Rapid Activation Pathway- *Speeding through Study Start-Up*

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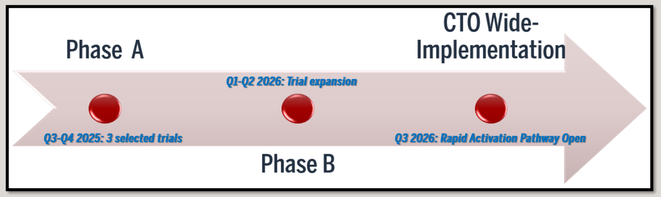
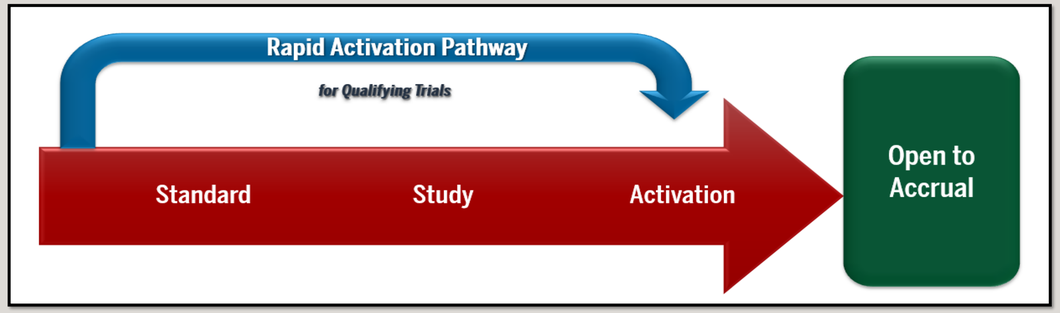
Background

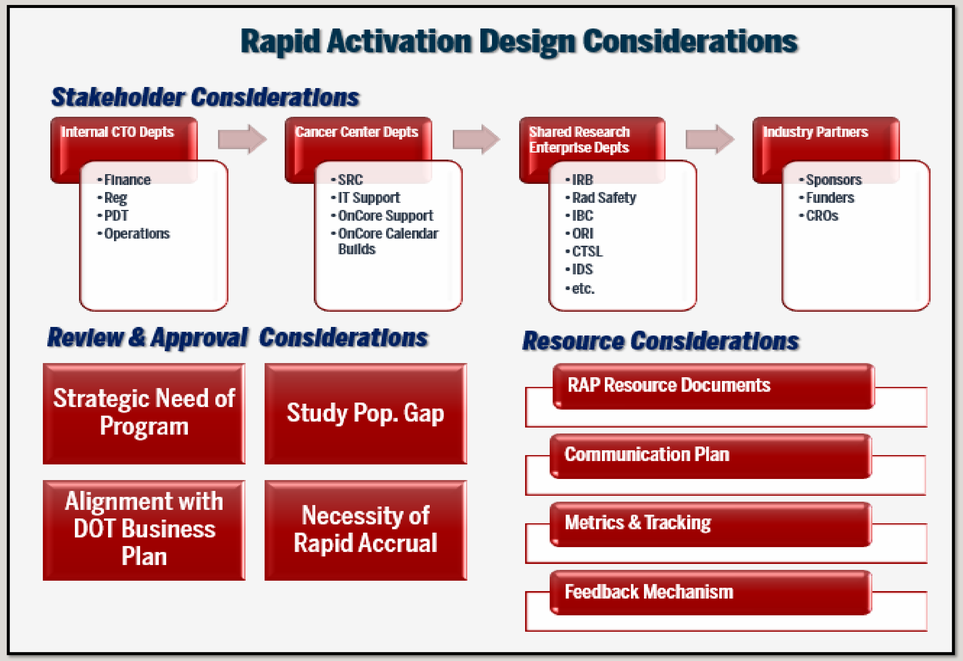
The IU Simon Comprehensive Cancer Center's (IUSCCC) Clinical Trials Office (CTO) is consistently looking to improve existing methods of clinical research support, including improving study activation timelines. Creating a successful pathway through which investigators can rapidly open trials of vital 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 (RAP), 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.

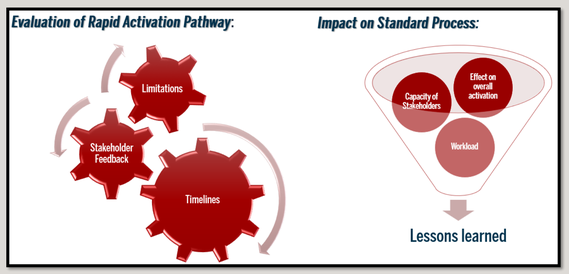


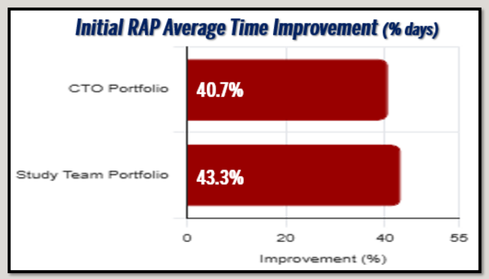
Solutions & Methods

- Create RAP Proposal & obtain stakeholder buy-in
- Develop RAP Process to review & approve protocols, communicate timelines with stakeholders, and provide pathways for escalation of unanticipated delays
- Track progress for RAP trials & compare data to study startup timelines for similar trials
- Develop feedback mechanism for all stakeholders internal or external to the organization









Goals

- Create RAP process for study identification and study activation
- Reduce study start up times for RAP approved protocols
- Provide internal & external stakeholders with metrics and timeline for RAP approved protocols

Lessons Learned & Future Directions

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

Outcomes

- RAP Initial Proposal requested & vetted – March to May 2025
- RAP Proposal approval by CC Exec Leadership – July 2025
- Presentation to study teams – August 2025
- RAP Pathway opened – end of August 2025
- Three protocols selected – September through November 2025 (one discontinued during process)
- CTO is currently collecting feedback on the two remaining trials in RAP
- Both remaining studies activated in Q1 2026 & demonstrated improved study activation timelines compared to historical data
- Metrics & feedback being gathered in 2026 will inform and determine the structure & size of Pilot Phase B