Development of a Study Activation Grid to Track and Review Start-Up Activities

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Background

The clinical trial activation process is very complex, with many activities happening in parallel. A need was identified to create a tool that increases visibility of these parallel processes, provides clear expectations and accountability for our clinical trials office departments and hospital partners, and reduces activation timelines.

Goals

- Develop a tool that highlights study start-up activities and lays out target dates for key steps in study activation
- Implement a defined, regular review process to track studies in activation
- Decrease overall study activation timelines

Solutions and Methods

In partnership with each of our clinical trials office departments (e.g., disease teams, regulatory, budget/contract), we have developed a standardized grid to track key milestones during study activation (**Figure 2**). The study activation grids highlight key submission dates and automatically project target dates for future tasks and submissions. The ultimate goal of the activation grid is to serve as a single, shared location where the study team can check the status of start-up activities in real time, and to help highlight bottlenecks in the process.

Along with the creation of the grid, we have implemented bi-weekly team meetings to review the status of each study and identify barriers to activation. These meetings include members of the clinical trials office operations team, regulatory team, budget and contract team, research managers, and hospital compliance office partners. Each department provides a progress update for all studies in activation during this meeting, with the goal of keeping all partners moving in the same direction towards the goal of timely study activation.

Figure 1: Median Activation Times

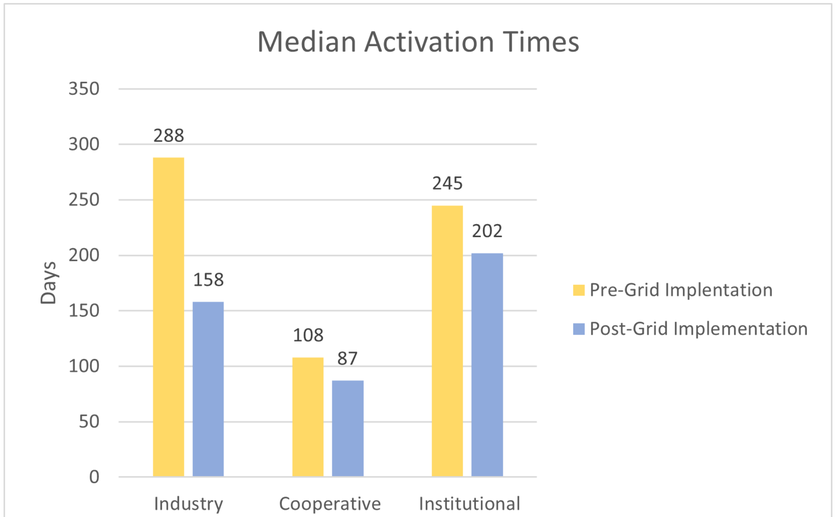

Figure 2: Study Activation Grid

Protocol:							
Version:							
Day	Task	Team	Expectation	Target Date	Completed Date	Notes	Supplemental Information
	DOT Meeting	N/A	N/A	N/A			Baseline for auto-populated target dates for items tossed on DOT meeting date. Post-DOT, Ops team will create folder in Idrive (under operations folder) so that we know when to start work.
Post-DOT	Protocol Calendar Requested	Ops/Budget	3 days from DOT				Following DOT approval, AAs to confirm with disease team manager that we have a final protocol and are site selected (via calendar checklist), and then communicate with Dean B that the calendar is ready to order. Dean will have access to CDA, and will submit the calendar order via Lab. AA to build protocol shell in oncore and send Dean the protocol. Calendar built notification will come to DTM, budget team, DOT AA, and Ops manager. Need IDSO approval after request is made before submitting.
	Protocol Calendar Received	DTM/Study Team	10 business days from request				Once the calendar is received by the manager, the manager will decide who from their staff will do the review. We do have some part time staff that are trained in calendar review. If the disease team can't review, they should reach out to Mike and he can assist in finding someone to complete the review.
	Protocol Calendar Review Completed (ready for SRC feasibility submission)	DTM/Study Team	10 business days from receipt				Calendar should be reviewed and completed by study team within 10 days of receipt. Manager/CRC should hit "Complete" button in Oncore (under eCRF/Calendars --> Specifications). Auto-notification sent to CTO Operations email; ops team will forward to C&S intake for CRC CA Sign Off
	Protocol Calendar CRC CA Sign Off (ready for OCRICC submission)	C&S/Ops	14 days from CRC Complete				Calendar Complete notification comes to Ops, CTO Ops to forward to C&S intake. Study documents (protocol, budget/contract, other documents) are uploaded to sharepoint by ops team (Dean). C&S will complete CRC CA Sign Off and auto-notification will come to Mike and budget team. Mike will submit to OCRICC.
	Submit to OFC	DTM	N/A	N/A			Manager will submit to OFC and copy Dean Blackwell, Tony Carabajal, Robert Sengbush, Regulatory Senior. Once all documents received, study will go on OFC agenda and documents uploaded to Florence by Ops team. DTM to include sponsor budget and regulatory contacts in initial submission email to OFC. Kristin- All Phase 1 and Breast/CNS: Raquel- all Cell Therapy/BMT: Marc- All other Baseline for auto-populated target dates that are based on OFC submission.
	OFC Meeting	Ops/DTM	N/A	N/A			Feasibility tool will be based on OFC date.
	Draft MCA	Budget/CTO Operations	14 days from Submit to OFC				Dean B will send budget template and other essential documents to vendor once all documents received- draft MCA should be completed by vendor and sent back to site (budget team) within 14 days of submission. Creation of funding proposal. Budget team to notify AA (copy to dean directly). Once Dean does administrative changes he will send the draft MCA to the DTM and Ops manager. MCA will be created by C&S using Oncore protocol calendar as a template, and will come to CTO in its current format (macro-enabled Excel spreadsheet, separate from Oncore calendar)
	Draft ICF (ALL ICFs)	Regulatory	14 days from Submit to OFC				Begin draft of ICF once all documents received (i.e. once the DTM submits study to OFC). Regulatory specialist should save the ICF draft in the I-drive ready to sit on the initial manager OFC submission email. Verify all essential documents have been received from sponsor.
0	SRC submit (SRC Feasibility Date)	CTO Operations/DTM	N/A	N/A			CTO operations will confirm draft ICF, MCA draft, Calendar (CTO review Complete status) and Operational Feasibility tool draft in place. DTM to confirm version of all documents still current and verify uploaded documents in Florence are correct. Mike will be keeping track of the above dates. Once he sees all 4 documents, he will rotate the date on the OFC/SRC tracker. Ideally, all 4 documents are available for SRC Feasibility Committee review, however delays from above timelines will not delay SRC review. Day 0 will be the date of the SRC submission (= SRC feasibility meeting date).
	Feasibility Tool Questions Sent	CTO/Operations/DTM	From OFC mtg				Feasibility tool questions to DTM to submit to sponsor (within 48 hours post-OFC meeting). Deadline of 7 days response time for Sponsor.
3	MCA draft reviewed & D1 created	CTO Operations	From SRC submit				Mike to review MCA and will incorporate D1 into the draft consent form. Mike will send any edits that need to be made to the draft MCA back to C&S and will involve the DTM if any questions. Mike to reply to reg coordinator and DTM letting them know that the draft ICF is ready for review in the i-drive.
10	Completion of draft ICF	Regulatory	From SRC submit				Review of Draft ICF and insertion of D1 from MCA. This draft will be found on the I-Drive. Manager to complete review of ICF and notify reg and ops that it is ready to submit to sponsor.
	Pursue email sent	Regulatory	From SRC submit				Regulatory to send out the pursue email per communication plan
	Smartform started	Regulatory	From SRC submit				This can be started sooner if ready
	Feasibility Tool Responses Received	CTO Operations/DTM	From OFC mtg				Outstanding questions from OFC should have been addressed. If not, reconnect with DTM/sponsor/PI.
12	Draft ICF to sponsor	Regulatory	From SRC submit				
14	MCA final draft	Budget/CTOops	From SRC submit				Final draft of MCA will be saved in the idrive in the Operations folder. Budget negotiation underway. If modifications needed (done by finance team/CTO Ops), send back to C&S with edits that were made
	Feasibility Tool Final	CTO Operations	From OFC mtg				Tool Complete- Final Ops tool document uploaded in Florence. Notification sent by Ops team to OFC group with link to Florence.
21	OCRICC submission	CTO Operations	From SRC submit				OCRICC now entering the draft of ICF as long as D1 is complete and the MCA is considered final for their review. Operations team will send nurse consultant the final ICF that is going to the IRB once complete. Prepare OCRICC application- ICF, MCA, Calendar, completed feasibility tool.
28	Contract negotiation commenced	Budget/Contracts	From SRC submit				Contract review, etc.
	Beacon draft submission	Beacon	From SRC submit				Regulatory pursue email is trigger for CTO Beacon team to begin working on Beacon submission. This goes into build folder to begin work. Beacon team doesn't prepare submission based on SRC date- submission is based on priority list from manager. Excel day-to-day is uploaded to Sharepoint, PGD sent to CRC, notification sent to IDS/CRC. 10 business days to complete review.
35	Willow Submission	IDS	From SRC submit				
	IBC Submission	Regulatory	From SRC submit				Draft application submitted to IBC for review (21 days ahead of would be assigned meeting date)
	ICF negotiations complete	Regulatory	From SRC submit				
42	Beacon pre-review complete	CRC/IDS	From SRC submit				Completion of pre-review by CRC and IDS. Whoever finishes their review last will move submission into "Submitted" in Sharepoint. Submission to EPIC team occurs after both reviews (CRC and IDS) complete.
50	IRB submission	Regulatory/DTM	From SRC submit				Final ICF needs to be submitted to OCRICC consultant by Operations team
60	Beacon Initial Build documents ready for review	Beacon, CRC	From SRC submit				Beacon builds/PGD complete and ready for review meeting. DOT AA to assist in scheduling Beacon review meeting. Epic Beacon team requires 10 business days to complete draft builds from the time all comments/questions are received (varies depending on how many questions there are and when CTO beacon team saw the questions posted in sharepoint).
80	Contract finalization	Budget/Contracts	From SRC submit				
	IRB review	Regulatory	From SRC submit				
	OCRICC approval	Operations/DTM	From SRC submit				Upon receipt of OCCRIC approval, CTO Ops will forward to C&S (with final MCA) and upload final MCA to Florence.
	Essential regulatory documents	Regulatory	From SRC submit				1572, FDA, etc. Training routed.
100	IRB approval	Regulatory	From SRC submit				Training completed, any remaining regulatory essential documents (e.g. DOA) completed
	Beacon Review Meeting	CRC/Beacon	From SRC submit				When initial builds are ready (from Epic team), schedulers begin work. Initial builds uploaded by Epic team, CTO Beacon team converts to word document and sends to schedulers. After review meeting, documents go back to sharepoint for Beacon team to apply edits (time to completion depends on number of edits, but varies between days/weeks- estimated 1 week average). Final version follows, but will be sent to production once study is opened to accrual (take about 1 day for that to happen).
105	SIV		From SRC submit				
120	Study Activation	DTM	From SRC submit				Need IRB approval, OCRICC approval, Site Activation from sponsor, Confirm with regulatory that all training and documents in order.

Outcomes

This tool, and associated bi-weekly review meetings, was implemented in August of 2023. Since then, we have activated 11 protocols using this process (5 industry, 4 national cooperative group, and 2 institutional). While this is a limited sample size, we have seen dramatic improvement in the activation times for studies that have gone through this review process. The median activation time for the 5 industry trials was 158 days, where the institutional median activation time in 2023 for industry trials was 288 days. The median activation time for the 4 national cooperative group trials opened through the grid review process was 87 days (institutional median in 2023 was 108 days), and the median activation time for the 2 institutional trials was 202 days (institutional median in 2023 was 245 days) (**Figure 1**).

Lessons Learned and Future Directions

The implementation of a study activation grid and regular review meetings has so far successfully demonstrated a reduction in study activation timelines for the projects that have gone through the process. In addition to the data gathered so far, this process has increased general collaboration on study start-up activities within the clinical trials office and with our hospital partners. Frequent working meetings provides the study team with needed accountability and visibility among all parties involved in study activation. We hope to continue to develop this process in partnership with MCW Cancer Center leaders and hospital partners to reduce activation timelines and ultimately bring more clinical trial options to our catchment area.

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