease teams have started to incorporate the dashboards into their weekly protocol review discussions.

Lessons Learned and Future Direction

Yale looks forward to incorporating feedback from the investigators, the research teams, and from leadership to further optimize the current dashboards and create additional dashboards as needed. In the future, the activation task list structure will be rolled out to all departments within the Yale School of Medicine.

Study Activation : Protocol Task Lists*

Protocol Search PCL20186543, The ask List Status (AII)	PCL20186543: The final test protocol for tasklists (Phase: II) PI: Hilty, Laura Primary Management Group: Breast Industry: Forte Pharmaceuticals	
Legend	Activation - Study Decision	
Not Started, Future Start	Activation - Feasibility (Oncology)	
Not Started, Past Due	Clinical Research Working Group Activation - Consent Form	
In Progress, Over Time	Activation - Beacon Build	
In Progress, Within Time	Activation - Budget Activation - Business Office	
In Progress, Projected Completion	Activation - Contract Task List Name: Budget (In progress, with Activation - Execute Contract (Ex) Target Start - Completion Dates: 6/30/2018 – 8/30/2018	
Completed, Over Time	Activation - PRC	(00 00 00 00)
Completed, Within Time	IRB Activation (Oncology) Activation (Oncology) Activation - Activation - Activation (Oncology) Activation - A	get)
No Target Duration Set		6/18

All Task Details	Task List Task Name		Task Status	Target Duration	Actual/Projected Duration	Days +/- Target	
	Working Group	Notification to regulatory team	Not yet started	8	8	0	^
		Consent form revisions started	Completed	0	11	11	
	Activation -	R/SOC determination complete	Completed	0	11	11	
	Consent Form	Consent form sent to Sponsor	Completed	5	3	-2	
		Consent form approved by Sponsor	In progress	7	7	0	
		Notify Beacon team that build can begin	Completed	0	1	1	
í	Activation - Beacon Build	Nurse and CRSL Build submitted to Epic	Completed	15	5	-10	
		ERX submitted to Epic	Completed	15	7	-8	
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*Sample Data

