

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

Rapid Activation Pathway: Speeding Through Study Start-up

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1. Background

The Indiana University Simon Comprehensive Cancer Center's (IUSCCC) Clinical Trials Office (CTO) is consistently looking to improve existing methods of clinical research support, including improving study activation timelines. Creating a successful pathway through which investigators can rapidly open trials of vital importance to their research portfolios is an important way to support investigators and their research, as well as a needed mechanism to support patients within the IUSCCC catchment area. Opening a trial requires coordination within the CTO, as well as multiple different non-centralized ancillary services, and even external partners. However, this means study activation timelines, and their delays, are not always within the scope of the CTO to address. To help address this concern directly, the IUSCCC's CTO has created a dedicated Rapid Activation Pathway, which is focused on collaboration within and across all stakeholders participating in the start-up activities of a study to identify barriers, troubleshoot solutions, and prioritize identified protocols.

2. Goals

- Create Rapid Activation Pathway for study identification and study activation
- Reduce study start up times for Rapid Activation protocols
- Provide internal and external stakeholders with metrics and timeline for Rapid Activation Pathway

3. Solutions and Methods

- Create Rapid Activation Pathway Proposal and get IUSCCC and all Indiana University ancillary partners to agree to participate in the process, including contributing to the format and structure of the two-phase pilot (Phase A and Phase B)
- Develop Rapid Activation Pathway Process to review and approve protocols, communicate timelines with stakeholders, and provide pathways for escalation of unanticipated delays
- Track progress and milestones for trials approved for Rapid Activation Pathway, and compare data to study startup timelines for similar trials
- Engage regularly with all stakeholders on Rapid Activation Pathway and utilize both structured and unstructured feedback to help inform next phase of pilot

4. Outcomes

- Rapid Activation Pathway Proposal was approved in July 2025, and Pilot Phase A was presented to teams in August 2025. Three protocols were selected for the process and approved to proceed through the pathway in Q3 and Q4. It is worth noting that only two have been

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continued throughout the pathway, and one trial was withdrawn due to delays from the sponsor. Pilot Phase A closed in December of 2025.

- CTO is currently collecting data on the two remaining trials in the Rapid Activation Pathway. One has successfully completed the pathway, with one ready to be active in March 2026.
 - Protocol 1- time to open to accrual at 92 days (51.3 percent improvement for therapeutic industry funded trials across CTO from 189.3 days; 55.3 percent improvement for disease specific team from 206 days)
 - Protocol 2- time to open to accrual- on track to hit 120-day target time frame (data trend pending open to accrual date)
- Metrics and feedback gathered in Q1 of 2026 from all stakeholders will inform and determine the structure and size of Pilot Phase B

5. Lessons Learned and Future Directions

- Collaboration with internal stakeholders is critical for success in early identification of priority trials, as well as troubleshooting obstacles to rapid activation of these studies
- Communication and expectation setting with sponsors has been important for the success of meeting rapid activation timelines
- Streamlining of the Rapid Activation Pathway process, including automatizing study updates and priority shifts, is a future direction the CTO is currently developing

