Category: Trial Start-up and Activation – Completed Project

Study Start-up Activation Dashboard - Improving Transparency

L. Wall, A. Spratt, N. Connellan

The University of Chicago Medicine Comprehensive Cancer Center

1. Background

The University of Chicago has an institution-wide initiative to reduce our study start-up timelines so that we can offer our patients novel cutting-edge treatment options. Study activation is a resource intensive process which involves time and effort from multiple stakeholders responsible for the discrete steps of the overall process. These include the principal investigator (PI), operations team, regulatory, budget managers, contracts/legal team, coverage analysts, and investigational drug pharmacy, in addition to the various institutional review committees. We sought to identify opportunities for efficiency and standardization to reduce start-up timelines. However, the biggest challenge was trying to understand "whose desk is it on." With multiple stakeholders and workflows involved it was challenging to know where trials would bottleneck as we lacked any common tracker that detailed the activation timeline for each trial in the activation pipeline. Effective communication and good collaboration across the various offices involved is critical to opening trials timely.

2. Goals

Identify and create an internal dashboard to provide transparency on where trials are in the start-up process. This dashboard had to be available to be edited by multiple users simultaneously as well as accessible from both on- and off-campus locations. This transparency will allow us to better analyze study start-up progress, identify areas where trials are bottlenecked, and develop metrics to track progress to ensure we are meeting our target timelines.

3. Solutions and Methods

We created a dashboard utilizing web-based team workspace that was freely available to us under a university-held license (Confluence). This platform allows for editing by multiple users and includes alert functions for when changes are made. The primary purpose of the dashboard is to provide the relevant stakeholders with status updates for each step in the activation process. This encompasses sponsor site selection/feasibility, first-tier scientific review, scientific and other internal review committees, coverage analysis, treatment plan build, contract/budget negotiations, site initiation visits, and research staff assignments. The dashboard is updated before each disease team's weekly research meeting.

4. Outcomes

The dashboard (see figure) has proven to be invaluable in identifying where the protocol is in the start-up process and has also helped hold the different parties accountable. Use of this dashboard has highlighted the commitment from all involved in shortening protocol activation timelines. In addition to increased transparency, it has spotlighted the volume of work across not only the individual disease programs, but the entire cancer center enterprise. This has helped with discussions regarding prioritization and clinical research staffing needs. It has also allowed us to identify, pause, or terminate studies earlier in the process, by calling attention to those that have hit significant roadblocks, thus ensuring that the research staff are focusing efforts on the projects that are the most value-add. It has

facilitated conversations with the PIs and sponsors regarding their role in the activation process, thus holding them accountable as well. Lastly, it has decreased the need for individual emails or calls amongst the stakeholders asking for frequent updates. In conclusion, the start-up dashboard has accomplished our goal of increased transparency and will help us build out metrics in the future. It will allow us to put in place effective and proactive measures to ensure that we are using start-up resources effectively. It's important that key stakeholders work together and partner to proactively identify study start-up related issues and execute action plans to mitigate risks to timely activation.

5. Lessons Learned

Transparency around this process helps hold stakeholders accountable for their role in the activation process. Study activation is a complex and time-consuming process. The dashboard has identified a need for continued and strategic prioritization of new trials across the disease teams so that resources are being spent on the right trials.

Figure:

	PI	Sponsor	Protocol #	Protocol Title	Date of Initial Email	Date of CDA	Date Feasibility Sent to Sponsor	SSV Date	Site Selected (Y/N)	Network Site Participation	Reg Packet Received	Notes/ Comments
1												
2												

First Stage Review

	PI	Sponsor	Protoool #	Protoool Title	Disease	Date of Review	Outcome	Comments	Priority
1									
2									

Protocol Start-up

	IRB#	PI	Sponsor	Protocol #	Protocol Title	CTRC status	IBC status	IRB status	Notes (consent status /issues, outstanding regulatory issues, etc)	Schema Status	CPIT Status	Contract Status	Budget Status	SIV
1	*Example 1*	*Minnie Mouse*	*Pharma A*	*Protocol 123*	*Drug for Cancer*	*Submitted date Status (meeting date, Rev. etc) Approval Date*	*Submitted date Status (meeting date, Rev. etc) Approval Date*	*Submitted date Status (meeting date, PC, etc) Approval Date*						