Study Start-up Activation Dashboard – Improving Transparency

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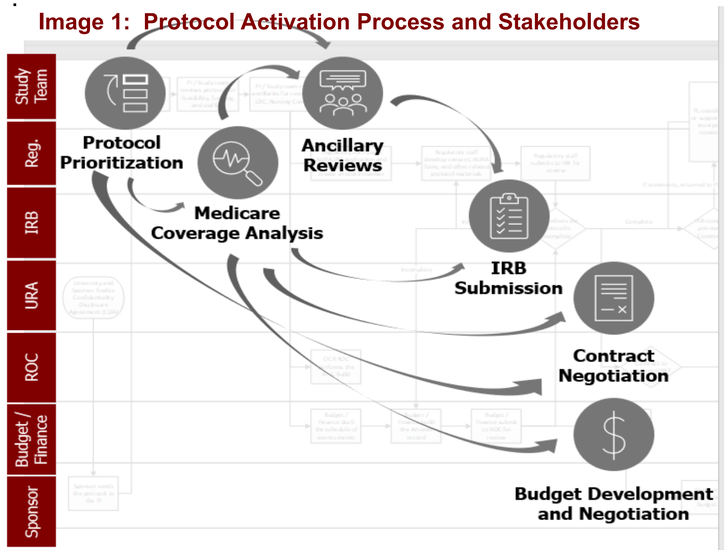
Background

The University of Chicago has an institution-wide initiative to reduce our clinical trial start-up timelines. Study activation is a resource intensive process which involves time and effort from multiple stakeholders responsible for the discrete steps of the overall process .

Image 1: Protocol Activation Process and Stakeholders



The biggest challenge in trying to identify opportunities for efficiency and standardization to reduce start-up timelines 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 timeline for each trial in the activation pipeline.

Goals

- Create an internal dashboard to provide key metrics and updates for clinical trials in study start-up phase
- Identify best platform for dashboard that allowed simultaneous editing by multiple users and which as accessible from locations both on- and off-campus.
- Create resource to allow Cancer Center and University administrators and leadership to identify areas where clinical trials bottlenecked in the activation process
- Develop metrics to track progress to ensure we are meeting target activation timelines.

METHODS

We created a dashboard utilizing a web-based team workspace that was freely available to use under a University-held license (Confluence). This platform allows for editing by multiple users and includes alert functions to notify relevant stakeholders when updates and changes are made.

The dashboard is central location to report and monitor status updates across the protocol activation process including:

- Sponsor site selection and feasibility
- First-tier scientific review at programmatic level
- Scientific Review Committee (SRC) submission, review, and outcome details and dates
- Institutional Review Board (IRB) submission, review, and outcome details and key dates
- Medicare Coverage Analysis (MCA)
- Treatment plan build
- Contract and budget key dates and milestones
- Site Initiation Visit
- Research staff assignments

The dashboard is updated on a weekly basis prior to each disease team's research meeting which is attended by principal investigators, research nurses, regulatory staff, coordinators, data managers, clinical pharmacists, and other individuals involved in clinical trials conduct at our site.

Clinical Trial Start-up Activation Dashboard

Site Feasibility

	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	Protocol #	Protocol Title	Disease	Date of Review	Outcome	Comments	Priority
1									
2									

Protocol Start-up

	IRB#	PI	Sponsor	Protocol #	Protocol Title	SRC Status	IBC status	IRB status	Notes (consent status/issues, outstanding regulatory issues, etc)	Network Site Interest/Status	MCA Status	Treatment Plan Status	Contract Status	Budget Status	SIV	RN	CRC	DM
1	*12-3456*	*Minnie Mouse*	*Pharma A*	*Protocol 123*	*Drug for Cancer*	*Submitted Review Outcome Approval*	*Submitted Review Outcome Approval*	*Submitted Review Outcome Approval*										

RESULTS

The dashboard has met the intended goal of increased transparency across the protocol activation process. It has proven to be invaluable in identify where the protocol is in the start-up process and has been successful in holding the different parties and groups accountable for their role in timely trial activation.

Key outcomes:

- Spotlight the volume of work across the individual disease portfolios as well as the entire Cancer Center enterprise. This has helped guide and facilitate discussions regarding prioritization and clinical research staffing needs.
- Identify and pause or terminate start-up activities earlier in the process for trials that have hit signification roadblocks to activation
- Ensuring that research staff across the protocol activation process are focusing efforts on the projects that have the most value-add for the Cancer Center.
- Facilitate discussions with principal investigators and trial sponsors regarding their roles in the activation process thus holding them accountable as well
- Decreased the need for individual emails or calls between the various stakeholders asking for frequent updates.

The dashboard tool has proven success largely due to the support and buy-in of all relevant stakeholders including leadership from our regulatory, financial, nursing informatics, pharmacy, and clinical operations teams highlighting the collaborative nature of clinical research and commitment across the University to shortening protocol activation timelines.

Transparency around this process helps hold stakeholders accountable for their role in 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.

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 has highlighted commitment and value of ensuring 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.