

## **Smartsheet in Action: Boosting Visibility and Improving Transparency Identifies Barriers to Reduce Study Activation Timelines**

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### **1. Background**

National Cancer Institute Comprehensive Cancer Centers (NCI-CCC) have an obligation to improve access to innovative oncology clinical trials within their catchment area. Study Start Up (SSU) teams are responsible for opening trials, requiring extensive coordination across multiple regulatory, contractual, and operational domains; susceptible to delays due to bottle necks at various stages. Monitoring key metrics and timelines is essential for identifying holdups that delay activation, where there is an opportunity to intervene. Project management tools enhance visibility by revealing trends, diagnosing delay drivers, and identifying improvement needs, enabling more efficient and coordinated clinical trial start-up.

### **2. Goals**

The goal is to assess the impact of implementing Smartsheet within the regulatory SSU team on reducing study activation timelines and maintaining target deadlines. This evaluation examines whether Smartsheet's real-time visibility, automated alerts with predefined timelines for each task, defined task ownership, and early identification of bottlenecks support more consistent adherence to activation timelines.

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

Smartsheet includes customizable templates that can be adjusted to meet varying operational needs. We developed our regulatory SSU tracker using the Project Schedule template, adapting it to include all required activation tasks and 77 workflow steps. Custom formulas were added to calculate task durations, enabling consistent performance measurement across studies and generate project-level and portfolio-level metrics, including specific timelines for key activities.

We focused on industry-sponsored trials and transitioned from Microsoft Excel to a Smartsheet Project Schedule in July 2025 to improve the accuracy and consistency of activation metric tracking. All SSU tasks, milestones, and deadlines were entered into Smartsheet for each new study. Study-specific variables are tracked in the Smartsheet. Estimated task specific timelines are assigned based on our historical data, supporting our overall goal of completing study activation within 90 days of PRMC submission. The template provides a centralized view of all tasks and their timelines, allowing ongoing activities to be monitored in one location, visible to leadership. Real-time updates through status fields, comments, and automated notifications enhance transparency and support timely communication. Smartsheet's reporting features allow tasks and timelines to be aggregated across studies, enhancing tracking of performance and trends, allowing for earlier interventions and more automated reporting.

### **4. Outcomes**

Implementation of the Smartsheet Project Schedule improved visibility into study activation progress by consolidating all start-up tasks, timelines, and updates into one platform, enabling stakeholders to quickly assess current status and identify areas requiring attention and intervention. Real-time status updates, task-level comments, and automated notifications helped keep assignees on track and supported timely completion of start-up activities.

## 5. Lessons Learned and Future Directions

Transitioning to Smartsheet demonstrated the value of consistent task structures, clear dependencies, and built-in reporting to maintain reliable activation metrics, while also reducing the manual study-metric tracking burden. Its dashboards and reports across multiple studies were beneficial for spotting bottlenecks and understanding where delays commonly occur. Moving forward, we will build dashboards to visualize activation progress and increase automation to help identify delays earlier. Continued evaluation across a broader set of studies, including additional sponsor-types, will help determine long-term impact on achieving the 90-day activation goal and guide ongoing refinement of activation processes.

Forms Connections Dynamic View SSU\_Industry\_v3 ☆

Status	Task Name	Assigned To	Start Date	Complete Date	Duration	Predecessors	Estimated Timeline	Comments
	[Insert Protocol # and add Name, if applicable]							
	+ Phase I: Pipeline							
	- Phase II: Feasibility							
Not Started	WG Approved				0			
Not Started	Study Assignment				2d 13		0-3d fr Feasibility Completion	
Not Started	Create eIRB Initial Application				2d 10		0-3d fr WG Approved	
Not Started	Feasibility Initiation				1d 9		0d fr WG Approved	
Not Started	Feasibility Completion				3d 9		3d fr WG Approved	
	+ Phase III: Contract & Budget							
	+ Phase IV: Treatment Orders							
	- Phase V: Start-up							
Not Started	Add Study to Current Roster				5d 10		0-5d fr Study Assignment	
Not Started	SSU Sends Email to Sponsor				2d 10		0-3d fr Study Assignment	
Not Started	SSU Sends Email to PI				5d 10		0-5d fr Study Assignment	
Not Started	OnCore							
Not Started	Complion							
Not Started	ICF							
Not Started	Prepares ICF				3d 10		0-3d fr Study Assignment	
Not Started	Sends ICF to Sponsor				3d 55		0-3d fr Study Assignment	
Not Started	Sponsor Approves ICF				21d 56			
Not Started	PRMC							
Not Started	Send PI ePRMC Application to Submit				1d 13		0-1d fr Feasibility Completion	
Not Started	PRMC Submission				2d 59		0-3d fr sand to PI	
Not Started	PRMC Approval				14d 60			
Not Started	Ancillary Reviews							
Not Started	OIT							
Not Started	RSC							
Not Started	RSC Submission				4d 10		0-4d fr Study Assignment	
Not Started	RSC Approval				7d 67			
Not Started	IBC							
Not Started	Radiology							
Not Started	EML							
Not Started	CRKP Submission				5d 10		0-5d fr Study Assignment	
Not Started	REMS							
Not Started	IRB							
Not Started	Complete eIRB Initial App & Request PI to Submit				2d 57		0-2 days of Sponsor Approved ICFs	
Not Started	PI Submit eIRB Initial App				2d 83		0-2d fr PI request to Submit	
Not Started	Received eIRB Institutional Sign-off				21d 84			
Not Started	Complete and Submit External IRB App				1d 85		0-2d fr Institutional Sign-off	
Not Started	IRB Approval Received				14d 86			

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Idea

ICF Process\_Industry

Grid | C | 67 Sheets | 7 Columns | 1 Filter | 2 Groups | 1 Summary | Sort

Primary	Start Date	Complete Date	Duration	Status	Comments
Sheet Name					
ICF	09/24/25	10/17/25	24d	Complete	
Prepares ICF	09/24/25	09/29/25	6d	Complete	
Sends ICF to Sponsor	09/29/25	09/29/25	0	Complete	
Sponsor Approves ICF	09/30/25	10/17/25	18d	Complete	
Sheet Name					
ICF	07/22/25	08/08/25	18d	Complete	
Prepares ICF	07/22/25	07/29/25	8d	Complete	
Sends ICF to Sponsor	07/30/25	08/06/25	8d	Complete	
Sponsor Approves ICF	08/07/25	08/08/25	2d	Complete	
Sheet Name					
ICF	10/21/25	11/10/25	21d	Complete	
Prepares ICF	10/21/25	10/22/25	2d	Complete	
Sends ICF to Sponsor	10/22/25	10/22/25	0	Complete	
Sponsor Approves ICF	10/23/25	11/10/25	19d	Complete	